Challenges of Implementing Artificial Intelligence in Interventional Radiology

Sina Mazaheri, MD[1] Mohammed F. Loya, MD[1] Janice Newsome, MD[1,2] Mathew Lungren, MD[3] Judy Wawira Gichoya, MD[1]

[1] Department of Radiology and Imaging Sciences, Emory University School of Medicine, Atlanta, Georgia
[2] Department of Interventional Radiology, Emory University School of Medicine, Atlanta, Georgia
[3] LPCH Pediatric Interventional Radiology, Stanford University, Stanford, California

Address for correspondence Sina Mazaheri, MD, Emory University School of Medicine, 1364 Clifton Road NE, Atlanta, GA 30322 (e-mail: sina.mazaheri@emory.edu).

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Abstract

Artificial intelligence (AI) and deep learning (DL) remains a hot topic in medicine. DL is a subcategory of machine learning that takes advantage of multiple layers of interconnected neurons capable of analyzing immense amounts of data and "learning" patterns and offering predictions. It appears to be poised to fundamentally transform and help advance the field of diagnostic radiology, as heralded by numerous published use cases and number of FDA-cleared products. On the other hand, while multiple publications have touched upon many great hypothetical use cases of AI in interventional radiology (IR), the actual implementation of AI in IR clinical practice has been slow compared with the diagnostic world. In this article, we set out to examine a few challenges contributing to this scarcity of AI applications in IR, including inherent specialty challenges, regulatory hurdles, intellectual property, raising capital, and ethics. Owing to the complexities involved in implementing AI in IR, it is likely that IR will be one of the late beneficiaries of AI. In the meantime, it would be worthwhile to continuously engage in defining clinically relevant use cases and focus our limited resources on those that would benefit our patients the most.

Keywords

- artificial intelligence
- machine learning
- interventional radiology
- use cases
- challenges

Artificial intelligence (AI) continues to remain a hot topic in healthcare. The global AI in healthcare market size is expected to grow from USD 4.9 billion in 2020 to USD 45.2 billion by 2026.[1] Broadly speaking, AI is an umbrella term that encompasses computer algorithms able to perform functions typically attributed to human cognition. Machine learning (ML) is a subset of AI and refers to specific algorithms which, through exposure to large amounts of data, are able to adapt their function and output and effectively "learn" from their mistakes until an optimal level of performance is achieved.[2] While ML has been around for decades, the recent exponential growth in its popularity and application has been through the advent of deep learning (DL). DL refers to a subset of ML algorithms or models that employ multiple interconnected layers of mathematical "neurons" working in parallel to process massive troves of data to almost independently gain insights and offer predictions in line with the task at hand.[2]

The uses and impacts of AI and ML are becoming more evident in day-to-day life from self-driving cars, smart personal assistants on mobile phones, commerce and social media, and even legal assistance.[3] Medicine and healthcare as a whole are also experiencing their own paradigm shift thanks to AI. Arguably, no medical field is as inherently equipped for this technology as the field of radiology, particularly due to mature data-science infrastructure and workflows, universal interoperable data formatting (DICOM, HL7), and the central image analysis tasks with parallels to existing AI applications. Over the past few years, there have been numerous publications and reports showcasing new

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models and use cases for ML in diagnostic radiology.[4–7] Many startup companies have been established in this space, with further involvement of larger, well-known tech companies that acquire these startups or establish their own capabilities.[8] However, while multiple studies have pointed out the great potential AI and ML have for procedural medical specialties such as interventional radiology (IR),[9–14] to date practical applications of ML in IR have not been introduced to clinical practice. In fact, in a recent article by van Leeuwen et al reviewing 100 commercially available AI products in radiology, there is a notable absence of IR in the listed applications.[4]

In this article, we set out to break down some of the possible factors and challenges contributing to this slow implementation of AI and ML in general, and more specifically in procedural fields such as IR. We will briefly summarize previous work in the context of new developments toward AI-enabled IR applications and workflows, and discuss in-depth approaches for achieving successful AI implementation in IR.

