MEDICAL SCIENCE MONITOR

EDITORIAL

e-ISSN 1643-3750
© Med Sci Monit, 2021; 27: e933675
DOI: 10.12659/MSM.933675

Received: 2021.06.20
Accepted: 2021.06.21
Available online: 2021.06.21
Published: 2021.06.28

Editorial: Artificial Intelligence (AI) in Clinical Medicine and the 2020 CONSORT-AI Study Guidelines

Dinah V. Parums, MD PhD

Science Editor, Medical Science Monitor, International Scientific Information, Inc., Melville, NY, U.S.A.

e-mail: dinah.v.parums@isi-science.com

Abstract

Artificial intelligence (AI) in clinical medicine includes physical robotics and devices and virtual AI and machine learning. Concerns have been raised regarding ethical issues for the use of AI in surgery, including guidance for surgical decisions, patient confidentiality, and the need for support from controlled clinical trials to use these methods so that clinical guidelines can be developed. The most common applications for virtual AI include disease diagnosis, health monitoring and digital patient consultations, clinical training, patient data management, drug development, and personalized medicine. In September 2020, the CONSORT-A1 extension was developed with 14 additional items that should be reported for AI studies that include clear descriptions of the AI intervention, skills required, study setting, inputs and outputs of the AI intervention, analysis of errors, and the human and AI interactions. This Editorial aims to present current applications and challenges of AI in clinical medicine and the importance of the new 2020 CONSORT-AI study guidelines.

Keywords: **Editorial • Artificial Intelligence • Machine Learning • Robotics • Guidelines as Topicl**

Artificial intelligence (AI) was first used in the 1950s as an engineering term for intelligent machines that could perform human-like tasks [1]. In the 1940s, the concept of computational analysis and machine learning to achieve human-level performance in cognition-related tasks was recognized, developed, and implemented by Alan Turing [2]. From the 1990s, AI-based clinical research and development increased and by 2016, the main areas of research funding in AI were for medicine and health care [3].

Currently, there are two main roles for AI in medicine, physical and virtual AI [3]. Physical AI includes robotics and devices that assist in surgery, intelligent prosthetics for the disabled, and physical aids for the elderly [3]. An example of surgical AI is the Da Vinci robotic surgical system (Intuitive Surgical, Inc., Sunnyvale, CA, USA), mainly used for urological and gynecological surgery [4]. The Da Vinci robotic arm mimics the surgeon's hand movements and is combined with a magnified imaging system [4]. Recently, an opinion editorial published in JAMA Surgery supported that AI clinical decision support systems (AI CDSS) could reduce errors and increase the accuracy of surgical procedures [5]. However, there are ethical issues that need to be addressed for the use of AI in surgery, including guidance for decisions regarding surgery, patient confidentiality, and the need for support from controlled clinical trials for the use of these methods so that clinical guidelines can be developed [5,6]. Physical AI and robotics lack uniquely human traits such as empathy, emotional intelligence, critical thinking, creativity, and communication skills, which means that they will never entirely replace the clinician.

Virtual AI in clinical medicine involves machine-learning algorithms and software to mimic human cognition in the analysis of complex medical data [3]. In the past decade, there have been increasing publications in the medical literature on AI application in clinical medicine [3]. The most common applications include disease diagnosis, health monitoring and digital patient consultations, clinical training, patient data management, drug development, and personalized medicine [3]. Radiologists have been at the forefront of using virtual AI in diagnostic medicine [7]. Image acquisition, storage, and communication now rely on computer-assisted diagnosis (CAD), particularly screening mammography, and have improved diagnostic accuracy [7,8]. In 2016, the Digital Mammography DREAM Challenge included several computer networks to establish an AI-based algorithm following a review of 640,000 digitally recorded mammograms [9]. Although the diagnostic specificity (0.81) and sensitivity (0.80) did not indicate that these systems should replace radiologists, there is a possibility that AI can be used in quality control, audit, and training of radiologists [9]. AI systems can review many images within minutes and develop experience and expertise beyond any individual. Therefore, AI-based decision-making approaches may be used in diagnostic situations where experts may disagree, such as identifying pulmonary tuberculosis on chest radiographs [8].

