Use of Artificial Intelligence-Based Software as Medical Devices for Chest Radiography: A Position Paper from the Korean Society of Thoracic Radiology

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INTRODUCTION

Chest radiography (CR) is the primary examination for the evaluation and follow-up of various thoracic diseases. The number of examinations is steadily on the increase, as is evidenced by the national health insurance data in Korea [1]. However, due to the relative shortage of experienced radiologists, many institutions cannot provide timely interpretation of CRs or depend on outsourcing for interpretation [2,3].

In this background, artificial intelligence (AI) for the evaluation of CR has been actively investigated, and several AI-based software as medical devices (AI-SaMDs) have begun to be used in clinical practice. However, there has been limited discussion on how to use AI-SaMDs in clinical practice; there are also concerns about inappropriate use or abuse of AI-SaMDs resulting in patient harm and liability for physicians.

This article introduces the current situation regarding the application of AI-SaMD for CR in clinical practice and presents the opinion of the Korean Society of Thoracic Radiology (KSTR) toward use of this application.

DEVELOPMENT OF CONSENSUS OPINION

KSTR organized an expert panel of 10 thoracic radiologists with expertise in development or validation of AI-SaMDs for CR or their utilization in clinical practice. The panel held online and offline conferences to develop seven key questions regarding the use of AI-SaMDs for CR in the daily practice. A two-round Delphi technique was adopted to develop consensus opinions for key questions among the experts (Fig. 1). Panelists answered each question using a nine-point scale. Responses of scores 1–3 were regarded as negative answers to the question, while scores 7–9 were considered as positive answers. A consensus opinion was established when ≥ 70% panelists’ opinions were either positive or negative to the question.

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CONSENSUS STATEMENT

Utilization of AI-SaMDs for CR

1) AI-SaMDs currently available for CR cannot replace radiologists’ interpretation.

2) AI-SaMDs currently available for CR can be used as an assistance tool in the interpretation by radiologists.

3) AI-SaMDs currently available for CR can be used as a decision support tool for clinicians in a situation where radiologists’ interpretation is unavailable.

Performance of AI-SaMDs for CR and Considerations for Its Clinical Application

4) Adjustments or recalibrations of AI-SaMDs for CR for the target institution or population are recommended.

Policy and Education on AI-SaMD for CR

5) A separate fee for using AI-SaMDs for CR may be required for its clinical implementation.

6) Education programs for medical students and radiologists assuming the use of AI-SaMDs for CR in daily clinical practice need to be established.

DISCUSSION

Approved AI-SaMDs for CR in Korea

As of the end of May 2021, the Korean Ministry of Food and Drug Safety (KMFDS) has approved seven AI-SaMDs for CR for clinical use (Table 1) [4]. Every AI-SaMD was approved as an assistance tool for physicians’ interpretation, and not as a stand-alone interpretation tool. All approved devices can detect specific abnormalities in a single CR. Three of the seven approved AI-SaMDs can detect only lung nodules, while the others can detect various types of abnormalities. However, AI-SaMDs cannot cover all types of abnormalities that need to be evaluated in a CR. Furthermore, none of the approved devices provide differentiation of detected abnormalities or diagnosis of a specific disease.

Performance of AI-SaMDs for CR and Considerations for Clinical Application

AI-SaMDs for CR have shown excellent performance in early investigations, achieving radiologist-level or higher performances for a single or limited number of pre-specified tasks [5-9]. However, the reproducibility of those...
performances in the actual practice remains unclear, since retrospectively collected data may not fully reflect the prevalence and diversity of abnormalities in the actual clinical situation [10,11]. Several recent investigations reported excellent performance of AI-SaMDs for the identification of specific abnormalities or diseases such as pulmonary nodules [12], tuberculosis [13-15], and coronavirus disease pneumonia [16,17], in consecutive cohorts reflecting actual clinical situations. Nevertheless, further investigations validating the performance of AI-SaMDs during their utilization in the real clinical practice should be conducted to confirm the reproducibility of such in the daily practice.

Discussions regarding the application of AI-SaMDs in the daily practice are also necessary. The currently approved method, utilization as an assistant tool for physicians’ interpretation is the most traditional and conservative method [18]. Based on studies reporting improved detection performance of radiologists with the assistance of AI-SaMD [5-8,19], it would be feasible to use currently available AI-SaMDs as an assistance tool for radiologists’ interpretation. In several studies, non-radiologist clinicians also exhibited improvement of detection performance with the assistance of AI-SaMD, and the magnitude of improvement in the clinicians was greater than in the radiologists [7,8,20,21]. Therefore, the use of AI-SaMDs as a decision support tool for clinicians would be acceptable in situations where radiologists’ interpretation is unavailable.

