ARTIFICIAL INTELLIGENCE IN MEDICAL DEVICES: PAST, PRESENT AND FUTURE

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ABSTRACT

Artificial Intelligence (AI) has been drawing attention in the field of medical devices. 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.

This study presents a narrative commentary on the applications of artificial neural networks (ANN) and machine learning (ML) algorithms in medical devices, past, current and future perspectives of application. One research focus of this study was on identifying problems and issues related to the implementation of AI in medical devices.

The commentary is based on scientific articles published in PubMed, Scopus ad ScienceDirect databases, official publications of international organizations: European Comission (EC), Food and Drug Administration (FDA), and World Health Organisation (WHO) published in 2009 – 2020 period.

AI is revolutionizing healthcare, from medical applications to clinical engineering. However, before grasping the full potential ethical, legal and social concerns need to be resolved and its application needs to be harmonized and regulated regarding equitable access, privacy, appropriate uses and users, liability and bias and inclusiveness.

Key words: Artificial intelligence; Machine learning; Neural network; Medical devices; prediction; diagnosis;

INTRODUCTION

According to The Business Research Company's research report (Busines Research company, 2020), Global Medical Device (MD) market is increasing due to rising infectious and chronic disease cases, the increase of number of healthcare facilities, healthcare expenditure, technological advancements, and rapid growth of the elderly population. The demand for MDs used in diagnosis, prognosis, and treatment has significantly increased since the emergence of COVID-19 globally (Badnjevic, 2020). Nowadays, it is evident that simply manufacturing a device, and putting it into the use in healthcare sector have been long surpassed. Users are now expecting to have more than a device. Even though there is high demand for healthcare, governments around the world are focused in cost reduction including MDs, but they want to have better patient outcomes. In other words, users of MDs are nowadays expecting more functionality which can be seen in prediction of clinical outcome, advanced classification or other functions which are for which intelligence is required.

Artificial Intelligence (AI), described as the 4th industrial revolution, refers to machines that can simulate human thinking in learning and analysis and therefore can work in solving the problem (Schwab, 2016). AI covers digital methods, ranging from computer vision to deep learning techniques, which model intelligent behavior without human intervention (Hamet, 2017). It has been applied to many areas of medicine (Long, 2020), especially to aid the detection and prevention of disease (Catic, 2018) (Gurbeta, 2018) (Badnjevic, 2018) (Saric, 2020). In respect to traditional computer programming, AI methods emulate the decision-making process of humans (Deo, 2015).

Nowadays, application of AI in healthcare is one of the strategic pillars for further advancements of the field, offering possibility on increasing efficiency while decreasing costs. Regulators worldwide have recognized (European Council, 2017) (FDA, 2020) recognized the importance of this innovative tools to improve healthcare and move away from hospital-centered systems towards integrated care while strengthening health promotion and disease prevention and implementing personalized medicine. Many countries have formulated or are formulating national AI strategies and policies to promote the research, development and adoption of these methods and technologies (Ravi, 2017) (LeCun, 2015). As a result of integration of AI in MD, variety of MDs for everyday usage in daily life are available, such as remote patient monitoring devices, wearable medical equipment, Electronic Health Records (EHR), etc. Medicine is a huge cognitive process, but it is also to a great extent an Information management task, since decision making is based upon expert knowledge, information of the patient and the doctors experience. Given the growing amount of data generated in healthcare, the potential of AI application is huge from clinical decision-making and public health, to biomedical research and drug development, to health system administration and service redesign.

The usage of AI in medical devices in healthcare is reviewed from the past, the present and future situation. From the perspective of its possible benefits and difficulties, the future applications of artificial intelligence in the medical field, as well as the application in medical devices. New AI functions provide novel solutions for healthcare, and the development of healthcare requires AI skills to reach a new level. The combination of both, demand and the development of AI and healthcare will enable these two fields to develop significantly in the foreseeable future, and ultimately benefit the quality of life of people in need.

METHODS

This paper is presented in the form of narrative commentary based on scientific articles published in PubMed, Scopus ad ScienceDirect databases, official publications of international organizations: European Comission, Food and Drug Administration (FDA) and World Health Organisation (WHO) published in 2009 – 2020 period.

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”. 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.

The following criteria were used to limit the research: papers/materials published from 2009 to 2020); language (English); and full-text publications.

RESULTS AND DISCUSSION

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes is considered to be medical device. This is definition which is adopted by various regulatory bodies, from European Commission, Food and Drug Administration (FDA), World Health Organisation (WHO) and others. In the 21st century, one of the biggest emerging trends shaping the medical device industry is software as a medical device (SaMD). The category of Software as a Medical Device (SaMD) refers to software products that operate as medical devices independently from any other medical device. They generally run with non-medical technology such as computers, smartphones, tablets, or wearable devices.

