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AI-Assisted Diagnosis of Bone Tuberculosis: A Design Science Research Approach

Short Paper

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Abstract

Bone Tuberculosis (TB) is a significant public health challenge requiring early and precise diagnosis for effective treatment. Traditional methods like radiography and biopsy are invasive and costly. Our study introduces a holistic AI-assisted orthopedic clinical diagnosis system developed through an Action Design Research approach. Unlike previous efforts focused solely on algorithmic design, our system is iteratively validated with real-world clinical data, ensuring both theoretical rigor and practical applicability. By fine-tuning AI algorithms to meet actual clinical needs, we bridge the gap between technological innovation and healthcare relevance. Our research offers innovative insights into the design and evaluation of AI-assisted systems, emphasizing the role of empirical data and diverse evaluation metrics. The study is expected to have broader implications for the adoption of AI in clinical settings, offering a more comprehensive and reliable solution for bone TB diagnosis.

Keywords: Tuberculosis (TB), bone TB, design science research, AI-assisted clinical diagnosis, machine learning, deep learning, image segmentation, detection algorithms, medical images, CT scan, public health

Introduction

Tuberculosis (TB) is a major public health problem, with bone TB being one of its most difficult-to-treat forms (Choksi, 2022). Bone TB occurs in the synovium of the joint. It is formed by TB (human TB, bovine TB) infection, secondary to pulmonary TB and intestinal TB. Bone TB spreads through hematogenous or lymphatic spread to spongy bone rich in blood vessels and heavy-duty, more active synovium of the joint (Hayat Khan, 2023). Despite advances in diagnostic techniques, bone TB remains a difficult clinical condition to diagnose, often leading to delayed care for patients, as evidenced by recent case studies such as isolated Tarsal Navicular TB (Choksi, 2022).

In light of these challenges, our study adopts an Action Design Research (ADR) approach (Sein et al., 2011), aiming to bridge the gap between technological rigor and real-world clinical applicability. This approach allows us to iteratively validate AI-based diagnostic algorithms using real-world data, a dimension often overlooked in existing research. Early and accurate diagnosis of bone TB is crucial for successful treatment and preventing the spread of the disease (Choksi, 2022). However, traditional methods for diagnosing bone TB, such as radiography and biopsy, can be invasive, time-consuming, and costly (Hayat Khan, 2023). The application of artificial intelligence (AI) in the medical field has been a focus of research in healthcare IT, with the potential to improve the accuracy and efficiency of diagnosis and treatment (Jussupow et al., 2021). AI has already shown promising results in various fields such as tumor diseases, cardiovascular systems, and chronic disease complications. However, despite its potential benefits, AI also has its limitations, such as high R&D costs, long R&D cycles, and semi-autonomous limitations (Jain et al., 2021; Jussupow et al., 2021).

Our research uniquely integrates the design and evaluation of AI-based diagnostic algorithms with their iterative validation in real-world clinical settings, thereby contributing a novel perspective to the existing body of literature. For instance, in the field of orthopedics, accuracy in data learning is essential for generating accurate image interpretation, highlighting the need for multidisciplinary efforts. While AI can assist in clinical decision-making, it has not yet developed to the point where it can replace doctors entirely (Litjens et al., 2017). Therefore, there is a need for further research to explore the feasibility and effectiveness of AI-assisted diagnostic systems in the medical field. In this regard, design science research (DSR) provides a structured approach to developing and evaluating innovative solutions (Hevner et al., 2004) to complex problems in healthcare IT.

DSR aims to create and evaluate new artifacts, processes, or systems that solve real-world problems and improve how we live and work (Hevner et al., 2004; Hevner & Chatterjee, 2010; Peffers et al., 2007). As such, there is a need to focus on developing AI-based image segmentation and detection algorithms for bone TB as a DSR problem. By designing and evaluating new AI-based algorithms for bone TB diagnosis, we can create and assess the effectiveness of new solutions that have the potential to improve the accuracy and efficiency of TB diagnosis and lead to better outcomes for patients. This includes exploring different approaches such as deep learning (DL), machine learning (ML), and other techniques (Litjens et al., 2017), as well as evaluating their relative strengths and weaknesses.