Using AI-SaMDs in screening for images with findings of emergency disease requiring timely interpretation, automated assignment of interpreting radiologists according to the presence of abnormality or difficulty of interpretation, and automated notification of suspected interpretive errors have also been proposed [18,22]. However, their usefulness in clinical practice has yet to be validated.

Finally, the performance of AI-SaMD may differ depending on the characteristics of the target population or institutions, including disease prevalence, diversity of image findings, and equipment or techniques for radiographic acquisition. Therefore, it may be necessary to adjust the threshold of detection or recalibrate the numerical scores of the AI-SaMDs, depending on the characteristics of the target population or institution [23,24].

**Policy on AI-SaMD for CR**

Apart from approval for clinical use by the KMFDS, the use of AI-SaMD for CR interpretation currently does not grant additional reimbursement in Korea. According to the guidelines of the Health Insurance Review and Assessment Service in 2019 [25], AI-SaMDs for detection or diagnosis on medical imaging can undergo Health Technology Assessment only when they show significant improvement in accuracy or reduction in errors compared to humans. Based on the result of this assessment, a separate reimbursement can be considered when the AI-SaMD shows a significant improvement in diagnostic performance compared to existing practices, provides new diagnostic information that cannot be obtained using existing practices, or proves therapeutic effectiveness. Currently, medical institutions need to cover the cost of using AI-SaMDs by themselves. In a situation where timely reading of CRs is difficult and considering the risk of interpretive errors, medical institutions may voluntarily implement AI-SaMD at their own expense for patient safety and practice efficiency. However, in order for AI-SaMDs for CR to be implemented

**Table 1. List of Approved Artificial Intelligence-Based Software as Medical Devices for Chest Radiographs in Korea**

| Device Name          | Manufacturer            | Date of Approval (Year. Month. Date) | Target Abnormalities for Detection                                                                 |
|----------------------|-------------------------|--------------------------------------|------------------------------------------------------------------------------------------------------|
| Lunit Insight CXR nodule | Lunit                  | 2018. 8. 14                          | Pulmonary nodule                                                                                   |
| Auto Lung Nodule Detection | Samsung Electronics    | 2019. 6. 7                           | Pulmonary nodule                                                                                   |
| Vuno Med Chest X-ray   | Vuno                    | 2019. 8. 20                          | Pulmonary nodule, consolidation, interstitial opacity, pleural effusion, pneumothorax              |
| Lunit Insight CXR MCA   | Lunit                  | 2019. 10. 21                         | Pulmonary nodule, consolidation, pneumothorax                                                     |
| JVIEWER-X              | JLK                     | 2020. 1. 13                          | Not available                                                                                     |
| DEEP:CHEST-XR-01       | Deepnoid                | 2020. 5. 15                          | Pulmonary nodule                                                                                   |
| Lunit Insight CXR       | Lunit                  | 2020. 10. 19                         | Pulmonary nodule, consolidation, pneumothorax, fibrosis, atelectasis, calcification, cardiomegaly, pleural effusion, pneumoperitoneum |

The order of the device is based on the date of approval. The tabulation is as of end of May 2021.
in clinical practice in the long term, consideration should be given to charging of a separate fee, as the devices demonstrate further improvement in performance and validation of clinical usefulness.

**Education on AI-SaMD for CR**

Since interpreting CR using AI-SaMD may gradually expand in daily clinical practice, reorganization of education system for radiologists including trainees and medical students seems necessary [26,27]. Education on AI needs to be strengthened, covering a basic understanding of the technology as well as the function and working principle of AI-SaMDs in the interpretation of CR. It would also be important to maintain the traditional education on the technique and knowledge for interpreting CR to accurately interpret and judge the results of AI-SaMD.

**Liability Related to the Utilization of AI-SaMD**

As AI-SaMDs for CR begin to be applied in clinical practice, there is a growing concern regarding the legal liability for any patient harm related to the utilization of AI-SaMDs. It is difficult to present an evidence-based opinion regarding liability, as AI-SaMD itself or its clinical introduction remains in its infancy. However, considering the current legal system in Korea, an AI-SaMD that assists physicians’ interpretation cannot be a legal subject. Thus in case of patient harm, the physician would be held liable.

