A MARKET STUDY ON ADOPTION OF ARTIFICIAL INTELLIGENCE (AI) IN MEDICAL IMAGING

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree of

Master of Business Administration (MBA)

in

Hospital and Health Management

by

Dr. Shruti Aggarwal

Under the Supervision and Guidance of

Dr. Neetu Purohit

2021

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled 'A Market Study on Adoption of Artificial Intelligence (AI) in Medical Imaging' 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 Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Name of Student: Dr. Shruti Aggarwal

Date:

CERTIFICATE

This is to certify that (Name of Student) in partial fulfilment of the requirements for the award of the degree of MBA (Hospital and Health Management)/MBA (Pharmaceutical Management)/MBA (Rural Management) from the IIHMR University, Jaipur has successfully completed her/his internship at (name of the organization) during March 22, 2021, to June 19, 2021.

Place: EMeRG
Date:

Preceptor/Head of the Organization
Name of the organization

CERTIFICATE

This is to certify that dissertation titled 'A Market Study on Adoption of Artificial Intelligence (AI) in Medical Imaging' is a record of the research work undertaken by (Name of Student) in partial fulfilment of the requirements for the award of the degree of MBA (Hospital and Health Management)/MBA (Pharmaceutical Management)/MBA (Rural Management) from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide: Dr. Neetu Purohit
IIHMR University, Jaipur
Date

School Dean
IIHMR University, Jaipur
Date

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This report is based on the research conducted on secondary data obtained to study the adoption of artificial intelligence in medical imaging. I am grateful to those who have supported and helped me complete this work.

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ACRONYMS/ABBREVIATIONS

AI- Artificial Intelligence

ML- Machine Learning

CT- Computed Tomography

MRI- Magnetic Resonance Imaging

PET- Positron Emission Tomography

USD- United States Dollar

FDA- Food and Drug Administration

US- Ultrasound

CAGR- Compound Annual Growth Rate

I ABSTRACT

Purpose

The aim of this dissertation was to study the adoption of artificial intelligence in medical imaging at a global level to find out the year wise number of AI imaging products from 2014-2020, identify the healthcare areas and imaging modalities where AI medical imaging products are focussed and identify the regions where the AI medical imaging companies are centred over the world map.

Methodology

For this study, the secondary data was used. The data was compiled and analysed on *Microsoft Excel.*

Findings

This study found that there was a total of 126 AI products that were approved by FDA between the years 2014 to 2020. There was an increase in FDA approvals for AI medical imaging products over the years from 2014 to 2020 with increasing focus on neuroradiology followed by pulmonology. The study revealed that largest AI market for medical imaging was in USA followed by Israel. Additionally, the study indicated that the Computed Tomography (CT) was the main AI imaging modality.

Keywords

AI, Medical Imaging, Radiological Imaging, Artificial Intelligence, Market Trend

1. INTRODUCTION

1.1 AI in Medical Imaging

Medical imaging is a diagnostic procedure which creates visual aids and image representations of the human body. This helps in keeping track of the functioning of organs of the human body (1). It is known to save many lives each year. Not only does it help the clinicians and the radiologists to determine and infer a wide range of diseases, but also improves the clinical and operational workflow. Therefore, the healthcare industry is continuously innovating to deliver enhanced care to the patients. This motivates the stakeholders to continue investing in research in medical imaging technology (2).

Artificial Intelligence (AI) is an offshoot of computer sciences that mimics human intelligence and actions in machines (3). Machine learning (ML) is used to develop artificial intelligence in which huge stack of data (such as thoracic X-rays, MRI, CT scan) is put into an algorithm with some understanding about the data (such as the presence or absence of breast cancer). This logical functionality operates on this data, trains on it and then use this training to predict, example presence or absence of colon polyps on pilot images. This helps the algorithm to optimize its specification to enhance the reliability and exactness of diagnosis (4).

