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AI in Ultrasound: Can I Trust It?

Artificial intelligence (AI) has made significant advancements in various fields, including medical imaging, such as ultrasound (US). AI methods can be employed to enhance the analysis and interpretation of ultrasound images. The trustworthiness of AI in ultrasound depends on various factors and AI algorithms should undergo ongoing monitoring and improvement processes, and clinical expertise should always be incorporated.

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key points

- Artificial intelligence (AI) has made significant advancements in the field of ultrasound (US) and has the potential to greatly enhance medical imaging and diagnosis.
- There are several challenges associated with artificial intelligence procedures in US, even in cases where specific applications have received FDA approval.
- AI can contribute to advancements in image resolution and quality. However, it is necessary to balance these advancements with safety concerns.

Introduction

Artificial intelligence (AI) has made significant advancements in the field of ultrasound (US) and has the potential to greatly enhance medical imaging and diagnosis. AI algorithms can assist in various aspects of ultrasound imaging, including image segmentation, detection and classification of abnormalities or lesions, and prediction of outcomes such as benign or malignant as well as prognosis.

Safety of its use is critical when considering the use of AI, no less so in US.

Now, let's delve into the basics of how these methods work and the different network types.

In the realm of image segmentation, there are dedicated network structures designed for this purpose. Notably, convolutional neural networks and innovative generative adversarial networks can already produce an artificial US image that closely resembles real images, making it challenging to distinguish between the two.

One notable example from the field of cardiology is an artificial network that detects and performs precise measurements for the chamber view of the heart. One can illustrate the normal heart as well as hypoplastic hearts. The algorithm can segment all these structures in a very defined and exact way.

Regarding uterine examinations, after volume acquisition, AI-based methods can reconstruct the uterine anatomy and give a representation of the shape, indicating if it is normal or not.

There are several challenges associated with artificial intelligence procedures in US, even in cases where specific applications have received FDA approval. While FDA approval is an important validation before medical use, it's essential to recognise the specific conditions and limitations under which the approval is granted.

Companies or startups introducing AI-based ultrasound measurements face the challenge of establishing trust and credibility. It is essential for such companies to take responsibility for the products and services they offer. So, what are the FDA approval procedures for these artificial intelligence methods? The FDA has specific procedures for the approval and clearance of AI methods used in medical imaging. It is based on up-to-date classifications.

The FDA categorises medical devices into different classes based on their intended use and associated risks.

The normal pathway for medical device clearance (class I & II) follows a standard process to ensure safety and assess the technology used. Moreover, manufacturers are responsible for providing transparent information about the safety and performance of their devices.

The market approval process is particularly stringent for high-risk applications, specifically class III devices. These applications carry significant potential risks, and it is crucial that the benefits of the device outweigh these risks.

However, there is an important consideration when it comes to the evolving nature of artificial intelligence (AI) methods. AI algorithms and software may require updates or enhancements over time to improve their performance and address emerging challenges. Currently, the regulatory processes primarily focus on the initial version of the AI method during the approval process. But a new review is needed for significant updates or performance changes over time.

In some cases, certain devices or artificial intelligence procedures may have self-learning capabilities, allowing them to adapt and continue to be trained. These AI devices can be trained on new images and data collected by users. However, this is different from the approval procedure by the FDA because they believe the algorithms are locked and non-adaptive.

> AI-based segmentation can be a valuable tool in medical imaging, assisting healthcare professionals

Properties of FDA-approved AI devices are mostly based on retrospective studies and often lack comparison with clinicians' performance. While companies may train these algorithms using different datasets, evaluation against routine clinical practice is often limited, as well as evaluation against diverse image assessments from different hospitals.

For medical devices incorporating AI algorithms, clinical validation studies are typically required. These studies aim to evaluate the device's performance in real-world settings and compare it to existing methods or the clinical judgment of healthcare professionals.

To further ensure the accuracy and effectiveness of medical AI devices, it is important for studies to have an adequate sample size that represents a diverse patient population as well. Moreover, high-risk devices should undergo comprehensive evaluations to ensure devices are safe and effective.

Several important factors can influence the reliability and performance of medical AI devices, including different image storage formats, types of equipment, demographic information, disease prevalence, post-marketing surveillance, and sample size. These factors play crucial roles in the development, evaluation, and ongoing monitoring of medical AI devices.

Different clinics may also have their own protocols and practices for data acquisition or procedures. It is essential to account for these variations as variability can potentially influence the performance and accuracy of medical AI devices. Proper validation procedures are needed to extract transparent information; we need to consider how many experts have evaluated these kinds of procedures and the number of various equipment involved.

Clinical validation procedures are also essential because misuse by clinicians can happen. Clinicians may be provided with the tools, but without an introduction or familiarity with how to use it, there may be misuse of it.

If there is a concern for the safety of the patient, then we need to be more transparent. The responsibility for ensuring safe and effective results lies with multiple stakeholders. We need more transparent and stricter

regular regulatory processes with more input from the manufacturers regarding the algorithms, training, validation procedures, and testing processes used in the development.

Regarding the ability of artificial intelligence methods to produce highly detailed, high-resolution and improved-quality images, AI can contribute to advancements in image resolution and quality.

However, it is necessary to balance these advancements with safety concerns. It is critical we ensure patient safety and the reliability of AI algorithms; thorough validation and testing procedures are necessary.

Different imaging modalities, such as MRI, CT, and US, have unique characteristics that can impact the results of AI-based medical procedures. Defining the requirements for AI-based medical procedures should involve a thorough understanding of the specific modality being used. This includes considering image quality, resolution, noise reduction, and artefact correction.

For US, the brightness of the images can be changed, as well as the frequency or contrast, among many other parameters. All these parameters can influence the result of AI models, and therefore it would be good to define these requirements so researchers and developers can tailor AI models to optimise their performance.

It is also important to consider how many training datasets are needed to get reliable results. Generally, a larger dataset can enhance the generalisation capability of AI models. However, we need a balance between dataset size and quality to prevent the underrepresentation of certain cases.

AI assistance in the segmentation process is very important as it can provide valuable insights to both experienced and inexperienced users. AI algorithms can be trained to effectively segment and identify regions of interest, such as lesions, based on the contrast with neighbouring tissues. Users can still edit and make the final decision – supplementing the AI here. This approach acknowledges that the final decision should be made by the user who utilises their clinical information.

Overall, AI-based segmentation can be a valuable tool in medical imaging, assisting healthcare professionals and providing further insights. However, it is crucial that a balance is found between leveraging the capabilities of AI and embracing human expertise to attain optimal results.

Conflict of Interest

None. ■