In case of patient harm, the key factor in determining a physician’s liability would be whether the physician followed the existing standard of care [28,29]. Currently, the standard of care for the interpretation of CR is interpretation by radiologists, and interpreting radiologists’ decision to reject the result of AI-SaMD would be within the range of standard of care. Therefore, the discrepancy in interpretation between AI-SaMDs and radiologists cannot be the basis for judging liability. However, if AI-SaMDs are used for unapproved purposes (e.g., using AI-SaMD results without physicians’ confirmation), this could be deemed as a deviation from the standard of care, and the physician may incur liability in case of patient harm.

**CLOSING REMARK**

Automation of a considerable portion of medical image analysis seems inevitable, and interpretation of CR seems to be at the forefront of this trend. In this regard, the role of radiologists and academic societies as experts would be to guide AI technology towards the ultimate value in medicine, which is contributing to patient safety and welfare. The key elements of this mission would include thorough validation of AI-SaMDs, development of appropriate indications for AI-SaMDs, and creating the clinical environment in which AI-SaMDs are being put to best use to support clinical practice.

**Key words**

Chest radiography; Artificial intelligence; Deep learning; Computer-aided detection

**Conflicts of Interest**

Eui Jin Hwang received research grants from Lunit Inc., Coreline Soft, and Monitor corporation, outside the present study.

Jin Mo Goo received research grants from Infinit Healthcare, Dongkook Lifescience, and LG Electronics, outside the present study.

Soon Ho Yoon works in the MEDICALIP as a chief medical officer.

Chang Min Park received research grants from Lunit Inc. and Coreline Soft, outside the present study; holds stock of Promedius and stock options of Lunit Inc. and Coreline Soft.

Kwang Nam Jin received research grants from Lunit Inc. and JLK inspection, outside the present study; reports secondary studies with Deepnoid and Monitor corporation. Other authors have no conflicts of interest to disclose.

