

Liver Biopsy – A Bottleneck to NASH Diagnosis



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BACKGROUND

The effective treatment of Non-alcoholic Steatohepatitis, or NASH, is a priority for the healthcare industry. NASH is a severe form of non-alcoholic fatty liver disease (NAFLD) and is a silent disease that affects 3% to 12% of adults in the United States. Liver biopsies are the gold standard in diagnosing NASH, and with the first generation of NASH therapeutics on the horizon, it is essential to understand the extent to which liver biopsies may limit access to care.

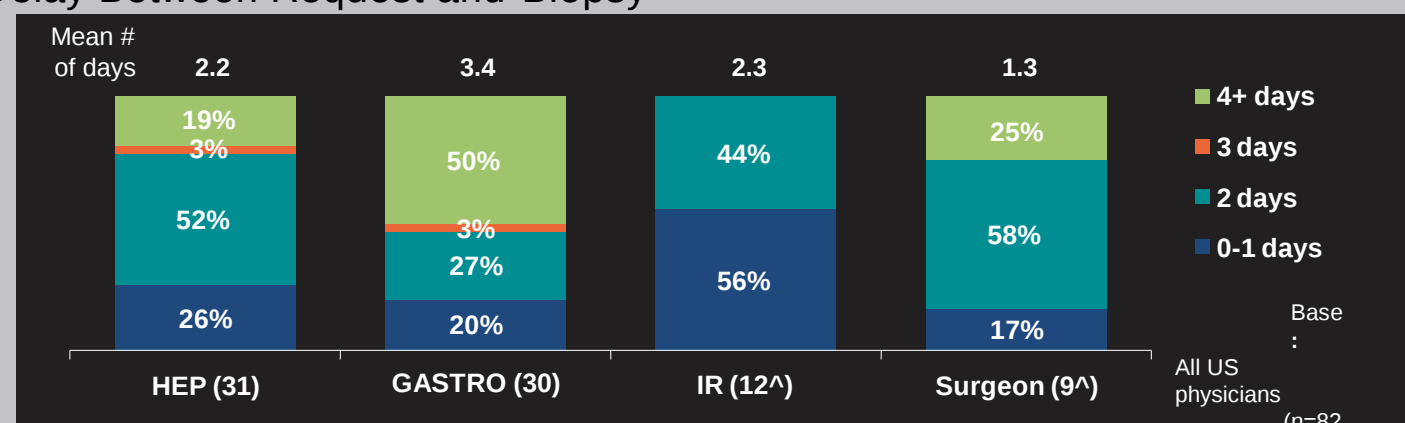
METHODOLOGY

Data from Ipsos' US Liver Diagnostic Monitor were used. The Liver Diagnostic Monitor is a perceptual study that was conducted online from September - November 2018 and captured information from 82 respondents (31 hepatologists (HEPs), 30 gastroenterologists (GASTROs), nine interventional radiologists (IRs), and 12 surgeons) that had conducted a biopsy and managed NAFLD/NASH patients. Physicians reported on attitudes, beliefs, behaviors, future trends and key metrics around diagnosis and biopsy of liver disease. Descriptive analysis was conducted using appropriate statistical tests.

RESULTS

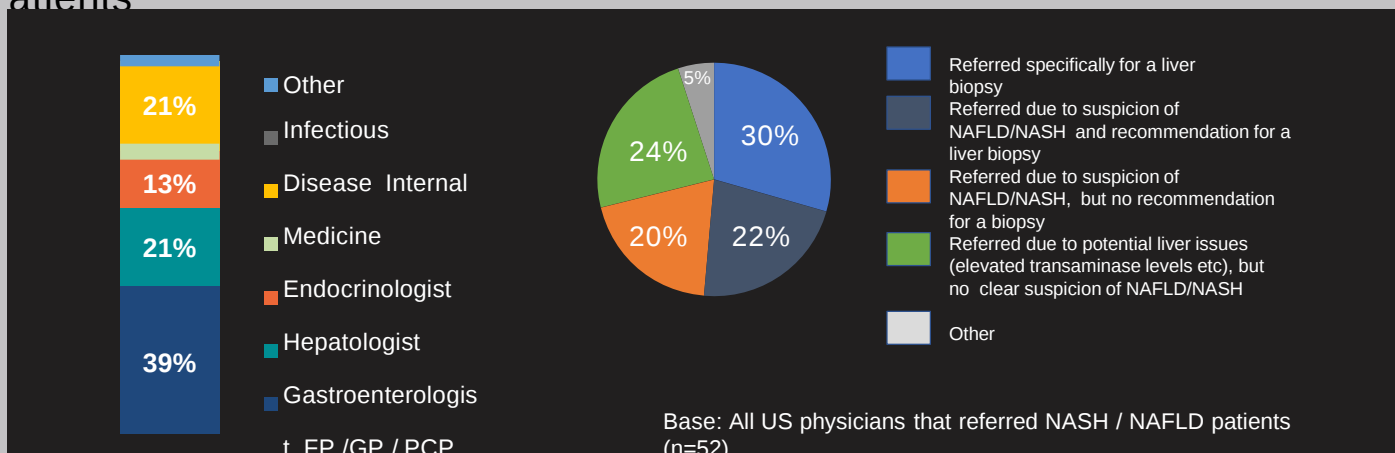
Among general liver disease-treating physicians, the average wait time from deciding on the requirement for a biopsy to a patient receiving a biopsy varied by specialty, with HEPs having an average wait of 2.2 days, GASTROs 3.4 days, IRs 1.3 days, and surgeons 2.3 days.

