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EXPLORING THE PROGRESSION OF ARTIFICIAL INTELLIGENCE IN MEDICAL DEVICES: A JOURNEY THROUGH PAST AND FUTURE

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ABSTRACT
Artificial Intelligence (AI) has garnered significant interest within the realm of medical devices due to which the medical device industry is undergoing transformative shifts, showcasing accelerated growth. However, due to system complexity, the variability of their architecture, as well as ethical and regulatory concerns there is an ongoing need to analyze its application and performance. In essence, as stewards of the future of healthcare, our collective efforts must be guided by a commitment to innovation, integrity, and inclusivity, with the overarching goal of advancing human health and well-being in an ever-evolving landscape. By leveraging these advanced technologies, medical devices are not only becoming more effective and reliable but are also paving the way for a new era of personalized and data-driven medicine. This study centers on exploring the utilization of AI and machine learning (ML) algorithms in medical devices, encompassing their historical, present, and prospective applications. The current study's main goals are to assess the level of technological accessibility, acknowledge artificial intelligence's (AI) enormous potential in the healthcare industry, and monitor new scientific findings to serve as a source of inspiration for researchers in this field.

KEYWORDS: Artificial intelligence; Machine learning; Medical devices; Evolution, Revolution, Journey.

INTRODUCTION

Artificial Intelligence (AI) is often likened to the 4th industrial revolution. It delineates the domain of machines capable of emulating human thought processes in learning and analysis, enabling them to tackle problems effectively (Schwab, 2016). This multifaceted field encompasses various digital techniques, from computer vision to deep learning, enabling machines to exhibit intelligent behavior autonomously (Hamet, 2017). Its pervasive applications extend across many medical domains, particularly aiding in disease detection and prevention (Long, 2020) (Catic, 2018) (Gurbeta, 2018) (Badnjevic, 2018) (Saric, 2020). In contrast to traditional computer programming paradigms, AI methodologies replicate human decision-making processes (Deo, 2015).

In contemporary times, the incorporation of Artificial Intelligence (AI) into healthcare stands as a pivotal strategic cornerstone for advancing the domain further, offering promising avenues for enhancing efficiency while concurrently mitigating costs. Regulatory bodies on a global scale, including the European Council (2017) and the FDA (2020), have duly acknowledged the significance of these innovative tools in healthcare improvement. They encourage a shift towards integrated care systems that focus on promoting health, preventing diseases, and personalizing medicine. Many countries are developing national AI strategies to promote research and adoption of these technologies. Numerous nations have either devised or are in the process of formulating national AI strategies and policies to stimulate the research, development, and adoption of such methodologies and technologies (Ravi, 2017) (LeCun, 2015).

The integration of AI into Medical Devices (MD) has led to the development of various devices for everyday use, such as remote patient monitoring tools, wearable medical gadgets, and Electronic Health Records (EHR). Medicine involves complex decision-making based on expert knowledge and patient information. Given the escalating volume of data generated within the healthcare domain, the potential applications of AI are vast, spanning from clinical decision-making and public health initiatives to biomedical research, drug development, and health system administration and service restructuring.

The utilization of Artificial Intelligence (AI) within medical devices in the healthcare sector undergoes scrutiny across temporal dimensions encompassing the past, present, and anticipated future landscapes. Delving into the realm of prospective benefits and challenges, expectations extend towards forthcoming applications of AI within the medical domain, particularly within the realm of medical device integration. Novel AI functionalities present innovative solutions for healthcare problems, while the evolution of healthcare relies upon the cultivation of AI expertise to propel it to new heights. The demand and the evolutionary trajectory of AI and healthcare sectors promise significant developmental steps in the foreseeable future, promising to ultimately enhance the quality of life for individuals in need.

This paper is presented is based on scientific articles published in PubMed, Scopus ad ScienceDirect databases, official publications of international organizations: European Commission, Food and Drug Administration (FDA) and World Health Organization (WHO) published in 2009 to till date. The PubMed, Scopus, and ScienceDirect databases were searched to identify papers published using the search terms "medical device," "artificial intelligence," "machine learning", "artificial neural network", "history of AI", "Journey of AI in medical device. Papers reporting data on AI applications in medical devices were included. In view of the evolutionary nature of the AI field, both academic literature and grey literature are included in the search.

Artificial Intelligence in medical devices: Past

The application of AI in medicine is closely linked to development in AI methods. Artificial intelligence (AI) was first described in 1950 (Vivek Kaul, 2020) and the concept of AI was introduced in medicine in the early 1970s (Patel, 2009) with the aim to improve the efficiency of medical diagnosis and treatment. It took around 30 years from its introduction to widespread application in health- care due to several technological limitations which have been overcome by the advent of deep learning. When AI first started to be used in medical devices, it was mostly used in rule-based expert systems that were intended to assist in clinical decision-making. AI technology developed progressively during the 20th century, opening the door to increasingly complex medical equipment that could do tasks like pattern recognition, picture identification, and natural language processing. For instance, AI-powered systems for computer-aided diagnosis in radiology and the interpretation of ECGs first appeared in the 1970s and 1980s. (Miller, R.A, 1982).