Indexed in: [Current Contents/Clinical Medicine] [SCI Expanded] [ISI Alerting System] [ISI Journals Master List] [Index Medicus/MEDLINE] [EMBASE/Excerpta Medica] [Chemical Abstracts/CAS]

Several AI systems exist to monitor patient diagnosis and treatment compliance. For example, in the US, the National Institutes of Health (NIH) has developed the AiCure App that includes a webcam and smartphone used to monitor patient compliance with medications [10]. Personal health trackers are increasingly used to monitor physical activity, sleep, heart rate, and ECG monitoring [11]. A further application of AI is in the training of healthcare professionals and in reducing time spent on administrative work. In 2016, a study showed that primary care physicians spent an average of 17% of their time interacting with their patients and more than 49% of their time adding content to electronic hospital records [12]. It is now possible for primary care physicians to use AI to take notes and record their interactions with patients directly into electronic health records [12].

One of the most exciting areas of AI in clinical medicine is drug development. Research and development and the conduct and analysis of clinical trial data of pharmaceutical agents for a specific disease usually take several years and have a high cost. Deep learning architecture algorithms are now used in drug development to facilitate pattern recognition skills used by chemists [13]. AI and machine learning have been used in the design of drugs, with evaluation of all the available drug data [14].

The IBM Corporation AI platform known as Watson has been used to assist patient diagnosis and to suggest therapeutic options that oncologists may not have considered [15]. Therefore, it is possible that if AI systems have sufficiently large amounts of data, they may improve the diagnostic ability of clinicians and improve treatment planning. In oncology, large amounts of clinical data and gene sequencing data may be difficult to analyze by clinicians who wish to implement the most effective personalized approaches to patient care [16].

There are increasing numbers of publications on AI in clinical medicine. For example, in ophthalmology alone, between 2015 and 2020, 728 publications included artificial intelligence or deep learning as keywords [17]. The US Food and Drug Administration (FDA) continues to develop new pathways for regulatory approval with awareness of the potential benefits of AI and the potential risks [18]. Therefore, evidence-based guidelines are required to standardize the reporting of AI studies, and initial guidelines are based on those designed for reporting randomized clinical trials. The Consolidated Standards of Reporting Trials (CONSORT) and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines were originally developed to standardize the reporting of clinical trials and clinical trial protocols [19,20]. In September 2020, the CONSORT-A1 extension was developed [21]. The CONSORT-AI extension includes 14 additional items that should be reported for AI interventions [21]. Investigators are required to provide clear descriptions of the AI intervention, skills required, study setting, inputs and outputs of the AI intervention, analysis of errors, and the human and AI interactions [21]. The CONSORT-AI guidelines will promote reporting of clinical trials for AI interventions, assist journal editors and peer reviewers, and help to develop the required evidence for future recommendations in the use of AI in clinical medicine [22].

Conclusions

Developments in virtual AI and machine learning in clinical medicine continue to improve diagnostic accuracy, identify new treatments, improve patient care, improve medical training and quality of care, and reduce administrative burdens for clinicians, which will provide more time for individualized patient care. Developments in physical AI or robotics devices that assist surgeons may also reduce surgical time and improve outcomes but will require specialized training. The development of the 2020 CONSORT-AI guidelines for AI studies is an important advance that will increase the likelihood of future evidence-based guidelines to support AI in all areas of clinical medicine.