As a DSR problem, we propose to develop an AI-assisted orthopedic clinical diagnosis system based on empirical data. This system would use artificial intelligence (AI) techniques, such as image segmentation and detection, to analyze medical images and identify areas of the bone infected with TB (Litjens et al., 2017). By accurately identifying the affected areas, doctors can more accurately diagnose and treat the disease. This paper can contribute to developing new tools that can help in the fight against this serious and widespread disease (Jussupow et al., 2021), as well as advance our understanding of the potential and limitations of AI-based approaches for bone TB diagnosis. This can ultimately lead to the creation of more effective and efficient solutions (Bardhan et al., 2020) for diagnosing and treating bone TB, improving the lives of patients and healthcare providers.

The multidisciplinary research roadmap proposed by Bardhan et al. (2020) serves as a foundational framework for our study. They advocate for a systems-thinking approach that integrates various data sources and stakeholders in chronic disease management. The proposed system would be developed and evaluated using real-world data based on clinical observations and outcomes. This would allow for the development of a system that is grounded in reality and has the potential to be implemented in clinical practice (Jussupow et al., 2021). To develop and evaluate the proposed system, we collect a dataset of medical images with ground truth labels indicating the presence or absence of TB. We would then use this dataset to train and test AI algorithms for image segmentation and detection, with the goal of developing algorithms that can accurately and reliably identify TB-infected bone tissue. The performance of the algorithms would be evaluated using metrics such as accuracy, sensitivity, and specificity, and the system would be refined and improved based on these results (Hevner & Chatterjee, 2010; Peffers et al., 2007).

While existing research has made invaluable contributions to the diagnosis of bone and spinal TB, these studies often focus on isolated aspects such as computer-aided diagnosis through ML algorithms or the efficacy of conventional diagnostic methods. However, they frequently overlook the importance of iterative validation using real-world clinical data, thereby limiting their practical applicability. In contrast, our study adopts an ADR approach, which uniquely integrates the design of AI-based diagnostic algorithms with their iterative validation in real-world clinical settings. This holistic methodology ensures that the developed algorithms are not only theoretically robust but also fine-tuned to meet actual clinical needs and constraints. By doing so, we aim to bridge the gap between technological rigor and organizational relevance (Sein et al., 2011), thereby enhancing the potential for real-world application and contributing a novel perspective to the existing body of literature.

Literature review

In the medical field, computer vision and robotics are widely used, among which the most widely combined with computer image recognition is medical imaging technology (Jussupow et al., 2021; Litjens et al., 2017). In the clinical diagnosis and treatment of orthopedic diseases, imaging data has important reference value. The AI technology developed based on imaging data can provide a reliable basis for the occurrence and

development, clinical diagnosis, surgical guidance, and prognosis evaluation of orthopedic diseases (Litjens et al., 2017). In addition, the application of AI based on medical imaging has achieved many results in the intelligent diagnosis of tumor diseases, cardiovascular system, chronic disease complications and other fields (Jussupow et al., 2021; Litjens et al., 2017).

AI-assisted orthopedic clinical diagnosis

Diagnosing most diseases in orthopedics is inseparable from X-ray, CT, MRI, ultrasound and other imaging examinations (Litjens et al., 2017). Advances in information technology have led to the emergence of digital imaging in healthcare, which has become a staple in clinical practice. ML is a branch of AI that can be applied to develop pattern recognition techniques for medical images (Litjens et al., 2017). Specifically, when a ML algorithm is applied to a set of data, such as imaging images of a tumor, along with associated indicators (e.g., the benignity or malignancy of the tumor), the system can autonomously learn from this training data. Subsequently, it can use this acquired knowledge to perform a diagnosis, such as determining whether a tumor is benign or malignant (Jussupow et al., 2021). The process of continuously optimizing the parameters of the algorithm system to improve performance (improving the speed and accuracy of diagnosis) is the process of building ML tools.