Artificial Intelligence in Medical Devices: PAST

The application of AI in medicine is closely linked to development in AI methods. 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 healthcare due to several technological limitations which have been overcome by the advent of deep learning.

Artificial Intelligence in Medical Devices: PRESENT

Medical device manufacturers are using these technologies to innovate their products to better help healthcare providers and improve patient care (Flaxman, 2018) (Burki, 2019) (Weungart, 2000).

New AI advances in hardware and software have allowed interpretation of physiological data from sensors which enabled rapid growth of wearables like smart watches, which contain digital health-monitoring applications. This trend in the growing number of wearables entering the market impacts digital health monitoring segment (Jha, 2016). With the continuous development of assistive diagnostic technology, a large amount of data is used in the process of disease detection, diagnosis and treatment (Abernethy, 2010). For clinicians, organizing and analyzing these data in a short period of time is a challenge. Therefore, AI is increasingly used in medicine to help doctors predict diseases and treatment outcomes.

From analysis of medical imaging such as echocardiograms, computed tomography (CT), endoscopy, and skin photographs, to tissue histology and physiological data, such as electrocardiograms (ECG), these technologies have demonstrated enormous potential for health care. They are designed to screen for diseases, classify malignancies, and provide personalized treatment recommendations, among other things, often sooner than has been possible using traditional technologies.

Machine learning is one of the most effective algorithms in machine learning. In recent years, ML have played an important role in medicine, especially in disease prediction. Patients with a history of idiopathic hemorrhagic ulcers may have a higher rate of ulcer recurrence. If serious complications (such as a ruptured ulcer) occur, the safety of the patient is threatened. In 2018, machine learning was used to build a high-precision model to predict the rebleeding of idiopathic peptic ulcer, which is called IPU-ML (Wong, 2019). In another case, enterovirus caused Severe hand, foot and mouth disease rarely causes serious complications in children, such as pulmonary edema and myocarditis (Liu, 2014). In 2019, in order to predict severe hand, foot and mouth disease, the CatBoost model was established, which showed higher specificity and sensitivity than other models (such as decision trees and SVM) (Wang, 2019). In addition, machine learning can predict the effectiveness of radiation therapy.

Combining new imaging technology and an artificial intelligence engine that uses a large number of historical images can improve current detection methods through faster analysis, real-time diagnosis and human error (Graber, 2005). Conditions like epilepsy, Alzheimer's Illness and stroke are a daunting challenge. Current diagnostic technologies (such as MRI, EEG) generate large amounts of data to detect, monitor, and treat neurological diseases. Data analysis is often difficult. It is essential to use intelligent systems that can accumulate, manage, analyze and automatically detect abnormalities in the nervous system. The application of artificial intelligence in this field will improve the consistency of diagnosis and increase the success rate of treatment (Blahuta, 2012). Diabetic retinopathy (DR) is one of the leading causes of preventable blindness worldwide. In a study published by the American Academy of Ophthalmology, a total of 75,137 public fundus images of diabetic patients were used to train and test an artificial intelligence engine to distinguish between healthy fundus and DR. results. The results showed an impressive sensitivity and specificity of 94% and 98%, respectively (Gargeya, 2017). AI is becoming more and more popular in image recognition applications. AI using deep learning algorithms can automatically perform a quantitative and more efficient assessment of complex medical imaging features. One application is to use radiology, ultrasound, and nuclear medicine to image the liver for possible liver disease. In image analysis, artificial intelligence is used to detect and evaluate focal liver lesions, promote treatment, and predict the appropriate response to treatment (Zhou, 2019). AI can be used for in vitro diagnostics, using real-time imaging to capture the fluorescence signal from cells passing up to. Use AI algorithms to distinguish cells by size, shape, and emission wavelength, and classify them as predictors of specific diseases. In addition, combined with other hardware technologies, can be completed in the real world. The integration of AI into the in vitro diagnostic platform can improve device diagnostic performance and accuracy (Smith, 2018).

As for approval of expert systems and medical devices that run on AI / ML statistics show that there is around 222 devices approved in the United States and 240 devices approved in Europe. (Urs, 2020) Since 2015, the number of approved AI / ML-based devices has increased significantly, many of which have been approved for radiology. However, few qualified devices are high-risk devices. Among the 124 generally recognized AI / ML-based devices in the United States and Europe, 80 were first approved in Europe. One possible reason for the earlier approval in Europe than in the United States may be that the evaluation of medical devices in Europe may be relatively less stringent.