Delay Between Request and Biopsy



When looking specifically at the management of NASH/NAFLD patients, general practitioners (including family practice and primary care providers) account for 39% of NASH/NAFLD referrals and GASTROs/IDs 21%. 52% of physicians referring NASH/NAFLD patients do so with a specific recommendation for a liver biopsy. It is important to note that HEPs and GASTROs perform over half of their liver biopsies themselves rather than referring patients to surgeons or IRs.

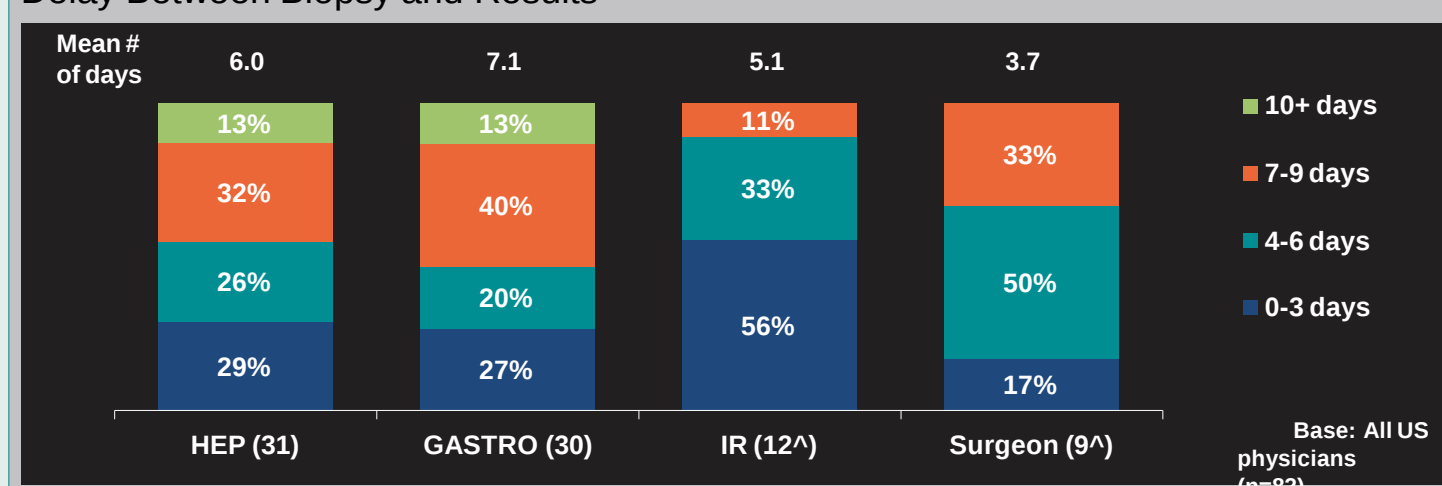
Specialties Referring NASH / NAFLD Patients