AI is being adopted in various industries transforming the way we communicate, receive information and purchase goods and services. In healthcare too, the AI is rebuilding care delivery and other parts of value chain, through machine learning and natural language processing (5). AI imitates human cognition and analysis of medical and diagnostic imaging data. It is mainly used to analyse the association between techniques for treatment and clinical outcomes for the patient (5). It has been helping healthcare industry since it was first used in 1980s for antibiotics dosing (4).The advancements in the medical imaging industry can be transformed with the potential of AI. The use of AI enables physicians to go through vast volumes of imaging scans and comprehend them within a short span of time. The analytics driven by AI helps to boost the accuracy and momentum of clinical conclusions (2). The present advancements in technology in radiological imaging are largely pivoted on the amalgamation of AI into all imaging modalities of the equipment (6). Further, AI has been used in radiation oncology too for segmentation of organ and lesion, registration of image, detection of markers, radiomics, and many more (7).

Even though many AI systems have been permitted for use by different regulatory authorities, there are more in the pipeline (4). The unpredictable repercussions of using AI and ML for data analysis and clinical decision-making, makes the AI powered medical devices of high-risk nature. Hence, the requirements for licensing of such medical appliances, equipment and gadgets have been strictly regulated by the FDA (8). For AI and ML based medical devices, FDA has three levels of clearances which are, 510(k), premarket approval and the de novo pathway. Each of these need to be specifically fulfilled as per the criteria for the approval to be granted (8). It is reported that since 2014, at least 50 companies have received FDA approval for machine learning (ML) and artificial intelligence (AI) algorithms (9). With respect to medical imaging, these companies are focussed on developing algorithms that help analyse medical visual data for the detection of abnormalities, lesions, normal organ function, etc (9). They aim to improve the clinical and operational workflow for better clinical decision making and diagnosis. Cases requiring faster turnaround time such as treatments for stroke can be diagnosed by use of AI systems (10). For Example, Viz.ai aids physicians in identifying the abnormalities in brain scans using machine learning (ML). Aidoc helps radiologists spot acute abnormalities through deep learning and AI algorithms. Ezra's full-body MRI protocol is claimed to determine about 13 cancers in women and 11 cancers in men. Moreover, Israeli start-up, Zebra Medical Vision Ltd., has developed 48 algorithms to address 48 different medical conditions. IDx-DR by Digital Diagnostics, aids in detection of diabetic retinopathy before it causes blindness. This company is currently working on additional AI-based algorithms to detect eye disease, glaucoma, presenile dementia, heart disease, and risk of brain attack (9). Further, 3D retinal OCT scans can be read by Google's DeepMind. It aids in diagnosis of 50 different ophthalmic conditions (2).

As per industry reports, over a forecast period of 2021-2016, the worldwide AI market in Medical Imaging is estimated to record a CAGR of 30.4% because of the growing elderly population and increased investments in the medical management and wellness ecosystem (1). The AI market growth in the medical imaging is predominantly guided by the initiatives by the government to expand the adoption of AI-based technologies. Increasing need for tools enabled by AI in the medical sector, growing focus on minimizing radiologist's load of tasks, flooding of massive and complicated sets of data, growing funds for start-ups in AI, and growing number of cross-industry partnerships and associations has further driven the growth in this sector (11). According to a report by Johns Hopkins Medicine published in June 2020, the artificial

intelligence was found to have potential in strengthening the role of chest imaging and work on large-scale data for quick detection, containment, and treatment of COVID-19 (1). It was reported that artificial intelligence and medical imaging technology will be used together to improve the detection and treatment of COVID-19, by the National Institute of Health (NIH) which launched the Medical Imaging and Data Resource Centre (MIDRC) in August 2020 (1).

Furthermore, another report by Signify Research forecasted that the global market for AI solutions in medical imaging will come to approximately 1.5 billion USD by the year 2024 with a peak annual growth rate of 44% for the year 2022, despite the COVID 19 pandemic (12).