AI has existed in medical devices for nearly 30 years, with AI devices receiving market approvals starting in the 1990s. With the development of deep learning algorithms and machine learning (ML), the late 20th and early 21st centuries saw a dramatic shift in society. The modern era of AI began in the early 2000s and saw some of the most expansive leaps for AI both in its applications to healthcare and also to human daily living. Medical devices are now able to learn from data, adjust to new information, and gradually increase performance through AI approaches. With the rising use of ML algorithms in medical imaging equipment, functions including organ segmentation, illness categorization, and tumor identification are made easier. (Mintz, Y, 2019).

Artificial Intelligence in medical devices: Present

According to Flaxman (2018), Burki (2019), and Weungart (2000), medical device manufacturers are utilizing these state-of-the-art technologies to transform their devices in order to better support healthcare practitioners and improve patient care. The interpretation of physiological data obtained from sensors has been made easier by recent advances in artificial intelligence, both in hardware and software. This has led to an exponential growth in the number of wearable devices, such as smart watches with built-in digital health monitoring applications. According to Jha (2016), the wearable technology trend that is rapidly taking over the market has a significant impact on the digital health monitoring industry. Furthermore, as noted by Abernethy (2010), the continuous advancement of assistive diagnostic technology necessitates the use of enormous volumes of data in the areas of illness detection, diagnosis, and treatment. It might be difficult for physicians to quickly organize and analyze this data. AI is therefore being utilized more and more in medicine to assist physicians in forecasting patient outcomes and illness states.

Through the scrutiny of medical imaging modalities like echocardiograms, computed tomography (CT), endoscopy, and dermatological photography, alongside tissue histology and physiological data such as electrocardiograms (ECG), these technologies have showcased vast potential within the realm of healthcare. Their design aims at disease screening, malignancy classification, and dispensation of personalized treatment recommendations, among other functions, frequently achieving these objectives more expeditiously than conventional methodologies have permitted. Meticuly, a medical technology company based in Thailand, uses generative AI to develop personalized bone implants. Meticuly feeds the patients' CT scans into an AI deep learning algorithm to design the implant. Meticuly eliminated that need and reduced operation time by hours, improving outcomes for patients. NuVasive, a medical device company based in the United States, uses generative design to create 3D printed porous titanium spinal implants. (The frontier of MedTech; 2023)

Machine learning is one of the most powerful algorithms available, especially in light of its growing importance in medicine—particularly in the area of disease prognosis—in recent years. For example, in 2018 as documented by Wong (2019), the application of machine learning yielded the development of a high-precision predictive model known as IPU-ML for the recurrence of idiopathic peptic ulcers as Idiopathic hemorrhagic ulcer patients are more likely to experience ulcer recurrence, which might lead to serious consequences. In another case, enterovirus-induced Severe hand, foot, and mouth disease occasionally precipitate severe complications in pediatric patients, including pulmonary edema and myocarditis, as elucidated by Liu (2014). Furthermore, now a day, radiation therapy efficacy may be predicted using machine learning.

The combination of artificial intelligence and state-of-the-art imaging technology with a large retain of outdated images has the potential to improve current detection techniques through accelerated analysis, real-time diagnosis, and reduction of human error (Graber, 2005). Tremendous diseases like epilepsy, stroke, and Alzheimer's require novel techniques to treat. Current diagnostic techniques such as magnetic resonance imaging (MRI) and electroencephalography (EEG) provide large amounts of data for the identification, tracking, and treatment of neurological disorders, but they also face complex data analysis. Therefore, it is essential to incorporate intelligent systems that are able to gather, manage, examine, and recognize nervous system abnormalities on their own. Artificial intelligence's incorporation into this field holds well for improving therapy efficacy and diagnostic consistency (Blahuta, 2012). It's evident that artificial intelligence (AI) is becoming more and more popular, particularly with recognizing images applications. By using deep learning algorithms, AI can perform an autonomous quantitative and remarkably effective analysis of complex characteristics in medical imaging. A prominent use is in the imaging of the liver with radiography, ultrasound, and nuclear medicine modalities to identify possible liver diseases (Zhou, 2019).

Artificial intelligence (AI) finds further applications in in vitro diagnostics, where fluorescent signals released by moving cells are captured by real-time imaging. Cells are classified as prognosticators of particular diseases by using AI algorithms to distinguish them according to criteria including size, shape, and emission wavelength. It may also be easily integrated into practical applications by combining this method with other hardware technologies. Combining AI with the in vitro diagnostic framework has the potential to improve the accuracy and performance of the devices (Smith, 2018).

The demand for medical devices with AI/ML capabilities has increased significantly in the last few years, and this increase has been amplified in the last few months due to the introduction of large language models (LLMs). The FDA has carefully reviewed and approved a growing number of devices in the last ten years that utilize AI/ML in various areas of medicine that are made available through paths like premarket approval, De Novo requests, and 510(k) clearance. All of these devices harness the potential of AI/ML across diverse domains of medicine and anticipates a sustained trajectory of this trend moving forward.

