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Review Article

Artificial intelligence: A transformative role in clinical laboratory

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ABSTRACT

Every industry is experiencing a surge in technological innovation. Expert systems, facial recognition, language translation, chatbots, health trackers, mobile phone applications, robotic surgery, etc., have all progressively become a part of our everyday lives. Artificial intelligence (AI) has emerged as a transformative force in laboratory medicine and healthcare systems. Digitalization of laboratories generates huge electronic health records data. These data are processed and meaningfully interpreted by AI algorithms, thus potentially enhancing the speed and accuracy of diagnosis, clinical decision-making, illness monitoring, patient care, and patient safety. A comprehensive literature search was conducted to write this review article, including databases such as PubMed, ResearchGate, Web of Sciences, Scopus, and Google Scholar. This review article focuses on the introduction of AI and machine learning, the interpretation of huge laboratory data, the ability to spot patterns, and their applications in routine biochemistry clinical laboratories. Technology although very beneficial also provides critical threats to patients' privacy, safety, ethics, and opportunities for employment. The study also highlights the various challenges faced by developing countries such as inadequate data availability, digital infrastructure deficiencies, and unavailability of trained and technical staff. The article envisions the future of clinical biochemistry laboratories that will employ these methods to make significant perfections in efficiency and diagnostic accuracy.

Keywords: Accuracy, Algorithms, Artificial intelligence, Laboratory data, Machine learning

INTRODUCTION

Artificial intelligence (AI) is a technological innovation that has become gradually intertwined with our daily lives. It can potentially improve or completely change many facets of the healthcare system that will revolutionize diagnostic and patient care.[1] The state-of-the-art, AI-based computer algorithms have attained a high level of accuracy, which is at par the human experts in the field of medical sciences. AI is being used in laboratory medicine to decrease errors, increase accuracy and efficiency, improve diagnostic processes, and optimize the treatment plan.[2] With a focus on AI in biochemistry clinical laboratories, this review aims to explore the background, significance, implications, and ethical challenges in clinical laboratory services.

ARTIFICIAL INTELLIGENCE (AI)

In 1956, John McCarthy (1927–2011), an American scientist, used the term AI. According to him, AI is the "theory and development of computer systems that execute tasks that generally entail human intelligence."[3] Geoffrey Hinton and John Hopfield are the pioneers of AI. Geoffrey

Hinton is known as the Godfather of AI. They laid the foundation of machine learning (ML) and artificial neural networks (ANN) using physics. For their exceptional work, they were awarded the Nobel Prize in October 2024. AI is a field of computer science that is designed to simulate the human brain, its thinking process, learning abilities, solving complex problems, and knowledge storage.[4]

Approximately 70% of the opinions regarding diagnosis, treatment, and discharge of the patients are being made based on the laboratory test results.[5] The increasing population and the workload, overpriced healthcare, and demand for high precision and accuracy require continuous upgradation of the laboratory processes.[6] To overcome these demands, diagnostic laboratories are rapidly shifting to digitization and automation by implementing laboratory information management systems (LIMS). AI is the next phase in the evolution of laboratory software. The unremitting advancement and progress of AI in clinical laboratory medicine have reached an unprecedented prosperous stage from the era of manual medical tests to semi-automatic and fully-automatic analysis.[7]

MACHINE LEARNING (ML)

A lot of data is produced by clinical laboratories daily.[8] This is known as big data; it incorporates data generated from the pre-analytical, analytical, and post-analytical phases and the data that are completely and incompletely captured in LIMS.[9] AI has huge data storage capacity.[10] For optimal function of algorithms, it is imperative that this laboratory data should be accurate and reliable.[11]

AI is a broader field while ML is a subset or "brain" of AI, which is being largely used in the field of laboratory medicine. ML refers to statistical models and computer algorithms to teach machines from previous examples. The objective of ML is to take the input data to create rules through pre-set algorithms and apply these rules to new data for classification and prediction.[12] These data are being processed, i.e., organized into data tables, imputing missing values, and merging observations so that they can be concise and fed into a model. If the model is trained on a labeled database, i.e., target or outcome variables are known, it is known as supervised ML. It includes linear and logistic regression, support vector machines (SVM), and tree-based models such as random forest (RF) and extreme gradient boosting (XG Boost).[13]

ML models, where an algorithm discovers patterns and relationships using unlabeled data, are known as unsupervised ML. The primary goal of unsupervised learning is frequently to notice the hidden patterns, resemblances, or clusters within the data, e.g., clustering-nearest neighbors (KNN) and principal component analysis.[14]

The retrospective data that are used to develop ML models are divided into two sets, i.e., the training set and the testing set. The algorithms learned from the training set and made certain rules to be followed up in testing set data. If the data collected targets a particular race, a particular gender, and a specific age group, the subsequent model will be biased, known as biased data. Therefore, the data collected must be a true representation of the population for which its use is envisioned.[15]