2. RESEARCH GAP, QUESTION and OBJECTIVES

2.1 Research Gap

Of all the literature relevant to this study, most of the data available was centred around the AI specified products in the market with respect to medical imaging. However, this study attempts to put light on the number of AI products in the medical imaging versus the actual number of AI medical imaging products approved by the FDA.

2.2 Research Question

The research question for this study was that "What is the market trend over the last seven years for the adoption of AI in medical imaging?"

2.3 Objectives

1. To find out the year wise number of AI medical imaging products from 2014-2020

2. To identify the healthcare areas where AI medical imaging products are focussed

3. To identify imaging modalities on which AI medical imaging products are focussed

3. To identify the regions where the AI medical imaging companies are centred over the world map

3. LITERATURE REVIEW

3.1 AI Adoption in Medical Imaging

The medical imaging trade for AI is projected to grow at a fast speed in the coming years owing to multiple factors, such as improved computation capacity, learning algorithms, and accessibility to massive data sets, which are procured from various wearable health and medical devices (13). According to a research paper, the count of publications on AI for diagnostic imaging has risen from approximately 100-150 per year to 1000–1100 per year over a period of 2007 to 2018 (7).

AI in medical imaging may significantly impact countries such as Mexico who have low radiologists to population ratio (1). Some of the examples on how hospitals are adopting AI in their routine medical imaging for COVID 19 screening to reduce human contact include: In the absence of radiologists, Zhongnan Hospital (China) uses AI for interpretation of CT scans and identification of COVID-19 symptoms. Likewise, utilization of AI to screen individuals for COVID-19 before interaction with the hospital staff and other patients by Tampa General Hospital (Florida, US). Use of AI enabled robots that acquire vital signs and provide care to COVID-19 patients, at Massachusetts General Hospital (Boston, US). Thus, to acknowledge and answer to the medical imaging needs in an efficient and quick manner, physicians are making use of the augmented abilities of AI (11).

AI's potential seems to be driving a surge in funding start-ups for research and use in medical imaging. It is also attracting interests from larger companies either through collaborations or acquisitions, or by building capabilities on their own. This has led the companies follow their prior funding in cloud infrastructure for storage solutions for big data. This big data is important in coaching the AI algorithms (14). As per a research, between the years 2014 and 2019, finances in AI-based medical imaging companies were estimated at 1.17 billion US Dollars. This was almost twice the amount that was initially reported for the period 2012 to 2017. There has also been an increase in the number of companies by almost thrice, in this market segment (14).

Majority of the development in AI powered radiology is pursued in the areas of determination and segregation of image, precision medicine that connects genomic and imaging data, substitution in screening programmes that reads twice and quick triage and detection of abnormality in emergency situations. This would lead to improved workflow efficacy that would help in prioritization of reports, evaluation of quality of

image in real-time, and creation of study guidelines for follow-ups. Moreover, enhanced standard of images from noisy low-standard images would reduce the need for repeat examinations and thereby decrease the radiation dose exposed to the patient (4).

As per a study by American College of Radiology, over a period of 2015 to 2020, adoption of AI by radiologists in clinical settings has increased from none to 30% (15). According to some industry reports, in the global market for radiology in 2018, AI was estimated at 21.5 million US Dollars. It is anticipated to come to 181.1 million US Dollars by the year 2025 with a CAGR of 35.9% over the forecast period (10). The worldwide trade for AI in medical imaging can be segmented across different categories. This could be based on the type of solution, technology or AI algorithm, technology for acquisition of image, consumers, clinical application, and geography. Based on the type of solution, the AI in medical imaging market could be further divided into devices, software tools or platforms, and services. In terms of AI technology, the market could be categorized into deep learning, computer vision, natural language processing (NLP) technology. Further, the image acquisition technology for AI in radiology market could be classified into routine X-ray, computed tomography (CT), magnetic resonance imaging, ultrasound imaging, and molecular imaging. The consumers could be segmented into hospitals, Research and Development centres, laboratories, and diagnostic centres. The clinical application in AI powered medical imaging market could be divided into cardiovascular, neurology, nephrology, pulmonology, breast (mammography), oncology, pathology, gastrointestinal or abdominal, oral diagnostics, and rest of the body. As per the geography, the market could be segregated into North American, South American, European, Asia Pacific, and Middle East & African regions (15).