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REFERENCES

1. Healthcare Bigdata Hub. Statistics on medical practices. Opendata.hira.or.kr Web site. http://opendata.hira.or.kr/op/ ocdp/opcdpDiagBhvInfo.do. Accessed June 28, 2021
2. Woo H, Choi MH, Eo H, Jung SE, Do KH, Lee JS, et al. Teleradiology of Korea in 2017: survey and interview of training hospitals and teleradiology center. J Korean Soc Radiol 2019;80:684-703
3. Choi MH, Eo H, Jung SE, Woo H, Jeong WK, Hwang JY, et al. Teleradiology of Korea in 2017: a questionnaire to members of the Korean Society of Radiology. J Korean Soc Radiol 2019;80:684-703
4. Ministry of Food and Drug Safety. Medical device information portal. Udiportal.mfds.go.kr Web site. https://udiportal.mfds. go.kr/search/data/P02_01. Accessed June 28, 2021
5. Nam JG, Kim M, Park J, Hwang EJ, Lee JH, Hong JH, et al. Development and validation of a deep learning algorithm detecting 10 common abnormalities on chest radiographs. Eur Respir J 2021;57:2003061
6. Kim Y, Chung MJ, Kotter E, Yune S, Kim M, Do S, et al. Deep convolutional neural network–based software improves radiologist detection of malignant lung nodules on chest radiographs. Radiology 2020;294:199-209
7. Hwang EJ, Park S, Jin KN, Kim JJ, Choi SY, Lee JH, et al. Development and validation of a deep learning–based automated detection algorithm for major thoracic diseases on chest radiographs. JAMA Netw Open 2019;2:e191095
8. Nam JG, Park S, Hwang EJ, Lee JH, Jin KN, Lim KY, et al. Development and validation of deep learning–based automatic detection algorithm for malignant pulmonary nodules on chest radiographs. Radiology 2019;290:218-228
9. Park S, Lee SM, Lee KH, Jung KH, Bae W, Choe J, et al. Deep learning-based detection system for multiclass lesions on chest radiographs: comparison with observer readings. Eur Radiol 2020;30:1359-1368
10. Kim DW, Jang HY, Kim KW, Shin Y, Park SH. Design characteristics of studies reporting the performance of artificial intelligence algorithms for diagnostic analysis of medical images: results from recently published papers. Korean J Radiol 2019;20:405-410
11. Park SH, Han K. Methodologic guide for evaluating clinical performance and effect of artificial intelligence technology for medical diagnosis and prediction. Radiology 2018;286:800-809
12. Lee JH, Sun HY, Park S, Kim H, Hwang EJ, Goo JM, et al. Performance of a deep learning algorithm compared with radiologic interpretation for lung cancer detection on chest radiographs in a health screening population. Radiology 2020;297:687-696
13. Lee JH, Park S, Hwang EJ, Goo JM, Lee WY, Lee S, et al. Deep learning-based automated detection algorithm for active pulmonary tuberculosis on chest radiographs: diagnostic performance in systematic screening of asymptomatic individuals. Eur Radiol 2021;31:1069-1080
14. Khan FA, Majidulla A, Tavaziva G, Nazish A, Abidi SK, Benedetti A, et al. Chest x-ray analysis with deep learning-based software as a triage test for pulmonary tuberculosis: a prospective study of diagnostic accuracy for culture-confirmed disease. Lancet Digit Health 2020;2:e573-e581
15. Qin ZZ, Sander MS, Rai B, Tithahong CN, Sudrungrot S, Laah SN, et al. Using artificial intelligence to read chest radiographs for tuberculosis detection: a multi-site evaluation of the diagnostic accuracy of three deep learning systems. Sci Rep 2019;9:15000
16. Hwang EJ, Kim H, Yoon SH, Goo JM, Park CM. Implementation of a deep learning-based computer-aided detection system for the interpretation of chest radiographs in patients suspected for COVID-19. Korean J Radiol 2020;21:1150-1160
17. Murphy K, Smits H, Knoops AJG, Korst MBJM, Samson T, Scholten ET, et al. COVID-19 on chest radiographs: a multireader evaluation of an artificial intelligence system. Radiology 2020;296:E166-E172
18. Hwang EJ, Park CM. Clinical implementation of deep learning in thoracic radiology: potential applications and challenges. Korean J Radiol 2020;21:511-525
19. Sung J, Park S, Lee SM, Bae W, Park B, Jung E, et al. Added value of deep learning-based detection system for multiple major findings on chest radiographs: a randomized crossover study. Radiology 2021;299:450-459
20. Hwang EJ, Park S, Jin KN, Kim JJ, Choi SY, Lee JH, et al. Development and validation of a deep learning–based automatic detection algorithm for active pulmonary tuberculosis on chest radiographs. Clin Infect Dis 2019;69:739-747
21. Hwang EJ, Kim KB, Kim JY, Lim JK, Nam JG, Choi H, et al.
COVID-19 pneumonia on chest X-rays: performance of a deep learning-based computer-aided detection system. *PLoS One* 2021;16:e0252440

22. Annarumma M, Withey SJ, Bakewell RJ, Pesce E, Goh V, Montana G. Automated triaging of adult chest radiographs with deep artificial neural networks. *Radiology* 2019;291:196-202

23. Hwang EJ, Kim H, Lee JH, Goo JM, Park CM. Automated identification of chest radiographs with referable abnormality with deep learning: need for recalibration. *Eur Radiol* 2020;30:6902-6912

24. Kuo PC, Tsai CC, López DM, Karargyris A, Pollard TJ, Johnson AEW, et al. Recalibration of deep learning models for abnormality detection in smartphone-captured chest radiograph. *NPJ Digit Med* 2021;4:25

25. Ministry of Health and Welfare, Health Insurance Review and Assessment Service. Guideline on reimbursement for innovative medical technology. Hira.or.kr Web site. http://www.hira.or.kr/bbsDummy.do?pgmid=HIRAA020002000100&brdScnBltNo=4&brdBltNo=7655. Published December 26, 2019. Accessed June 28, 2021

26. Tajmir SH, Alkasab TK. Toward augmented radiologists: changes in radiology education in the era of machine learning and artificial intelligence. *Acad Radiol* 2018;25:747-750

27. Tang A, Tam R, Cadrin-Chênevert A, Guest W, Chong J, Barfett J, et al. Canadian association of radiologists white paper on artificial intelligence in radiology. *Can Assoc Radiol J* 2018;69:120-135

28. Price WN, Gerke S, Cohen IG. Potential liability for physicians using artificial intelligence. *JAMA* 2019;322:1765-1766

29. Tobia K, Nielsen A, Stremitzer A. When does physician use of AI increase liability? *J Nucl Med* 2021;62:17-21