The Current State of Artificial Intelligence in Interventional Radiology

Interventional radiology, due to its procedural nature, has arguably more in common with surgical subspecialties than with diagnostic radiology in many aspects. This pattern is also evident when considering AI and its implementation. Surgery has also seen a slow adoption of AI solutions into practice, and while multiple preliminary and hypothetical use cases have been reported in different fields such as orthopaedics, plastic surgery, trauma, cardiothoracic surgery, and ophthalmology, they all are currently in their infancy.[15] Likewise, despite the excitement and willingness to embrace AI in IR, the process of introducing new AI use cases into practice has been slow. For example, a review of the proposed AI use cases by the American College of Radiology Data Science Institute lists merely a single IR use case out of a total of 173 cases as of this writing.[16] Nevertheless, over the past few years several preliminary yet innovative approaches to using AI in IR have been published. Several review articles have touched upon some of these IR-related use cases and have discussed many additional hypothetical yet-untapped applications of AI in IR.[9–11,17–21] The proof-of-concept use cases published in this space can be loosely grouped into the following categories: workflow optimization (e.g., scheduling),[22] periprocedural imaging, treatment planning,[23] patient outcome and complication prediction,[24–29] intraprocedural support,[30–32] intraprocedural safety,[33,34] and intraprocedural guidance.[10,35–38] While still in the early stages, each of these examples holds great potential and can be plausibly incorporated into IR practice in the near future.

Challenges of Implementing Artificial Intelligence

While ML is not by any means a new field and has been around for decades, it has been undergoing changes and innovation at a rapid pace. Given the relative novelty and lack of precedence of ML in medicine, there will undoubtedly be many challenges to successfully implement such solutions in clinical practice. Multiple studies have briefly touched on some of the difficulties of implementing AI in procedural specialties and practices.[10,13,17,20,39,40] Here, we break down the most significant of these challenges in the following categories: inherent specialty challenges, regulatory challenges, intellectual property, raising capital, and ethical challenges.

Inherent Specialty Challenges

Perhaps the most apparent hurdle to creating an AI model applying to a procedural field such as IR would be the heterogenous nature of this specialty. The acquired intraprocedural imaging data, be it ultrasound, fluoroscopy, or even CT (computed tomography), can be heavily operator dependent. This results in variable positions of the equipment and captured images, which makes curating a standard dataset quite challenging. In addition given the inventive nature of IR and its practitioners, and the availability of many different endovascular devices and techniques, there may be multiple approaches to any given clinical situation that achieve the same outcome; for instance, during creation of a transjugular intrahepatic portosystemic shunt access can be obtained from either internal jugular veins, and portal visualization can be performed by intracardiac echo, direct puncture of the portal vein, transabdominal ultrasound or carbon dioxide portogram.

One essential factor contributing to the recent rise in the number of successful AI models in diagnostic radiology has been the presence of high-quality, publicly available datasets. As of this writing, no IR-exclusive datasets have been made available. This is presumably secondary to the inherent difficulties of compiling a dataset as discussed above as well as the resource-intensive nature of data annotation, especially in a highly specialized field such as IR where an expert's input cannot be easily replaced by and outsourced to untrained individuals or novice trainees. It is also worth noting that a great portion of the imaging data generated during an IR procedure in the form of fluoroscopic images are usually not saved by default and therefore lost.

Another complicating matter is that the currently available software is not vendor-neutral and is dependent on the manufacturer of the IR equipment, preventing the prospect of implementing universal AI solutions across different health systems. Additionally, most current diagnostic AI deployment mechanisms are not well suited to the typical IR workflow; they often require the technologist to send the images to the cloud server after completion of the study. However, to achieve a robust, real-time system, new IR-specific workflows need to be designed that minimize the need for human intervention.