The AI in medical imaging market is dominated by North America and Europe because of increased advancements in healthcare technological infrastructure and high disposable income in these regions (16). India, China, and Brazil are emerging markets that are anticipated to furnish remarkable growth opportunities for participants working in the AI in medical imaging trade, owing to the increasing patient population in these countries (11).

A report on AI market in medical imaging highlights, that in the past five years, there have been about 134 joint collaborations, associations, and partnerships, approximately 102 capitalization and financing, 101 approvals for AI products, 54 launches and

modifications of AI products, and six consolidations and possession of AI companies or AI products (17).

At present within radiology, most AI developments focus on detection of abnormality. Future AI developments are intended in molecular or microscopic imaging, radio-genomics, and screening for cancer for the entire population (4). Further implementation of AI in the mammogram image analysis could aid in decreasing false positive and false negative recalls and successfully triage up to 60% of all cases without any human interpretation (18). A recent report suggests that AI technology has positively influenced the medical imaging market by playing a crucial role in the speedy detection and determination of COVID-19 virus strains. It was proposed that for quick diagnosis of COVID-19 positive patients, the AI algorithms can be educated on thoracic CT images, history of exposure, clinical manifestations, microscopic and pathologic findings of patients infected with COVID-19 virus (19). It is suggested that post COVID-19, AI will aid in managing a backlog of non-urgent cases (20). As per some industry reports, the cardiac care is forecasted to show the largest revenue growth, followed by pulmonology care. Additionally, liver, and prostate automated analysis is also on the rise (12).

Despite the investments in AI in medical imaging, AI solutions are limited to specific conditions, imaging modalities, or disease states (14). It is observed that there is a reluctance among the clinicians regarding adoption of new technologies (11). For AI to be trustfully adopted into medical imaging, it needs to be robust, lawful, and ethical (4). For example, there is a misapprehension that AI will replace doctors in the future. Clinicians believe that emotions such as empathy and persuasion cannot be replaced with technologies. Additionally, it is feared that patients may be excessively inclined towards such automation and may avoid undergoing necessary treatments by visiting the clinician in person (11). Further a study revealed that radiologists are sceptical about the current diagnostic capabilities of AI, specifically for complicated patient cases (14).

Further, the scarcity of authorized approvals of AI in medical imaging has been recognized as another major barrier in its adoption. This might alter if more FDA approves more AI algorithms or if the FDA reform its structure of regulations for changes to AI- and ML-based software in medical equipment. In this view, outlines have been published by the FDA for premarket review of AI- and ML-based software modifications. The approval process for AI and ML algorithms could be clarified by the FDA suggested “total product lifecycle” regulatory approach (14). However, the unclear

guidelines of FDA for AI or ML based medical devices in medical imaging, hampers the evaluation process. Moreover, in the announcement and summary section of FDA website, specific searches are not permitted, which hinders the accessibility to database (8).

Furthermore, the AI in medical imaging market is challenged by concerns over data privacy and security regarding the healthcare data, increasing medical imaging costs and expenses, lack of trained staff (17) and inherent bias in the data (8).

Additionally, increased demand for funding in AI in medical imaging has resulted in emergence of many new start-ups. However, these start-ups are smaller and lesser funded. This could partially explicate the slow adoption of AI in medical imaging (14).

4. METHODOLOGY

The research methodology will constitute following elements:

4.1 Search Strategy

4.1.1 Literature and Data Basis

For this research, the search for various related articles and studies was conducted via online platform. The databases included FDA, Lancet, NCBI, medRxiv, PubMed and Research gate.