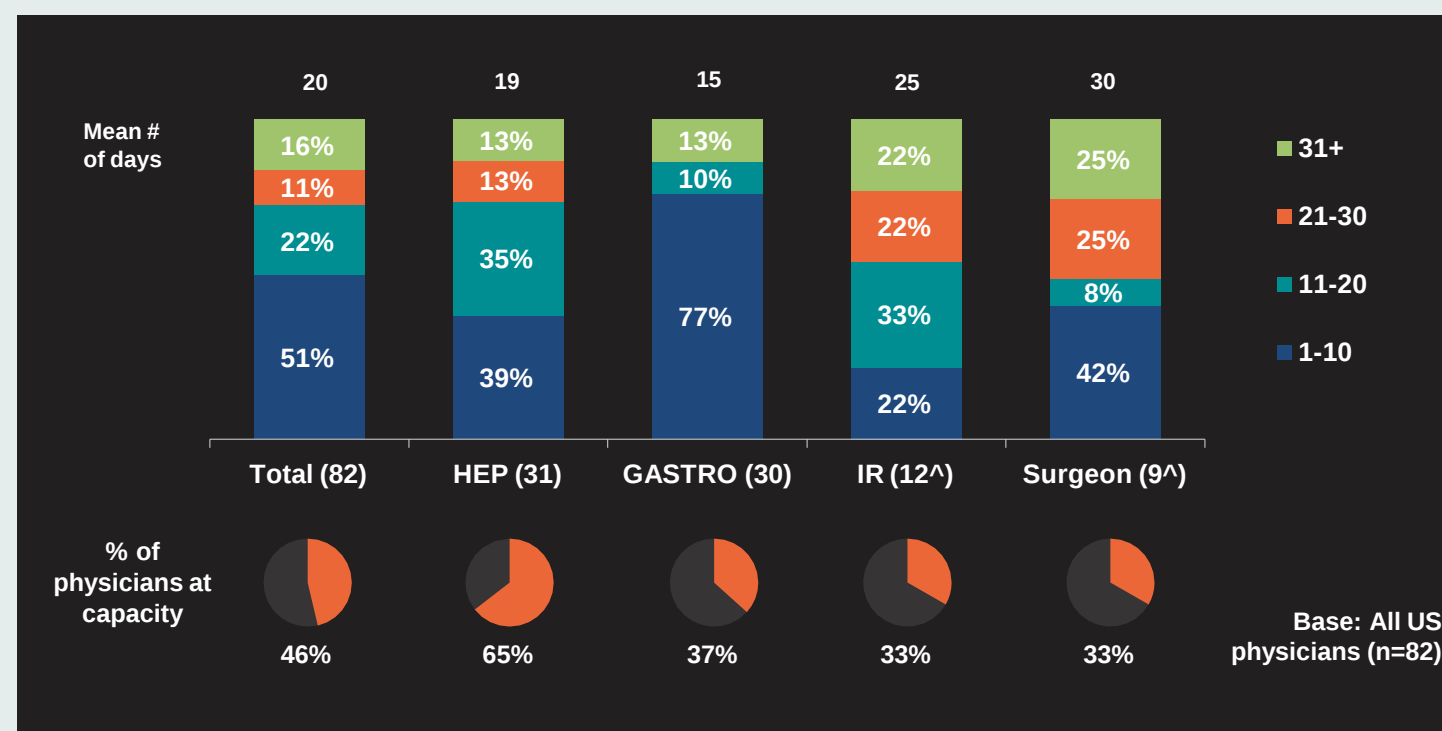
RESULTS

In conjunction with the wait time from the decision to request a biopsy to one being performed, there is the time required for the results to be received. HEPs had an average wait of 6 days, GASTROs 7.1 days, IRs 5.1 days, and surgeons 3.1 days. When considering their patients seen in the last 3 months who received a liver biopsy, HEPs performed 75% of these biopsies themselves.

Delay Between Biopsy and Results



A further protraction to the liver biopsy process that requires consideration is that of capacity. HEPs had a weekly capacity for 19 biopsies, with GASTROs, IRs, and surgeons stating 15, 25 and 30, respectively. 46% of respondents reported that, in the last three months, they were at capacity for performing liver biopsies while 38% were below capacity. The 38% was driven mainly by the nine interventional radiologists, of which 67% believed they were below capacity, and GASTROs, of whom 50% stated they were also below capacity. 65% of HEPs reported that they were at their weekly capacity.



CONCLUSIONS

Using liver biopsies for the diagnosis of NASH is resource-intensive, has limited scalability and may impact the number of patients who will be eligible for treatment. Surgeons and IRs

have the most flexibility while HEPs have the most limited biopsy bandwidth. With NASH therapeutics on the horizon, the need for biopsy confirmed NASH is likely to increase and further protract this process.

DISCLOSURES

All authors are current employees of Ipsos, LLC

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