References:

1. Mintz Y, Brodie R. Introduction to artificial intelligence in medicine. Minim Invasive Ther Allied Technol. 2019;28:73-81
2. Turing AM. Computing machinery and intelligence. Mind. 1950;236:433-60
3. Amisha Malik P, Pathania M, Rathaur VK. Overview of artificial intelligence in medicine. J Family Med Prim Care. 2019;8(7):2328-31
4. Hagen ME, Jung MK, Ris F, et al. Early clinical experience with the da Vinci Xi Surgical System in general surgery. J Robot Surg. 2017;11(3):347-53
5. Binkley CE, Green BP. Does intraoperative artificial intelligence decision support pose ethical issues? JAMA Surg. 2021 Jun 16. doi: 10.1001/jamasurg.2021.2055 [Online ahead of print]
6. Loftus TJ, Tighe PJ, Filiberto AC, et al. Artificial Intelligence and Surgical Decision-making. JAMA Surg. 2020;155(2):148-58
7. Mayo RC, Leung J. Artificial intelligence and deep learning. Radiology's next frontier? Clin Imaging. 2018;49:87-88
8. Lakhani P, Sundaram B. Deep learning at chest radiography: Automated classification of pulmonary tuberculosis by using convolutional neural networks. Radiology. 2017;284:574-82
9. Schaffter T, Buist DSM, Lee CI, et al. Evaluation of combined artificial intelligence and radiologist assessment to interpret screening mammograms. JAMA Netw Open. 2020;3(3):e200265
10. Labovitz DL, Shafner L, Reyes Gil M, et al. Using artificial intelligence to reduce the risk of nonadherence in patients on anticoagulation therapy. Stroke. 2017;48:1416-19
11. Dias D, Paulo Silva Cunha J. Wearable health devices-vital sign monitoring, systems and technologies. Sensors (Basel). 2018;18(8):2414
12. Sinsky C, Colligan L, Li L, et al. Allocation of physician time in ambulatory practice: A time and motion study in 4 specialities. Ann Intern Med. 2016;165:753-60
13. Schneider G. Automating drug discovery. Nat Rev Drug Discov. 2018;17(2):97-113

Indexed in: [Current Contents/Clinical Medicine] [SCI Expanded] [ISI Alerting System] [ISI Journals Master List] [Index Medicus/MEDLINE] [EMBASE/Excerpta Medica] [Chemical Abstracts/CAS]

14. Merk D, L Friedrich, F Grisoni, G Schneider. De novo design of bioactive small molecules by artificial intelligence. Mol Inform. 2018;37(1-2):1700153
15. Jie Z, Zhiying Z, Li L. A meta-analysis of Watson for Oncology in clinical application. Sci Rep. 2021;11(1):5792
16. Patel NM, Michelini VV, Snell JM, et al. Enhancing next-generation sequencing-guided cancer care through cognitive computing. Oncologist. 2018;23(2):179-85
17. Campbell JP, Lee AY, Abràmoff M, et al. Reporting guidelines for artificial intelligence in medical research. Ophthalmology. 2020;127(12):1596-99
18. Faes L, Liu X, Wagner SK, et al. A clinician's guide to artificial intelligence: How to critically appraise machine learning studies. Transl Vis Sci Technol. 2020;9:7
19. Eaton LA. CONSORT guidelines In: Gellman MD, Turner JR, eds. Encyclopedia of behavioral medicine. New York: Springer, 2013;486-87
20. Moher D, Chan AW. SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) In: Moher D, Altman DG, Schulz KF, et al., eds. Guidelines for reporting health research: A user's manual. Hoboken, NJ: Wiley, 2014;56-67
21. Liu X, Cruz Rivera S, Moher D, et al; SPIRIT-AI and CONSORT-AI Working Group. Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: The CONSORT-AI extension. Nat Med. 2020;26(9):1364-74
22. Topol EJ. Welcoming new guidelines for AI clinical research. Nat Med. 2020;26(9):1318-20

Indexed in: [Current Contents/Clinical Medicine] [SCI Expanded] [ISI Alerting System] [ISI Journals Master List] [Index Medicus/MEDLINE] [EMBASE/Excerpta Medica] [Chemical Abstracts/CAS]