After creating models, the crucial step is the selection of the algorithm or model. The selection depends upon the task. After selection, the next important step is the evaluation of its performance. The evaluation is being done by many metrics such as sensitivity, specificity, accuracy, precision, recall, F1 score, and area under the receiver operator curve.[16]

Deep learning (DL) is a branch of ML. It mimics the intricate neural networks of the human brain. An ANN uses layers of interconnected nodes called neurons that work together to process and learn from the input data. DL is used in radiomics, i.e., the discovery of clinically significant patterns in imaging data that are beyond the recognition capacity of the human eye.[17] AI and ML are used for structured data and are predominantly used in the fields of medicine and clinical laboratories. For unstructured data like clinical notes and reports of patients, classical SVM, neural networks, modern DL, and natural language processing (NLP) have been used. ML and DL can handle large, complex, non-linear, and multidimensional data better than the old conventional statistical formulas.[16] NLP includes applications such as speech acknowledgment, manuscript scrutiny, paraphrasing, and other goals related to language. The fundamental approaches are statistical and semantic NLP.[18] NLP is involved in the formation, understanding, and classification of clinical documentation and research, analyzing unstructured clinical notes, preparing reports (radiology examinations), and recording patient interactions.[19,20]

ROLE OF FOOD AND DRUG ADMINISTRATION (FDA)

Currently available AI/ML-based medical devices and algorithms that have been approved by the US FDA. It is pivotal for the inventors of AI- or ML-based medical devices and algorithms that they have to go through laborious procedures and stringent guidelines recommended by the FDA. FDA made a regulatory body that has three levels of clearance, namely 510(k),[21] premarket approval,[22] and the *de novo* pathway,[23] each of which needs specific criteria to be fulfilled before granted.

APPLICATIONS OF ML AND AI

ML models are capable of processing enormous data, reducing time and improving diagnostic accuracy, designing patient-oriented care pathways that will adhere patients to medication, customize the dosages, etc.,[24] Several studies aimed at using AI in laboratory medicine that can improve the workflows, effectively use resources, and reduce costs, leading to higher efficiencies and safety of the patient.[25]

In 2015, a study by Lidbury *et al*. analyzed case reports of liver function tests (LFTs). They test the accuracy of Gamma-glutamyl transferase (GGT) prediction by the highest-ranked predictors of GGT response, alkaline phosphatase (ALP), and alanine aminotransaminase (ALT). The data from 20,000 LFT reports were analyzed using ML algorithms, recursive partitioning (decision trees), and SVMs. The study concluded that the ALT and ALP decision trees had an accuracy of up to 90% in predicting GGT, or the GGT estimation is not required in 90% of LFT because GGT can be accurately predicted by ALT and ALP estimations. Other parameters of LFTs such as bilirubin, lactate dehydrogenase, and albumin did not improve prediction or reduce the accuracy.[26]

Tuberculosis and its complications are commonly encountered in developing countries like India. Tuberculosis pleural effusion (TPE) is diagnosed by elevated levels of adenosine deaminase (ADA) and lymphocytosis. Pathological examinations are invasive, costly, and less specific.[27] The problem encountered with ADA is that its reference range is different in different studies, so a new method is required that should be less invasive and highly accurate.[28] A study by Ren *et al*. done in 2019 analyzed the data reports of patients with TPE (192), parapneumonic pleural effusion (54), and malignant pleural effusion (197). They used four ML algorithms such as logistic regression, KNN, SVM, and RF, to establish a diagnostic model for the diagnosis of TPE. The study demonstrated that this model may provide a more effective, economical, and faster diagnostic method that assists clinicians in better diagnosis and treatment decisions of TPE.[29]

Topcu and Bayraktar[30] in 2022 developed a novel formula for testing urine osmolality by applying the ML model. They analyzed the test results data of 300 spot urine samples and evaluated 183 ML models. The study concluded that using ML models, analysis of urine osmolality achieved better results than existing formulas (the ML R2 score was 0.83).

In a study done by Constantinescu *et al.*,[31] they integrated ML into mass spectrometry and interpreted the reports of steroid profiles. Based on these reports, they create algorithms. The study concluded that AI and ML improved diagnostic decision-making in unilateral primary aldosteronism.

