Safety regulation of machine learning in cardiac surgery

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Comment on: Miles TJ, Ghanta RK. Machine learning in cardiac surgery: a narrative review. J Thorac Dis 2024;16:2644-53.

When the machine learning techniques applied in the domain of cardiothoracic surgery, safety supervision must be considered. Miles (1) proved the benefits of machine learning technology in its research. But in-depth discussion of the potential risks and challenges has been relatively limited. The current period comes at a time of increasing concerns related to the application of machine learning. Different machine learning techniques have been used in cardiothoracic surgery (Table S1). The public, professionals and regulators are wary of the use of artificial intelligence (AI), especially when it comes to the sensitive healthcare sector. In this background, the attempt to introduce machine learning technology in the field of cardiothoracic surgery must adhere to the highest regulatory standards, combined with the 2024 edition of the Chinese Cardiothoracic Surgery Treatment Standards issued by the Chinese Medical Doctor Association to ensure the reliability and safety of AI-assisted decision-making. We need a safe monitoring frame-work for this. We emphasize the risk-based regulatory framework (2), with appropriate preventive measures to enable responsible innovation. At the same time, the application of machine learning needs to be coordinated with the existing supervision of cardiothoracic surgery to ensure that the two can be effectively combined to avoid duplication of supervision or regulatory gaps. Moreover, in the field of safety and process supervision in the field of machine learning cardiothoracic treatment, the results of validation measures should be focused on (3). Although it is the responsibility of regulators to ensure the safety of the process, the main driver of "white box" access is to improve the interpretability of the process. Safety verification can rely on "black box" evaluation (4), that is, no deep knowledge of the algorithm or dataset is required (5),

only methodological transparency, to ensure the safe use of machine learning in the field of cardiothoracic surgical treatment, while also protecting the incentive to innovate. To establish a coherent and risk-based regulatory framework for the full potential of machine learning in cardiothoracic surgery and to provide appropriate, targeted protections for patient safety (Table S2).

Acknowledgments

Footnote

References

1. Miles TJ, Ghanta RK. Machine learning in cardiac surgery: a narrative review. J Thorac Dis 2024;16:2644-53.
2. Bate A, Luo Y. Artificial Intelligence and Machine Learning for Safe Medicines. Drug Saf 2022;45:403-5.
3. Hines PA, Herold R, Pinheiro L, et al. Artificial intelligence in European medicines regulation. Nat Rev Drug Discov 2023;22:81-2.
4. Liu X, Glocker B, McCradden MM, et al. The medical algorithmic audit. Lancet Digit Health 2022;4:e384-e397. Correction appears in Lancet Digit Health 2022;4:e405.
5. Wang SV, Sreedhara SK, Schneeweiss S; REPEAT Initiative. Reproducibility of real-world evidence studies using clinical practice data to inform regulatory and coverage decisions. Nat Commun 2022;13:5126.