4.1.2 Search Criteria

The key terms used for searching articles relevant to this research were 'AI', 'Adoption of in medical imaging', 'Trends in trade for AI adoption in medical imaging', 'Market size for AI in medical imaging', 'AI adoption in radiological imaging, 'AI in radiology'.

The articles reviewed for this research ranged from the oldest to the most recent with respect to the relevant topic. Publication from year 2014 to 2020 were considered for this research.

Articles published in English language were preferred for this research.

4.1.3 Inclusion Criteria

Only AI products that received FDA approval between 2014 to May 2021 were included for this research.

Focus of this research was primarily on AI products in medical imaging on modalities such as X-ray, CT, MRI, MRA, OCT, Ultrasound, Mammography, Electroencephalography, Electrocardiography, Positron Emission Tomography and Angiography.

Articles and research papers with market trend analysis on adoption of AI in medical imaging and radiological imaging were included.

4.1.4 Exclusion Criteria

Articles and studies that analysed adoption of AI in healthcare in general were not included for this research.

4.2 Study Data

4.2.1 Study Design

This was an exploratory and deterministic analysis to study the adoption of AI in medical imaging.

4.2.2 Data Type

Secondary data that was available on online web portal was used for this study.

4.2.3 Data Source

The source for the compilation of the data for this study included FDA 510(k) database.

4.2.4 Data Size

126 FDA approved AI medical devices were analysed for this study.

4.2.5 Data Measurement

The data was compiled and analysed on *Microsoft Excel*. The medical imaging products that were specified as AI on the product website and had received FDA approval for the same were included in the list. The AI medical imaging products on which there was uncertainty over FDA approval, were removed from the list.

4.2.6 Limitations

The research was limited to 126 FDA approved AI medical imaging products in radiology. Data used was from the year 2014 to 2020. The data for the year 2021 was not included in this study.

4.2.7 Method of Analysis

For this research, FDA guidelines for AI algorithms and technology were reviewed and in-depth assessment and review of FDA 510(k) databases was done to understand and analyse the trend of clearances since first AI algorithm in medical imaging. To arrive at the number of AI products that have received FDA approval over the years 2014 to 2020, a percentage split was computed across different categories such as geography, imaging modality and care area.

4.2.8 Data Representation

Table, bar graphs and pie charts were used to depict absolute count and percentage split of AI products across different categories.

5. RESULTS

5.1 Year wise number of AI products in medical imaging from 2014-2020

It was reported that from the 01st of January 2014 to 31st December 2020, about 800 AI products were launched in the medical imaging space. Among those 800, only 126 received FDA approval. Out of these 126 AI products, only 2 were approved in 2014, none in 2015, 4 were FDA approved in 2016, 5 AI products were approved by FDA in the year 2017, 23 were FDA approved in the year 2018, 34 were approved by FDA in the year 2019, 58 were approved by FDA in the year 2020. This indicates approximately 70% increase in FDA approval in the year 2020, about 47.8% increase in FDA approvals in the year 2019, about 360% increase in approvals in the year 2018 and 25% increase in 2017.

5.2 Imaging Modalities on which AI medical imaging products are used

Out of 126 FDA approved AI products, about 47 were focussed on Computed Tomography (CT) as the imaging modality, 18 on Magnetic Resonance Imaging (MRI), 16 Ultrasound, 15 multi-modality, 10 X-ray and rest on others.

5.3 Healthcare Areas where AI medical imaging products are focused

Further, approximately 38 AI medical imaging products were adopted in neuroradiology care area, followed by 20 AI products specific to chest imaging. Additionally, 19 AI products were focussed in women's healthcare area which included breast imaging for screening and detection of lesions. About 17 AI products in cardiac care was adopted.

5.4 Regions where AI medical imaging companies are centered over the world map

About 60 AI products are from companies originating in USA, followed by 16 from Israel, 9 from Netherlands and 8 from Germany and rest belong to others.