Artificial Intelligence in Medical Devices: FUTURE

The future of AI application in MD can be seen in harmonizing standards and laws that specifically regulate the use of artificial intelligence in medical devices. Some advancements in the filed have already been done by FDA. Unlike the European legislators, the FDA has published its view on artificial intelligence in a document entitled "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)" which was published in April 2019. This document talks about the challenge of continuously learning systems. However, it observes that previously approved medical devices based on AI procedures worked with "locked algorithms".

While regulators are tackling the field, leading manufacturers are changing their business models from conventional manufacturing models into data driven intelligent models. For instance, Medtronic is committed to integrating artificial intelligence into its existing surgical industry, including advanced imaging, robotics and navigation, as well as increasing recruitment for remote patient monitoring. One of the key products Medtronic plans to implement in surgery is a preoperative platform called UNiD ASI, which can use predictive modeling algorithms to reconstruct the spine for digital modeling and perform measurements. UNiD ASI was developed by Medicrea GROUP, a French-based medical device company that provides surgical solutions for neurosurgeons and plastic surgeons.

On the other hand, Philips decided to focus on different market trends, especially AI diagnostics and workflow calculations with enhanced accuracy. In December 2020, Phillips signed a merger agreement to acquire BioTelemetry for US$2.8 billion. Bio Telemetry specializes in cardiac diagnostics, wearable heart monitors, artificial intelligence-based data analysis, and out-of-hospital monitoring positions ("The largest player in the medical technology industry embraces artificial intelligence: ruling on medical devices", 2021). In the world of medical equipment, artificial intelligence is a relatively new field. Unlike many traditional devices usually developed by teams of materials, mechanical, and electrical engineers, artificial intelligence-based medical devices require expertise in software programming and coding.

The future of AI application can be seen not only in increasing accuracy of treatment, but also in preventin injuries and deaths caused by medical devices. As healthcare is generating a lot of data, as in fact every medical device is generating a lot of data, those big data structures can be used to predict safety and performance of medical devices. For instance, the use of smart infusion pump systems has become the preferred method to ensure the safety of intravenous drugs. Most of these systems are based on AI expert systems rather than ML, but the durability and reliability of such devices have led to more comprehensive ML-based applications such as implantable insulin pumps and emerging closed-loop artificial pancreas devices.

Several examples related to healthcare have been cited above, and applications in healthcare are increasing rapidly due to ubiquitous memory and applications and cloud computing resources. For example, most smart infusion pump systems are now designed with ancillary modules and equipment, such as barcodes and radio frequency identification (RFID) readers, to help realize "Five Rights": The right patient, the right drug, the right dose, the right route, and the right time. The MD management strategy is very different from decades ago, so consider how we can contribute to the future.

Inadequate monitoring and improper monitoring of medical devices (MD) will bring a high risk of deviations from accuracy and safety of performance, which will affect clinical accuracy and the efficiency of patient diagnosis and treatment. Even as equipment technology matures, incidents involving defibrillator failure are not uncommon. Articles published in 2019, presents the results of the application of machine learning (ML) technology in the management of infant incubators and defibrillators in medical institutions (Badnjevic 2019, Kovacevic 2019). The results show that the introduction of machine learning algorithms in Machine learning management strategies can not only improve patient diagnosis and the safety and quality of treatment, and can benefit medical institutions in terms of cost optimization and management.

Such a systems present paradigm change, from reactive management and maintenance to predictive as they can be used to detect hardware deviations, which lead to incorrect diagnosis and incorrect treatment of patients. The results of this study show that clinical engineering and health technology management benefit from the application of machine learning in terms of cost optimization and medical equipment management.

CONCLUSION

The purpose of this study is understanding the availability of technology, appreciate the great potential of AI in healthcare, track new scientific achievement to provide inspiration to researchers in the field. So far, ethical discourses on artificial intelligence and health have occupied privacy and security, trust, prejudice, and accountability and accountability issues, and as the scale of the technology continues to expand, more problems will undoubtedly arise.

When medical devices are concerned, AI is still in its beginnings. It is expected that until 2030 manufacturers of medical devices will shift from traditional business model and incorporate new digital methods of artificial intelligence. In order to place AI based MDs on the martket regulatory framework needs to be developed. Leading regulatory bodies worldwide are still in the beginning of defining AI regulation and policies concerning MDs. To support the uptake of regulatory framework and to harmonize the market international standards concerning AI in MDs are needed. ISO, IEC and IEEE organizations are working on standardizing data quality management and application of AI affecting human wellbeing.

Even with recognized obstacles once can conclude that AI has aalready completely changed the traditional medical model, significantly improved the level of medical services, and ensured health in all aspects. It is yet to be seen how future development prospects of medical AI will impact the human population in tackling the rising challenges such as infectious pandemics, chronic diseases and elderly population.

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