A literature review of quality, costs, process-associated with digital pathology

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Digital pathology incorporates the acquisition, management, sharing, and interpretation of pathological information, including slides and data, in a digital environment. Digital slides are created using a scanning device to capture a high-resolution image on glass slides for analysis on a computer or a mobile device. Though digital pathology has drastically grown over the last 10 years and has created opportunities to support specialists, few have attempted to address its full-scale implementation in routine clinical practice. To incorporate new technologies in diagnostic processes, it is necessary to study their application, the value they provide to specialists, and their effects on improvements across the entire workflow, rather than studying a particular element. In this study, we aimed to identify what the current digital pathology systems contributed to the pathological and diagnostic process. We retrieved articles published between 2010 and 2020 from the databases PubMed and Google Scholar. We explored how digital pathology systems can better utilize existing medical data and new technologies within the current diagnostic workflow. While the evidence concerning the efficacy and effectiveness of digital pathology is mounting, high-quality evidence regarding its impact on resource allocation and value for diagnosis is still needed to support clinical diagnosis and policy decision-making.

Keywords: Digital pathology, Workflow, Quality, Artificial intelligence, Computational pathology

INTRODUCTION

The need for efficient resource distribution and innovative technology to provide quality care is emerging, with an aging population and an increase in chronic diseases (Kairy et al., 2009). It is clear that the adoption of new technology is a major driver of health care quality innovation, but policymakers must reconcile the adaptation to innovative treatments and their affordability, while providing incentives for innovation (Organisation for Economic Co-operation and Development, 2017). Applying new technologies to the job is a burden not only on the institutions’ decision-makers, but also on employees. Decision-makers want to reduce the burden economically while maintaining the benefits of innovation, and employees expect new technologies to help them without disrupting their existing workflow (Davenport and Kalakota, 2019).

Digital pathology incorporates the acquisition, management, sharing, and interpretation of pathological information, including slides and data, in a digital environment. Digital pathology refers to converting and storing a pathology slides into the digital images using a digital scanner, and performing a pathological diagnosis using these digital images. Digital slides are created using a scanning device that digitally captures a high-resolution image of the contents on glass slides for analysis on a computer or mobile device (Digital Pathology Association, 2020).

Though digital pathology has drastically grown over the last 10 years and has created opportunities to support specialists, few have attempted to address its full-scale implementation in routine clinical practice (Ho et al., 2014). In the 1990s, the commercialization of scanner equipment capable of digitizing pathological images improved research across the field of digital pathology. The ability to process, analyze, and store large amounts of data

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through scanners allows for creating digitized pathological images as whole-slide images (WSIs) (Hartman et al., 2017).

For using new technologies to be used in diagnosis, it is necessary to study their application, value to specialists, and effects of improvement across the entire workflow rather than simply studying a single element. The purpose of this study was to outline and elaborate the proposed values of implementing the digital pathology system by exploring in the latest research.

**MATERIALS AND METHODS**

We reviewed literature on this topic published between 2010 and 2020 from the public databases PubMed and Google Scholar (Table 1). For the present study, we defined digital pathology as using WSI for remote consulting, diagnosis, teaching, and image analysis. We searched articles published in English on PubMed. The keywords used included digital pathology and workflow.

The selection criteria were as follows: (a) We included only case studies that included implementing digital pathology compo-