ML technology can develop intelligent diagnostic systems as a powerful auxiliary tool for radiologists and clinical researchers (Litjens et al., 2017). Its advantages are as follows: The computer can 1. perform diagnostic tasks in a continuous and standardized manner; 2. help doctors focus on suspicious lesion areas and shorten the reading time (Jussupow et al., 2021); 3. help researchers carry out cohort studies of large-scale clinical data. Jamaludin et al. (2017) apply this technology to spinal MRI reading to diagnose intervertebral disc degeneration, and the accuracy rate reached 95.6% after testing. Leveraging big data and DL models, AI has been utilized in osteoporosis diagnosis. It can not only model the likelihood of fragility fractures but also assist in image segmentation and identification. Consequently, AI enhances fracture risk prediction. These supplementary tools are now being introduced to osteoporosis studies, and through ongoing refinements, their efficiency and precision have seen improvements. (Litjens et al., 2017). Olczak et al. (2017) apply five publicly available DL systems to X-ray interpretation of hand, wrist, and ankle fractures, adjust them based on the gold standard for fracture diagnosis, and compare the machine interpretation results with two senior orthopedic experts who conduct a comparison. The final accuracy rate of the system with the best performance is about 83%. This means that under ideal conditions when the imagery is compatible with the resolution of the system, the performance of machine interpretation can match that of experienced experts. Hemalatha et al. (2019), based on spatial analysis technology, locate the synovial area of the joint according to the echo intensity, divide the degree of fluid swelling in the synovial area into four different grades, and use DL technology to interpret ultrasound images.

For bone TB, histopathological examination is the qualitative gold standard and an effective reference for judging TB's invasiveness and patients' prognosis (Hayat Khan, 2023). The advent of whole slide scanning technology has supplanted traditional glass slides with high-resolution digital images, setting the groundwork for the development of AI-based systems for pathological interpretation. Based on training samples, DL technology enables the computer to mine image features from medical images and quickly lock and interpret lesion sites from a large set (Hemalatha et al., 2019; Olczak et al., 2017).

Although existing studies have made significant contributions to the diagnosis of bone and spinal tuberculosis, they primarily focus on specific aspects such as computer-aided diagnosis through DL algorithms (Li et al., 2022), the efficacy of conventional histopathology and GeneXpert MTB/RIF (Yu et al., 2020), or provide a comprehensive overview of the disease (Hayat Khan, 2023). However, these studies do not fully address the iterative validation of diagnostic algorithms using real-life data, nor do they employ a holistic research approach that goes beyond algorithm design.

In contrast, our research adopts an ADS approach, which is a more comprehensive methodology. This approach not only involves the design of AI-based image segmentation and detection algorithms for diagnosing bone TB but also emphasizes their iterative validation using real-world data. By doing so, we aim to develop algorithms that are not just theoretically sound but also practically applicable and reliable in clinical settings. This iterative validation ensures that the algorithms are fine-tuned based on actual clinical needs and constraints, thereby enhancing their potential for real-world application.

Spine image feature extraction and segmentation

ML methods can extract information such as vertebral bodies, intervertebral discs, and spine shapes from medical images such as X-ray films, CT, MR, and ultrasound images (Litjens et al., 2017). Localizing the spine structures in the dataset is often the first fully automatic step in segmenting the spine, classifying pathological features, and predicting treatment outcomes (Hemalatha et al., 2019). This section will analyze the related experiments from the two parts of image feature extraction and image segmentation.