ML algorithm models are more flexible and have higher accuracies than conventional methods. A recent study done in 2022 at All India Institute of Medical Sciences, Bhuvneshwar, described that ML models such as XG Boost and RF can be used to estimate low-density lipoprotein cholesterol (LDL-C) more precisely. This study included 13,391 test reports of LDL-C from the laboratory database. The data were divided into a training set (70%) and a test set (30%). The training set was used to create three ML models and a linear regression formula. These models were tested with test set data for validation. The performance of the models was compared and found to be more accurate than conventional formulas such as Friedewald's formula (1972)[32] and Martin's formula (2013).[33,34]

Diabetes and its complications have a significant impact on morbidity and mortality in patients.[35] The use of AI and ML for early diagnosis of diabetes complications is a growing global interest. A review study by Kanbour *et al*. was done in 2024, which focused on AI in predicting diabetic complications such as diabetic retinopathy (DR), diabetic nephropathy or diabetic kidney disease (DKD), and diabetic neuropathy (DN). The study reviewed 74 articles, 256 internally validated, and 124 externally validated ML models. The study concluded that for DR, DKD, and DN, predictive models achieved a mean ± standard deviation, c-statistic of 0.79 (0.09) on internal validation and 0.72 (0.12) on external validation. DKD models had the highest discrimination, with c-statistics of 0.81 (0.09) on internal validation and 0.74 (0.13) on external validation, respectively. Various factors such as prediction prospects, outcome explanations, number and type of predictors, and ML technique highly influenced model performance.[36]

DKD is the major cause of end-stage renal disease and renal failure.[37] At present, albuminuria and estimated glomerular filtration rate (eGFR) are legacy biomarkers for early diagnosis of DKD. However, albuminuria is also observed in non-proteinuria diabetic nephropathy patients, and it is an indicator of glomerular injury only.[38] For the calculation of eGFR, estimation of serum creatinine is required. Serum creatinine levels are affected by the muscle mass and diet pattern of the patient.[39] Hence, a new prognostic marker is urgently required. A cohort study by Chan *et al*. was done to predict the prognosis of patients with diabetic nephropathy. They used the AI-based RF algorithm combined with multiple biomarkers (kidney injury molecule-1, tumor necrosis factor receptor 1, and tumor necrosis factor receptor 2). The study concluded that the area under the curve (AUC) of the RF algorithm was 0.77 whereas the AUC of the KDIGO grading system was only 0.62. Therefore, ML algorithms have more advantages in predicting the prognosis of DKD.[40]

Diabetes is a major health problem that impacts a significant number of people globally. AI-based smart technology system (Guardian Connect system) will continuously predict the high and low blood glucose levels of the patient. DreaMed Diabetes System is a medical technology that uses AI and analytics to develop software for personalized diabetes treatment.[41]

AI has the power to reduce discrepancies and enhance the accuracy and quality of medical care by improving access to point-of-care testing. An *et al*. invented a point-of-care microchip device based on ANN and ML algorithms (AI-based). This device can be used for the estimation of hemoglobin (Hb) and Hb variants like sickle cell anemia. It can evaluate anemia with 100% sensitivity and 92.3% specificity.[42]

AI and ML advancements made a radical change in molecular diagnostics. It decreases the throughput time and plays a magnificent role in high multiplexity nucleic acid technology. Next-generation sequencing techniques play a significant role in evaluating millions of small clusters of tagged nucleic acids and producing enormous amounts of data (robust big data). Analysis of such huge data is not possible by conventional methods.[43]

The future of AI in healthcare is bright and promising; the automation of certain procedures can dramatically increase the sensitivity, speed, and generalizability of complex analyses and clinical decisions. It allows the doctors to perform more examinations or dedicate more time to each patient and yet much remains to be done.

CHALLENGES TO AI AND ML

Acceptance of new technology requires a mindset and willingness to change the current structure.[44] The medical field deals with human beings so various challenges and threats also need to be discussed.

Infrastructure constraints, limited facilities, unstable power supply, inadequate internet connectivity, and insufficient hardware and software resources are common challenges in developing countries. Another main concern is the cost. Ethical use of technology requires costs and benefits to be dispersed as equally as possible among the community of stakeholders. AI tools used in the laboratory for analysis and diagnosis require professional staff, skill based trainings and workshops.[45]

From the clinical point of view, four principles of biomedical ethics, like respect for patient autonomy, beneficence, non-maleficence, and justice, should be maintained.[46] The biggest limitation faced by AI algorithms in laboratory medicine is the quality of data. However, due to limited resources, fragmented health information systems, incomplete electronic health records, and insufficient data organization practices hitch in retrieving complete and diverse data.[47] The more information is available to the machines for accurate assessments, the chances of leakage of sensitive data are increased.[48] It also includes transparency of personal data (patient privacy), bias, and security of the data.

AI is a relatively young field in the health diagnostic sector. It needs stringent regulations and standardization.[49] FDA and other regulatory bodies should provide a clear overview of approved AI/ML-based medical devices and algorithms.[50]

CONCLUSIONS

AI and ML promise transformative progressions in laboratory medicine. AI algorithms and models are prevailing clinical decision support tools that help augment the utilization of laboratory tests. The application of AI in the laboratory certainly goes beyond the aspects mentioned in this article. Pioneers of AI have raised concerns about the safe and ethical use of AI. It is our responsibility to use new technology for the greatest benefit of humankind.

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