The following table (Table 1) shows the absolute numbers and percentage wise split of AI products across different categories that include year of approval, region, imaging modality and healthcare area:

Table 1 : Summary of Results

YEAR WISE

Year of FDA approval	Count of Product
2014	2
2016	4
2017	5
2018	23
2019	34
2020	58
Grand Total	**126**

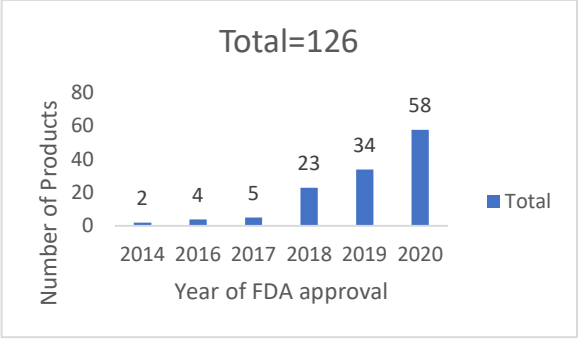

Figure 1 : Bar Graph depicting YoY count of FDA Approvals

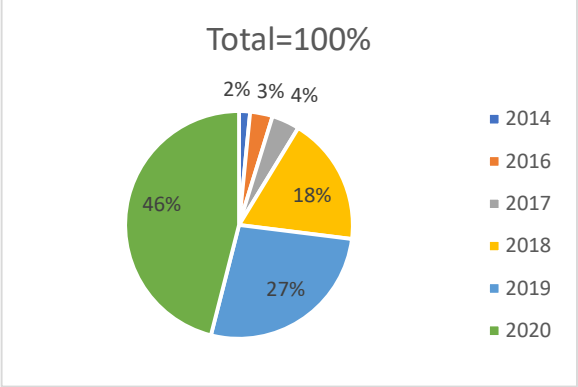

Figure 2 : Pie Chart depicting YoY % count of FDA Approvals

COUNTRY WISE

Country	Count of Product
Australia	3
Austria	1
Belgium	4
Canada	3
China	1
Finland	1
France	1
Germany	8
India	1

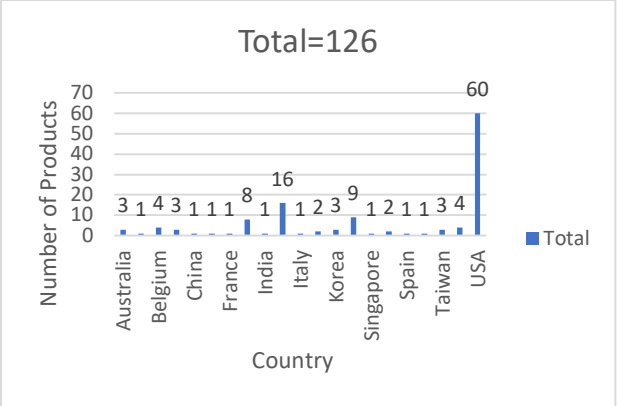

Figure 3 : Bar Graph depicting Country-wise count of

Israel	16
Italy	1
Japan	2
Korea	3
Netherlands	9
Singapore	1
South Korea	2
Spain	1
Sweden	1
Taiwan	3
UK	4
USA	60
Grand Total	**126**