Image feature extraction

The image features in this section mainly refer to the geometric features of the image, including feature points, edges, and regional features. In computer vision, traditional ML algorithms are often combined with feature operators such as HOG, and Haar (Wei et al., 2019) to detect and extract features. Using traditional ML algorithms to extract image features is essentially combining feature description operators in the visual field to achieve classification tasks. The SVM algorithm solves the classification problem with a high feature dimension by setting an appropriate kernel function (Lin et al., 2011). Adaboost detection algorithm can combine sliding windows to detect the edge and use a cascaded structure to improve the detection rate, which can realize vertebral body detection well. The biggest advantage of the neural network model lies in its high precision and insensitivity to noise, but it often requires sufficient data to train a large number of parameters (Li et al., 2022).

Image segmentation

Image segmentation is a key step in disease diagnosis based on spine images. Segmenting the spine within the image and extracting pertinent index features to provide a reliable foundation for clinical diagnosis and treatment, thereby aiding physicians in making more precise diagnostic decisions. The segmentation algorithms used in research include threshold-based algorithms, active appearance models, and fuzzy clustering algorithms (Litjens et al., 2017).

In recent years, DL has been the most commonly used algorithm, so this paper focuses on DL algorithms. There are many modalities of medical imaging, such as MR, CT, X-ray, and ultrasound images, etc. Experiments are carried out based on different image types. Most of the segmentation models are improvements to two classic segmentation networks (U-net and FCN), and Segmentation accuracy continues to improve. Various DL algorithms have been explored for spine image segmentation in medical imaging. For instance, Han et al. (2021) use Spine-GAN for MR image segmentation. Other studies have utilized U-net, dense U-net, and residual U-net for accurate segmentation of vertebral bodies and intervertebral discs from spine CT and MR images (Horng et al., 2019) demonstrating the potential of DL algorithms for efficient and accurate spine image segmentation.

The segmentation effect of DL networks is better than other segmentation algorithms, and most of the network models are improvements to the FCN and U-net segmentation networks. The FCN network intentionally fuses rough semantic information and fine appearance information, which improves the segmentation accuracy, but the training speed is relatively slow. Relatively speaking, the U-net model is a lightweight network that is suitable for the segmentation of medical images. Properly adjusting the model according to the experimental data in the application can improve the performance of the segmentation (Zhou et al., 2018).

Methodology

Data collection

We collect MRI scan data from a Chinese hospital. Medical image scanning has a high resolution and can clearly show the extent, size, quantity, location, and relationship with surrounding organs of TB in each stage of bone destruction, and diagnosis is very important for treatment and prognosis (Huang et al., 2022). We utilized a comprehensive dataset comprising 2,515 individual cases, each containing 45 images, resulting in a total of approximately 113,175 images for analysis. Each image has a file size of approximately 800KB. The dataset spans a temporal range from the year 2010 up to the current year, thereby providing a longitudinal perspective on the subject matter. This extensive and diverse dataset serves as a robust

foundation for our analyses, allowing for a high degree of statistical power and generalizability of our findings. We also acquire the full diagnosis data (see five example data in Table 1) as true labels for algorithm training. All procedures involving human participants in this study will be conducted in accordance with the ethical standards of the institutional research committee, and informed consent are obtained from all individual participants included in the study.

Patient No.	No. of hospitalizations	Discharge date	Full diagnosis
413020	1	9/24/2016	TB of the thoracic spine; TB of the lumbar spine; TB of the chest wall; tuberculous abscess of the spine; secondary pulmonary TB; TB of the ribs
412011	2	9/14/2016	bone destruction; lumbar disc herniation; pulmonary TB
407838	4	8/4/2016	Lumbar sprain; Lumbar disc herniation; Myocarditis sequelae; Obliterative peripheral atherosclerosis; Hypercholesterolemia; Post-concussion syndrome; Parietal lobe meningioma; Thyroid nodule; Fatty liver; Anxiety depression; Secondary TB; Chronic sphenoid sinusitis; Chronic maxillary sinusitis
404669	1	7/14/2016	Lumbar TB; Lung TB; Osteoporosis; Renal cyst
405004	1	7/6/2016	Lumbar TB; Spinal tuberculous abscess; Pulmonary TB; Hypertension; Chronic viral hepatitis
Table 1. Diagnosis Data Samples			

The comminuted type of bone destruction is the most characteristic and the most frequent type of bone destruction in bone TB, which is characterized by many small pieces of broken bone remaining in the diseased bone. In particular, a soft-tissue mass with only a mild periosteal reaction is characteristic of bone TB and does not occur in other infections or bone tumors (Nussbaum et al., 1995).