As we work on tackling the earlier-mentioned challenges, perhaps the best use of resources for the time-being would be to focus on AI solutions that are procedure and practitioner agnostic, such as scheduling and follow-up, patient and treatment selection, multimodality image fusion, low-dose reconstruction, and IR-related device identification such as type of IVC filters. Moreover, practitioners of IR should continuously participate in defining and scoping AI use cases that bring the most value to their practice and try to steer AI endeavors from feasibility studies into what is clinically relevant and beneficial.

Artificial Intelligence Regulation and the Food and Drug Administration

Once an idea is past the theoretical stage and has been tested out in a limited capacity, the model manufacturer, aiming to eventually introduce the software to the market, must face the hurdle of governmental approval. The U.S. Food and Drug Administration (FDA) regulates the sale and distribution of all medical devices and monitors their safety. A certain ML software is arguably a device in its own right which serves a certain function such as alerting physicians to a likely stroke (as in Viz.ai[41]), and is therefore placed in a unique category titled Software as a Medical Device (SaMD).[42]

Until recently, there has been a sense of uncertainty among AI practitioners and users on the clinical side as to how these SaMDs will be regulated. However, in January 2019, FDA published a paper laying the groundwork for its oversight protocols while inviting stakeholders to provide feedback,[42] and later in January 2021 published an action plan summarizing the received feedback and announced their goals based on a framework they call Predetermined Change Control Plan.[43] This plan would specify first "what" aspects of the SaMD the manufacturer plans to change as the model learns and improves over time (reffered to as Prespecifications) and "how" this learning and change will take place, (referred to as Algorithm Change Protocol).[43]

These steps, while broad and somewhat ambiguous, are a great start to assist ML practitioners to formulate a plan from the early stages of development to ensure successful passage through the regulatory process. It would be prudent for an ML practitioner aiming to introduce a new product into the market to familiarize themselves with the new and upcoming FDA guidelines to make this process more seamless.

To the authors' best knowledge, at the time of this writing only two IR-related AI-based products have received FDA clearance: the Indigo Lightning 12 thrombectomy system by Penumbra is equipped with their proprietary "Intelligent Aspiration," enabling detection of soft clot from nonclotted blood.[44] TrueFusion, on the other hand, is an AI-enabled application that integrates advanced ultrasound and angiographic imaging for improved navigation during cardiac endovascular interventions.[45]

Intellectual Property

Given the recent exponential surge in interest in AI and its application in clinical medicine, many groups from around the world have been tackling similar clinical problems in parallel. For example, a simple search for "COVID" and "machine learning" in Google Scholar returns approximately 130,000 results. To protect the time, effort, and economic investments poured into a successful and innovative ML model, it is imperative to be proactive and take the necessary steps to secure one's intellectual property. Patents are the most commonly used and effective method of protecting AI models and devices from being copied, although other less effective methods such as trade secrets agreements, copyright protection, and confidentiality agreements could provide additional assurances.

According to the World Intellectual Property Organization (WIPO), AI patents are on the rise in many different industries, including life and medical sciences which is mentioned in 19% of all patent documents, along with the other top-three dominant categories of telecommunications, transportation, and personal devices which are mentioned in 24, 24, and 17% of documents, respectively.[46]

The U.S. Patent and Trademark Office (USPTO), not unlike the FDA, has also been taking steps to keep pace with the constantly changing field of AI and issued the Revised Patent Subject Matter Eligibility Guidance[47] in January 2019 and the Patent Eligibility Guidance Update[48] in October 2019. These documents include examples of both approved and denied AI patent applications with brief explanations addressing their patentability or lack thereof.