FDA Approvals

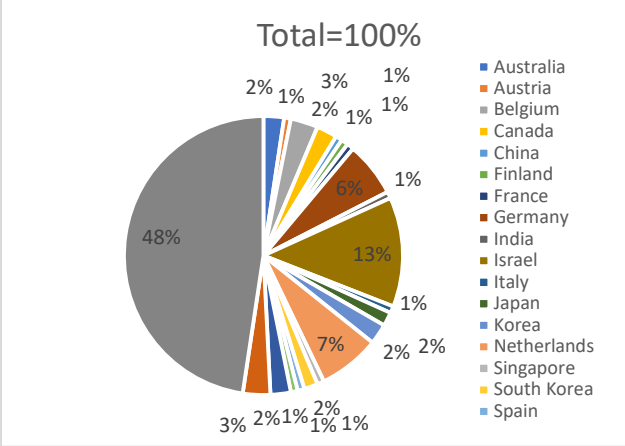

Figure 4 : Pie Chart depicting Country-wise % count of FDA Approvals

IMAGING MODALITY

Imaging Modality	Count of Product
OCT	1
CT	47
CTA	3
DBT	2
ECG	1
EEG	1
MAM	11
MRI	18
Multi	15
NCCT	1
U/S	16
X-ray	10
Grand Total	**126**

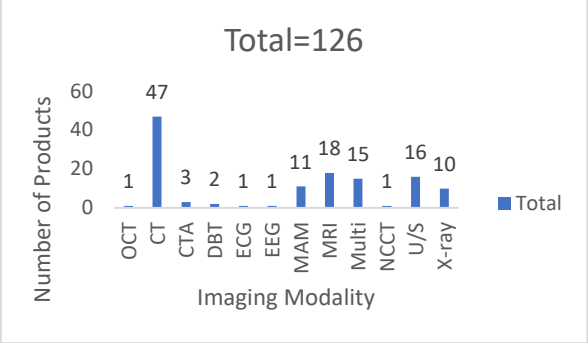

Figure 5 : Bar Graph depicting Imaging Modality wise count of FDA Approvals

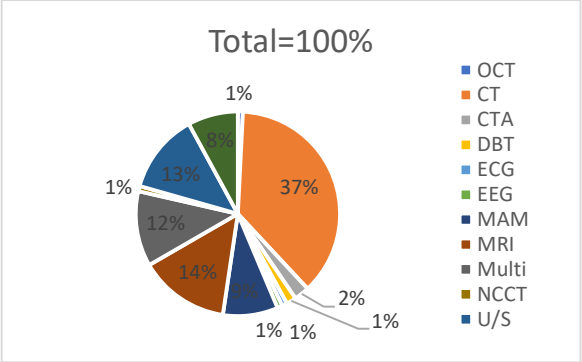

Figure 6 : Pie Chart depicting Imaging Modality wise % count of FDA Approvals

HEALTHCARE AREA

Healthcare Area	Count of Product
Abdominal	13
Cardiology	17
Chest	20
Multi	11
Musculoskeletal	8
Neuroradiology	38
Women's Imaging	19
Grand Total	**126**