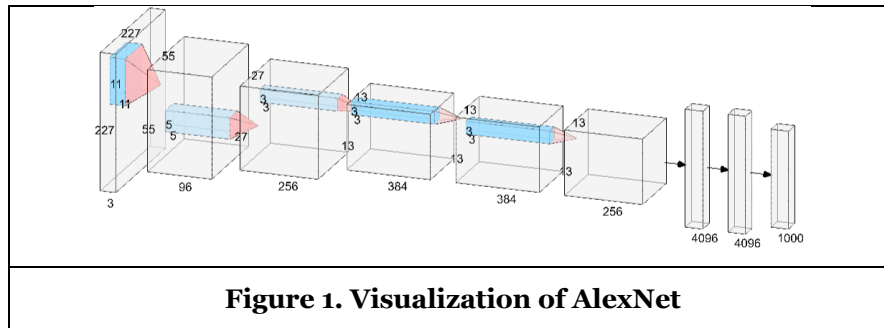
Design artifact

Image preprocessing is an essential step in the system pipeline, as it involves selecting the main area of the MRI image and reducing calculation loss. Since lesions in MRI images are typically located in fixed positions, it is necessary to edit the image and select only the main area to improve computational efficiency. The DL model used in the proposed system is a Convolutional Neural Network (CNN), which is a type of artificial neural network commonly used in image classification tasks. Specifically, the AlexNet model (see Figure 1), which consists of eight layers including convolution layers, ReLU conversion, pooling layers, normalization processing, fully connected layers, and a softmax regression function for classification, is used as the primary DL model. In addition to the AlexNet model, the proposed system also explores the use of VGG, an enhanced version of AlexNet that includes an additional layer after the fourth or fifth layer. The specific parameters used for the VGG model depend on the final image classification effect achieved during testing.

Algorithm evaluation

Algorithm evaluation is a critical step in determining the accuracy and effectiveness of the proposed diagnostic system. Our evaluation framework is aligned with the comprehensive approach outlined by Lin et al. (2017), which emphasizes the importance of real-world clinical applicability and early-stage disease prediction. The evaluation is based on several metrics, including the *True Positive Rate (TPR)*, which measures the ratio of the number of predicted positive results to the total number of positives in the sample, the *False Positive Rate (FPR)*, which measures the ratio of the number of incorrectly predicted positive results to the actual total number of non-positives in the sample. The *Receiver Operating Characteristic (ROC) curve* plots sensitivity against 1-specificity. *The area under the ROC curve* represents the diagnostic accuracy (AUC). AUC is a standard measure in predictive analytics that quantifies a model's trade-offs

between type I and type II errors. AUC ranges between 0.5 (equivalent to a random guess) and 1.0 (perfect performance). *Precision-Recall Area Under the Curve (PR-AUC)* is particularly useful when dealing with imbalanced datasets and focuses on the performance of a classifier with respect to the positive (minority) class.



Drawing from the methodology of Lin et al. (2017), we also consider the timing of the patient's medical history in our evaluation. Specifically, we sample visits from the first half of a patient's medical history to more realistically assess the predictive performance of the model. This aligns with the preventive nature of risk profiling, allowing for predictions at an earlier stage of the disease process.

Finally, the proposed system requires specialized hardware equipment to support the processing of large amounts of image data. Depending on the amount of project image data, either 1-8 NVIDIA GTX 1080 GPUs or the Alibaba Cloud server can be used for computational support.

