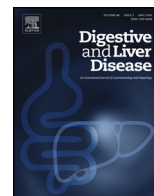




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Liver, Pancreas and Biliary Tract

Validation of whole-slide imaging in the primary diagnosis of liver biopsies in a University Hospital

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ABSTRACT

Background: Experience in the use of whole slide imaging (WSI) for primary diagnosis is limited and there are no comprehensive reports evaluating this technology in liver biopsy specimens.

Aims: To determine the accuracy of interpretation of WSI compared with conventional light microscopy (CLM) in the diagnosis of needle liver biopsies.

Methods: Two experienced liver pathologists blindly analyzed 176 consecutive biopsies from the Pathology Department at the Hospital Clínic of Barcelona. One of the observers performed the initial evaluation with CLM, and the second evaluation with WSI, whereas the second observer performed the first evaluation with WSI and the second with CLM. All slides were digitized in a Ventana iScan HT at 400× and evaluated with the Virtuoso viewer (Roche diagnostics). We used kappa statistics (κ) for two observations. **Results:** Intra-observer agreement between WSI and CLM evaluations was almost perfect (96.6%, $\kappa = 0.9$; 95% confidence interval [95% CI]: 0.9–1 for observer 1, and 90.3%, $\kappa = 0.9$; 95% CI: 0.8–0.9 for observer 2). Both native and transplanted biopsies showed an almost perfect concordance in the diagnosis.

Conclusion: Diagnosis of needle liver biopsy specimens using WSI is accurate. This technology can reliably be introduced in routine diagnosis.

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1. Introduction

Conventional light microscopy (CLM) has been the basic and, until recently, the only tool for the histological diagnosis of biopsy specimens. The development of the whole-slide imaging (WSI) technology has started to change this picture in the last few years.

The basis of the WSI technology is the use of high throughput scanners able to create high quality digital reproductions of glass slides containing a complete histological section and WSI viewers that allow navigation across the virtual slide. These tools enable the

use of the computer as a CLM. WSI has many practical applications that include education and teleconsultation [1–4]. In the last few years the medical community has shown increasing interest in the use of WSI for routine primary diagnosis [5–7].

Indeed, routine pathological diagnosis can benefit from the advantages of this technology. The WSI workstations are more ergonomic and facilitate a more efficient sign-out process. WSI allows viewing several slides at the same time on the same screen, which is particularly helpful for the evaluation of immuno- or histochemically stained slides that can be analyzed together with hematoxylin-eosin (H&E) staining (Fig. 1). The digital viewers incorporate tools that enable making annotations, rotating the images and making precise measurements [8]. WSI has a much larger field of vision than CLM and a wider range of magnifications, including very low magnifications that are very useful for the evaluation of surgical specimens. WSI facilitates sharing images and information with clinicians and other pathologists. This is not

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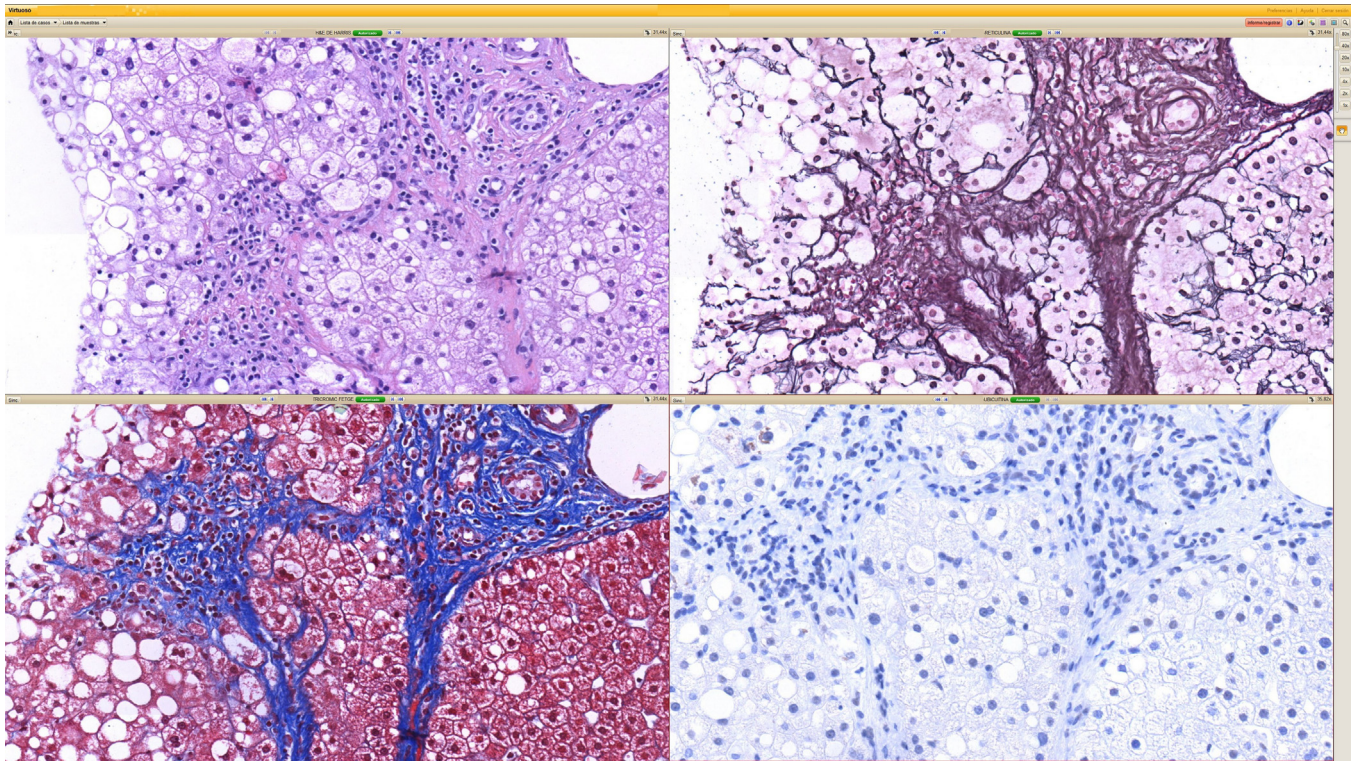