| Study | Study population, study design | Description of program technology used | Outcomes and effectiveness of methodology | Category |
|-------|---------------------------------|----------------------------------------|------------------------------------------|----------|
| Hanna et al. (2020) | 108 Cases, comprised of 254 individual parts and 1,196 slides | Telepathology (remote sign out) | Operational feasibility supporting remote review and reporting of pathology specimens, and evaluation of remote access performance and usability for remote sign out. | ✓ ✓ |
| L’Imperio et al. (2020) | 826 Cases (research), the routine renal biopsies collected from 14 different Italian nephrology centers | Digital microscopy | A standard model improved the diagnostic performance and reduced the turnaround-time. | ✓ ✓ |
| Steiner et al. (2020) | A total of 20 general pathologists reviewed 240 prostate core needle biopsies | A recently developed deep learning model for prostate biopsy grading | Decreases in the mean review time per case, decreases in interobserver variability for Gleason pattern quantitation. | ✓ ✓ |
| Torres et al. (2020) | Forty patients’ core biopsies with a high likelihood of prostate cancer based on magnetic resonance imaging | Direct multiphoton imaging yielded diagnoses | Reduced processing time and reduced processing complexity | ✓ ✓ |
| Achi et al. (2019) | Hematoxylin and eosin-stained slides of 128 cases including 32 cases for each diagnostic category | Automated lymphoma diagnostic screen | Diagnostic accuracy at 95%. | ✓ |
| Randell et al. (2015) | Nine pathologists participated in a counterbalanced crossover study, viewing axillary lymph node slides | A microscope, a 23-inch 2.3-megapixel single-screen display and a three-screen 11-megapixel display consisting of three 27-in displays | Easier to identify where cancer is located in the initial slide overview, enabling quick location of diagnostically relevant regions of interest. | ✓ |
| Wilbur et al. (2015) | 3 Pathologists interpreted and digital slides in sequence or in random order with a minimum of 7 days as a washout period. | Philips digital pathology system | Safety and effectiveness | ✓ |
| Romero Laura et al. (2013) | A large complex medical organization consisting of 20 hospitals with more than 110 diagnostic anatomical pathologists | The web-based solution which enables telepathology and image viewing | Easy gateway to real-time telepathology consulting and simplified the mechanism to obtain second opinions | ✓ |
| Krupinski et al. (2012) | A set of 250 breast biopsy virtual slide regions of interest (half malignant, half benign) were shown to six pathologists. | A calibration, characterization, and profiling protocol for color-critical medical imaging applications | There was no significant impact on diagnostic accuracy with the color-managed/calibrated display, however, observe a significant impact on interpretation speed. | ✓ |
| Zembowicz et al. (2011) | 1,229 Dermatopathology consultations cases | A web-based second opinion consultation software | Web-based communication facilitates rapid turn-around time and reduces costs and barriers to second opinion consultation. | ✓ ✓ |
nents. We selected and analyzed only case studies that involved applying new technology to the pathologic diagnosis workflow. Technical studies of digital pathology systems were excluded from this research. For example, we included studies using artificial intelligence for diagnosis but excluded studies reporting the development of artificial intelligence models from this research. (b) The technologies implementing for diagnostic workflow were included. Case studies not directly related to diagnosis were excluded. For example, laboratory automation and dyeing technology research were excluded.

RESULTS

Digital pathology was used only for educational or consulting purposes until their regulatory approval for clinical employment in routine pathological practice (L’Imperio et al., 2020). In studies in the United States and Europe, the regulatory approval of digital pathology research results has been reported, and the similarity of WSI diagnosis to the pathological diagnosis (using a conventional microscope) has been confirmed (L’Imperio et al., 2020).

The latest papers that discuss the effectiveness of digital pathology applied to diagnosis emphasized the content for workflow implementation and discussed quality and delivery, excluding cost, among the operational performance with respect to quality, cost, delivery. Hospitals that implemented digital pathology earlier have built up second-generation digital pathology and currently integrate artificial intelligence and image analysis (Hanna et al., 2020; Stathonikos et al., 2020).

Pathology departments follow diagnostic procedures that result in a diagnostic report. The report is the results of the final pathology examination, and the quality of the pathological diagnosis is determined by the accuracy, timely delivery, and completeness of the report (Nakhleh, 2006). Moreover, pathological work process involves long laboratory processing times owing to several standardized manual procedures. During the long work process, subsequent processes cannot be conducted until previous ones are complete. In this sense, it is necessary to identify the values provided by implementing a fully digital pathology workflow. (Griffin and Treanor, 2017; Serrano et al., 2010)

DISCUSSION

In this study, we attempted to identify what value has the current digital pathology systems contributed to the pathological and diagnostic processes in the last 10 years. As information technology is a strategic asset in companies (Müller et al., 2012), digital pathology can be deployed as an enabler of process innovation in healthcare. Digital pathology digitizes the existing pathology workflow, and artificial intelligence and algorithms can improve the accuracy and efficiency of pathological diagnosis.

From a process management perspective, it is necessary to establish a structured framework to improve its processes, based on the data, and measure the process performance (Pyon et al., 2009). To successfully implement algorithms into digital pathology not only highly accurate algorithms are required but also their organic integration with existing pathological workflows, user-centered interface design, and interoperability with existing laboratory information and electronic health record systems are required (Guo et al., 2016; Steiner et al., 2020).

Therefore, standardizing procedures and establishing performance measurements are necessary. Quality, cost, and delivery analysis will support process assessment with strategic organizational and operational improvements.

We hope that high-quality evidence regarding the impact on resource allocation and value for diagnosis is discussed to support clinical diagnosis and policy decision-making.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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