Validation of artifact

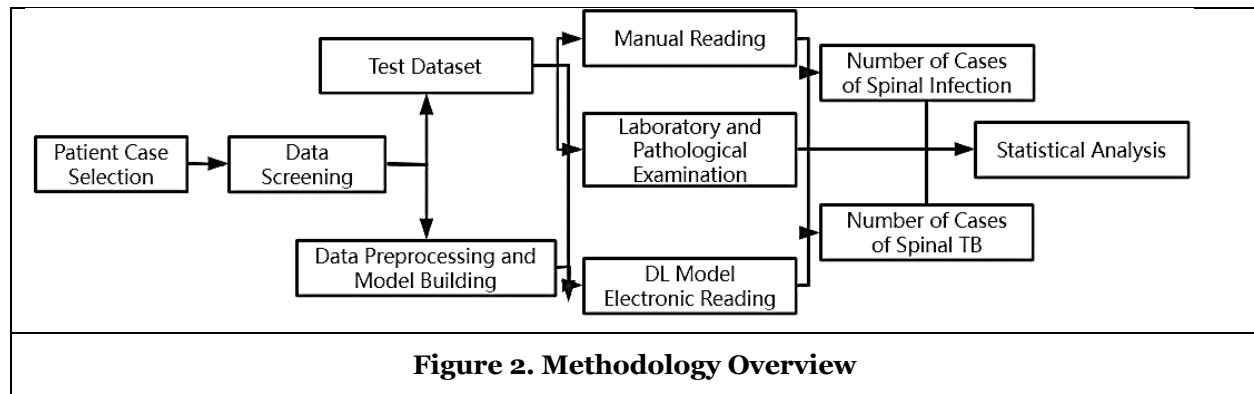
To validate the effectiveness and accuracy of the proposed AI-assisted diagnostic system for spinal TB using MRI imaging, a comprehensive approach will be adopted, informed by multidisciplinary research in chronic disease management and predictive analytics (see Figure 2).

Step 1: The MRI imaging data of 500 suspected spinal TB patients, including those with confirmed TB diagnosis and those with general suppurative spondylitis, will be imported into the DL model for analysis. Bardhan et al. (2015) emphasize the importance of large datasets for predictive analytics in healthcare, particularly for readmission of patients with chronic conditions like congestive heart failure. The accuracy of the model will be verified by comparing its diagnosis to the original diagnosis.

Step 2: Two attending physicians from the radiology department of our hospital will be invited to review and diagnose the same 500 cases of spinal MRI data. Bardhan et al. (2020) highlight the need for integrating human expertise with AI systems for effective chronic disease management. Their research roadmap suggests that a multidisciplinary approach involving medical experts can enhance the reliability of AI systems. If there is a discrepancy in diagnosis between the two physicians, a third physician will be invited to make a diagnosis of the images. The final diagnosis will be based on the majority.

Step 3: The 500 suspected spinal TB cases will be analyzed according to laboratory and pathological examinations, including Xpert test, DNA of TB non-TB mycobacteria, lesion histopathological examination, TB DNA\RNA. The final laboratory and pathological diagnosis will be completed for each patient. The results will be compared with the results of manual film reading and the results of DL model film reading to evaluate the accuracy and effectiveness of the proposed AI-assisted diagnostic system.

Step 4: By conducting these steps, the proposed AI-assisted diagnostic system can be evaluated and compared to the current standard of manual film reading and clinical diagnosis. Lin et al. (2017) use a Bayesian multitask learning approach for healthcare predictive analytics in chronic care. Their methodology underscores the importance of using advanced statistical methods to validate the effectiveness of predictive models in healthcare.