The FDA is continuing to scale up their authorizations of AI-enabled medical devices. (Kate Stephenson, 2024). The upward trajectory of AI/ML-enabled devices witnessed a deceleration in year-over-year growth rates, recording a 15% increase in 2021 and a subsequent 14% rise in 2022, following a remarkable surge of 39% in 2020 compared to the preceding year. However, projections indicate a resurgence in growth for AI/ML-enabled devices in 2023, with an anticipated increase exceeding 30% compared to the previous year's volume (Urs, 2020). As of August 2024, an overwhelming number of 950 AI/ML-enabled medical devices have been authorized. (Artificial Intelligence, 2024)

Artificial Intelligence in medical devices: Future

These devices aren't just pure instruments anymore; they've become so sophisticated, advanced, and 'smart' that they can analyze large amounts of patient data faster than you can say "diagnosis." (Clarissa Benfield, 2024) The next phase of artificial intelligence integration in the medical field is expected to take shape with the emergence of standard operating procedures and laws that are specifically designed to control the use of AI in medical devices. The Food and Drug Administration (FDA) has already made noteworthy progress in this area. The FDA published a document in April 2019 titled "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)," which outlined its position on AI in sharp contrast to their European counterparts. This document cogitates upon the intricate challenge posed by perpetually evolving learning systems. Nonetheless, it discerns that antecedently sanctioned medical devices leveraging AI methodologies operated on the premise of "locked algorithms."

As regulatory bodies grapple with the complexities of this burgeoning field, leading manufacturers are undergoing a paradigm shift in their business strategies, transitioning from conventional manufacturing paradigms to data-centric, intelligent models. A prime exemplar of this trend is Medtronic, which has unequivocally pledged to infuse artificial intelligence into its established surgical landscape. This initiative encompasses the integration of advanced imaging, robotics, navigation systems, and an expanded focus on remote patient monitoring. The UNiD ASI preoperative platform is a keystone of Medtronic's surgical augmentation approach. This creative instrument is an example of how cutting-edge technology and medical innovation can work together. It uses predictive modeling techniques to digitally recreate the spine and make exact measurements easier.

Conversely, Philips has opted to pivot towards distinct market trends, notably concentrating on AI-driven diagnostics and workflow optimization, prioritizing heightened precision. Philips concluded a merger deal in December 2020 to buy BioTelemetry for a considerable price of US$2.8 billion, which is a strategic move of this transition. Renowned for its prowess in cardiac diagnostics, wearable heart monitoring solutions, and AI-driven data analytics, BioTelemetry has carved a niche in the realm of out-of-hospital monitoring solutions. In the landscape of medical equipment, AI represents a relatively nascent domain. In stark contrast to conventional devices typically engineered by multidisciplinary teams encompassing materials, mechanical, and electrical expertise, AI-infused medical devices necessitate specialized proficiency in software programming and coding. This paradigm shift underscores the imperative for medical technology companies to recalibrate their skill sets and organizational structures to effectively navigate the evolving contours of the healthcare landscape.

The future of AI applications not only promises more accurate treatment but also aims to preempt injuries and fatalities caused using medical devices. Healthcare generates enormous amounts of data, which are further enhanced by the large amount of data that each medical device produces. These large data sets provide an ideal environment for predicting the effectiveness and safety of medical devices. A case in point is the widespread adoption of intelligent infusion pump systems, which have emerged as the preferred modality for safeguarding the administration of intravenous medications. While many of these systems rely on AI expert systems rather than machine learning, their demonstrated robustness and dependability have paved the way for the integration of more sophisticated machine learning-driven applications.

Indeed, the healthcare landscape is undergoing a profound transformation catalyzed by the proliferation of memory, applications, and cloud computing resources. Ancillary modules and equipment, such as barcodes and radio frequency identification (RFID) readers, are now a feature of these sophisticated systems, with the goal of achieving the fundamental "Five Rights": making sure the appropriate patient gets the right medication at the right time via the appropriate route in the appropriate dosage. (Badnjevic 2019, Kovacevic 2019).

CONCLUSION

The principal aim of the current study is to determine the degree of technological accessibility, to recognize the enormous potential of artificial intelligence (AI) in the healthcare domain, and to track emerging scientific discoveries in order to provide a source of motivation for researchers working in this field. In the realm of medical devices, the integration of artificial intelligence (AI) is still in its nascent stages. Projections suggest that by the year 2030, manufacturers of medical devices will transition from traditional business models to embrace novel digital methodologies incorporating AI. However, the introduction of AI-based medical devices into the market necessitates the development of a robust regulatory framework. Presently, leading regulatory bodies worldwide are in the incipient stages of delineating AI regulations and policies pertaining to medical devices. To facilitate the adoption of this regulatory framework and foster market harmonization, there is a pressing need for the establishment of international standards governing AI in medical devices. Moreover, AI's advent has engendered holistic improvements, ensuring societal well-being on a global scale.

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