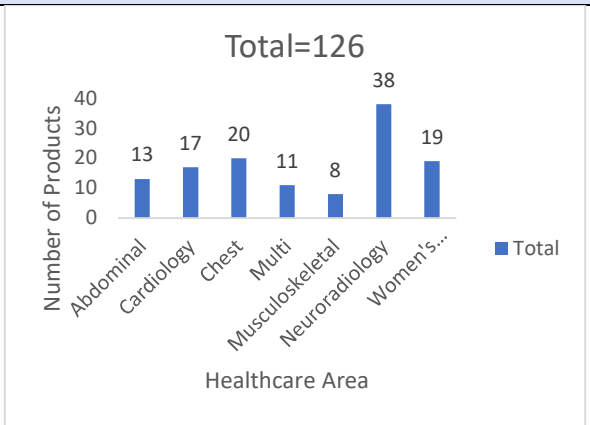

Figure 7 : Bar Graph depicting Healthcare area wise count of FDA Approvals

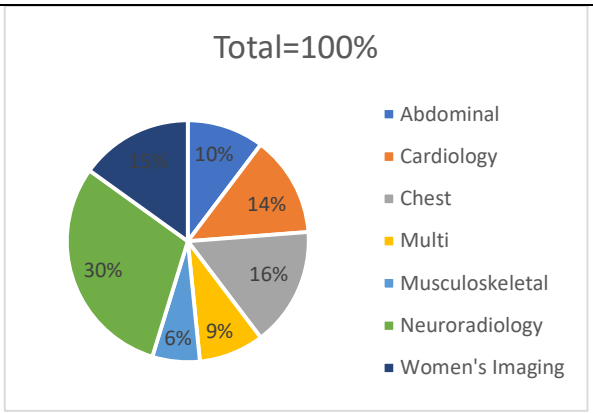

Figure 8 : Pie Chart depicting Healthcare Area wise % count of FDA Approvals

6. DISCUSSION

A percentage wise split was analysed across different categories such as geography, imaging modality, healthcare area and year on year. The largest share for FDA approved AI medical imaging products was found for products from USA, followed by Israel. Neurological care was found to be the most adopted healthcare area, while Computed Tomography was the most adopted imaging modality. Further, it was found that there was an increase in the number of FDA approvals from the years 2014 to 2020.

As per the results obtained in this study, there seems to be an increase in FDA approval for AI products in medical imaging. It is observed that the number of regulatory approvals for AI medical imaging products has been increasing, despite the minute count of AI systems being put to test in probable clinical settings (21).

The findings of this study coincide with findings of other market research. Similar studies report that countries in North America such as USA have more healthcare awareness, technologically advanced healthcare infrastructure coupled with more income. Additionally, the existence of key market participants of the AI medical imaging market and favourable government regulations have propelled the demand and research for AI in medical imaging (22). The increasing number of neurovascular disorders such as stroke and Alzheimer's disease, owing to the increasing stress level, have fuelled the requirement of AI in neurology space. The need for recognition of early warning signs for ischemia to prevent stroke, has made this care areas as one of the most researched for AI imaging (23). Additionally, the increase in presence of chronic lifestyle diseases such as heart related ailments, tumours and malignancies has been cited as the major reasons for AI adoption in Computed Tomography. The need for advanced tools for assessment such as triaging, in the emergency department has led AI companies to focus on CT as the imaging modality, to enable physicians to detect lesions that go un-noticed on an X-ray (1).

The increased advancements in technology have led to increase in number in number of FDA approvals over the years. Moreover, the pandemic itself has led companies to launch AI enabled products that can help radiologists to quickly analyse radiological images for detection of pneumonia patches due to COVID 19.

7. RECOMMENDATIONS

It is suggested that the imaging data needs to be filtered and purified. The image analysis should be cross verified and re-read multiple times by the radiologist, prior to attachment of an image with the report. This would reduce calculation rates and inbuilt preferences, so that AI can be trained on datasets that would show results that represent major part of the population (4).

There is a need to think on legal consequences for unsuitable clinical outcomes through AI powered medical imaging. For instance, who is to be held answerable if AI incorrectly reports “no significant abnormalities” when there is actually a tumour. Who will be liable in such a case- the corporation, the healthcare institution using the company’s AI or the medical specialist? (4).

It is assumed that the judgement and empathy of a doctor cannot be replaced. Therefore, even with the ability of AI to recommend diagnosis and prognosis for the treatment, the concerned clinician must have the final verdict especially on critical decisions such a choosing between treatment for cancers and starting palliative care for the same (4).

8. CONCLUSION

AI seems to have a cardinal role in diagnostic medical imaging. It helps in managing the enormous workload (7). It can expand the availability of resources and capabilities of overworked clinicians and help improve the entire workflow process saving time and effort. Use of AI in medical imaging provides insights and multiple perspectives by both patient and clinicians in continued monitoring of wellness and health (5). Further, AI algorithms can help offer a second opinion when there is a disagreement between the radiologists over a complicated medical image. This practice would help decrease the stress level related to clinical decision making (24). AI technology adds more precision and consistency to the routine radiographic procedures, improves clinical practice management and quality assurance (25). It is said that through integration of AI with electronic medical record, the multimodal sources could be utilized to drive decisions for triage and disease management (15).

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