In the evolving landscape of healthcare, there's a growing consensus on the necessity for transformative approaches, especially when addressing chronic diseases like bone TB. This transformation isn't solely about technological advancements; it encompasses a myriad of factors including socio-cultural dynamics, economic implications, legal frameworks, political considerations, and ethical dilemmas. Our research, following the contemporary framework "Connecting Systems, Data, and People: A Multidisciplinary Perspective," (Bardhan et al., 2020), underscores the importance of a holistic approach. We aim to create a solution that's not just technically adept but also organizationally harmonious and socio-culturally sensitive. This integrated perspective, drawing from a range of disciplines within the IS community, ensures our algorithm is both innovative and applicable, addressing the multifaceted challenges of modern healthcare.

Expected contributions

1. A holistic design solution for bone TB diagnosis: Drawing inspiration from the multidisciplinary research roadmap proposed by Bardhan et al. (2020), our paper goes beyond algorithmic design to offer a holistic solution for bone TB diagnosis. We employ an ADR approach to develop an AI-assisted orthopedic clinical diagnosis system. This approach ensures iterative validation using real-world clinical data, thereby contributing a more comprehensive and practically applicable design solution for improving the accuracy and efficiency of bone TB diagnosis.
2. Bridging technological rigor and organizational relevance in AI and healthcare: Our study resonates with the predictive analytics models of Bardhan et al. (2015) and Ben-Assuli & Padman (2020). Moreover, our study advances the broader field of AI and healthcare by demonstrating how AI algorithms can be fine-tuned to meet actual clinical needs and constraints. This contributes to a more nuanced understanding of the potential and limitations of AI algorithms in healthcare settings, thereby enriching the existing body of literature (Jain et al., 2021).
3. Innovative insights into the design and evaluation of AI-assisted systems: Our paper provides a unique perspective on the design and evaluation of AI-assisted systems by incorporating real-world clinical data into the research process. This not only emphasizes the importance of empirical data but also highlights the role of different evaluation metrics in a real-world context, thereby offering new insights into the design and evaluation of AI-assisted systems (Jussupow et al., 2021).
4. Enhancing real-world applicability through iterative validation: By focusing on iterative validation as part of the ADR approach, our study adds a layer of robustness to the AI algorithms developed, ensuring that they are not just theoretically sound but also practically reliable. This ensures that the algorithms are not just theoretically sound, as suggested by Bardhan et al. (2020), but also practically reliable. This is expected to have implications for the broader adoption of AI in clinical settings, offering a more comprehensive solution than existing models.

Limitations and future work

The present study, while contributing to the burgeoning field of AI in bone TB diagnosis, is not devoid of limitations. A salient constraint pertains to the data provenance, which is confined to a single healthcare

institution. Nonetheless, it is our contention that the design artifact possesses a degree of generalizability. The algorithmic framework is engineered for modularity and adaptability, necessitating only an initial conversion of MRI or CT scans into a standardized JPEG format for cross-institutional applicability. Subsequent computational procedures, encompassing image preprocessing, feature extraction, and classification algorithms, are designed to be invariant to the specific healthcare setting, thereby enhancing the system's adaptability.

The manuscript in its current form serves as a preliminary exploration and necessitates further scholarly endeavors for completion. Immediate plans for manuscript refinement include the incorporation of additional evaluative metrics and an expanded discourse on the algorithmic novelty. Longitudinal research trajectories will involve multi-institutional collaborations aimed at empirically validating the generalizability of our findings, thereby mitigating limitations associated with the single-institution dataset. These planned augmentations aim to fortify the academic rigor and practical applicability of our research contributions.

Conclusion

The development of AI-based image segmentation and detection algorithms for bone TB diagnosis is a promising area of research that has the potential to significantly improve the accuracy and efficiency of diagnosis. Through the proposed empirical study, we expect to demonstrate the feasibility and effectiveness of the AI-assisted diagnostic system in accurately diagnosing spinal TB from medical images. This study also contributes to the field of DSR by the development and evaluation of innovative solutions for clinical diagnosis and treatment. Ultimately, we hope that this research can contribute to the improvement of bone TB diagnosis and treatment, and benefit patients worldwide.

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