Fig. 1. The WSI viewer may simultaneously show and synchronously move several slides of a case. This is particularly helpful in the evaluation of liver biopsy specimens since it allows the analysis of an H&E stained slide together with histochemically and/or immunohistochemically stained slides.

only extremely useful in tumors boards, but also allows expert tele-consultation of difficult cases and frozen section intra-operative biopsies [9,10]. Finally, with WSI algorithms can be used for the evaluation and quantification of immunohistochemical stains, resulting in a more objective evaluation [11–14]. This tool is likely to become essential to achieve standardized diagnoses in the near future.

Although WSI is considered to be comparable to CLM, adequate correlation between WSI and CLM diagnoses should be confirmed before this technology is used for primary diagnosis. The number of studies aimed at validating WSI in the routine diagnosis of the different areas of pathology is rapidly growing [15]. However, whereas relatively abundant information is available in some areas of pathology, validation studies are very scant or even absent in other areas, such as liver biopsy. Indeed, while a few studies have used this tool in research and automated image analysis [16–24], there is a complete absence of studies validating the use of WSI in needle liver biopsies, which may lead to reluctance in implementing this technology in routine diagnosis.

2. Materials and methods

2.1. Characteristics of the institution

This study was performed at the Department of Pathology in the Hospital Clinic (Barcelona, Spain). This department is composed of 16 pathologists, 8 residents and a variable number of fellows. The specimens are divided into 14 subspecialties, and the pathologists limit their practice to one or two areas. In 2015 the Department handled 43,678 specimens with 11,081 paraffin blocks. The number of liver needle biopsy specimens during this year was 230. The study was approved by the institutional ethics review board/HCB/2014/0514.

2.2. Sample size calculation

The highest rate of discrepancy between the original diagnosis by CLM and that by WSI was calculated to be 3%, with a non-inferiority margin for WSI review of 5%. A 1-sided binomial test was used for comparison at a level of significance of .05. The power to be achieved was 70%, and the level of significance was .05. Based on these assumptions, it was calculated that 100 cases would need to be reviewed to establish non-inferiority [25].

2.3. Specimens included in the study

All consecutive needle liver biopsy specimens received at the Department of Pathology of the Hospital Clinic in a 9-month period (February–October 2015) and assigned to the same expert pathologist were included in the study ($n = 176$). This represented 76.5% of the total number of liver biopsies evaluated in 2015. All cases had a single paraffin block, containing one to five specimens (median 1). All specimens were routinely stained with H&E, Masson's trichrome and reticulin stain. Additionally, immunohistochemical stains were used for specific cases after the request of the pathologist. The total number of scanned slides was 1286. The biopsies included both native and transplanted livers ($n = 112$ and $n = 64$, respectively). The median age of the patients was 57 years (range 18–91).

2.4. Scanning process and characteristics of the WSI display

All the needle liver biopsies were scanned daily after CLM diagnosis. The scanning of the histological slides was performed on a Ventana iScan HT (Ventana Medical Systems, Tucson, AZ, USA) at a magnification of 400x. The scanning process run automatically, and includes the selection of the area that contains the tissue, the determination of the focus points, the calibration, and the scanning.

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