While the laws and legal requirements surrounding AI and ML patents can be complex, the single most important concept to understand is what makes a model patentable. Simply put, according to the U.S. federal law, abstract ideas (such as mathematical relationships which are fundamentally the basis of ML models), are in and of themselves not patentable.[49] In fact, many software patents have been denied or invalidated due to being considered "abstract ideas" following the supreme court decision on Alice v. CLS bank in 2014.[50] However, an inventive step that would use this model in a novel way and make a new technical contribution will transform the abstract idea into a patentable application. In other words, to have a successful patent application, discussing the details of the model architecture should be minimized and instead emphasis has to be placed on the novelty of its application and how it answers a technical need in the real world.

Raising Capital

As the interest and public fascination with ML increases, so does the investment in this space, including in the medical sector. According to the research by Alexander et al, the investments in the imaging companies based on AI in the 5-year period between January 2014 and January 2019 reached $1.7 billion, which is double the amount raised in the 2012–2017 timeframe.[8] In the meantime, the number of startups and companies targeting medical AI is on the rise, and reportedly more than tripled to 113 from 32 in the same time period.[8] Put differently, this disproportionate growth of startups and investments has resulted in less well-funded companies, which Alexander et al argued could explain the slower than expected pace of implementing AI in medical imaging, as well as other fields such as IR.[8]

On the other hand, research by the Signify Research Group on capital investment in companies developing medical imaging AI software shows that while the total capital investments in medical AI has increased globally despite the adverse economic effects of the COVID-19 pandemic, the funding for U.S. companies has been on the decline since hitting $410 million in 2018, reaching only $141 million in 2020.[51] This paradoxical trend is due to the significant rise in funding in Chinese medical AI companies, accounting for more than half of the total global funding in 2020.

As the investment in medical AI continues to grow, so does the competition for the limited available funding. Developers for ML models in IR will perhaps benefit from formulating a fundraising strategy from the start, which may include collaborating with and securing funding through established companies and venture capital firms.

Ethical Challenges

AI has the immense potential to change and transform whatever domain it enters, and with those changes come new and at times unforeseen ethical and societal challenges. Therefore, it is imperative that those trying to embrace AI and its uses into clinical practice formulate ethical guidelines and standards in parallel to the emerging models and use-cases to mitigate and hopefully resolve those issues promptly.

As discussed in a joint statement by multiple radiological bodies across North America and Europe, the ethical challenges of implementing AI in any medical field including IR can be summarized in three domains: data, algorithm/model, and practice.[52]

Regarding data, we must be transparent with our patients as to how their data are used, while being vigilant for ways and steps where bias can creep into our models, be it the data gathering, annotation, training, or evaluation steps. As for our trained models, we should strive for transparency and explainability, while acknowledging the risk of lesser performance, malicious attacks, and intellectual property conflicts as a consequence of improper model transparency. Finally, while it seems inevitable that AI will soon transform the diagnostic and IR practice workflows, it is crucial to not fall for automation bias and ignore one's intuition, while implementing means of continuous monitoring to guarantee our models perform as intended and without declining function over time.

Conclusion

Artificial intelligence is unquestionably in the process of transforming medicine in all its aspects. While many recent studies addressing the role of AI in IR have focused on and reiterated the hypothetical use cases of this novel technology, we chose to take a different approach and instead addressed its slow implementation in the field of IR and touched on some of the hurdles that might be contributing to this issue.

All in all, the IR procedural workflow is an amalgam of multiple intertwined, often simultaneous processes including diagnostic imaging, procedural maneuvers, navigating complex and variable anatomy, and delivering interventions. This level of complexity cannot be adequately addressed by the typical, narrow AI agents currently available and calls for a more broad and generalized AI solution, which may be currently unattainable. In fact, it is likely that, due to their innate complexities, IR and surgical subspecialties will be late beneficiaries of IR, when more advanced and omnipotent AI models similar to DeepMind's perceiver[53] become available.

It is easy to become lost in the promise of AI. Ultimately, we must use our patients' interest as a compass and identify the most beneficial use cases by continuously engaging all stakeholders and spend our limited resources accordingly toward that goal.

Conflict of Interest
There are no conflicts of interest.

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