S Borgia. Re: Kan V, Marquez Azalgara V, Ford J-A, et al. Patient preference and willingness to pay for transient elastography versus liver biopsy: A perspective from British Columbia. Can J Gastroenterol Hepatol 2015;29:72-6.

FibroScan® *access in Canada: Time for reform, a call for universal access*

To the Editor:

The article by Kan et al (1) in the March 2015 issue of the *Journal*, describing patient preference and willingness to pay for transient elastography (TE) versus liver biopsy, confirms other recent publications that FibroScan (EchoSens, France) is now the preferred modality for the assessment of liver fibrosis by clinicians caring for patients with liver diseases in Canada (1-3). Notably, it is the first article to address the key value in confirming that FibroScan is also the preferred modality for the most important stakeholders: patients.

Until the development of recent noninvasive testing modalities, such as FibroScan, percutaneous liver biopsy (PLB) was regarded as the gold standard for the staging and grading of liver fibrosis, including in patients with chronic viral hepatitis. However, PLB has considerable disadvantages: it is an uncomfortable invasive procedure that, in approximately 1% of patients, accrues the risk of hemorrhage, infection, perforated viscus and pneumothorax, and very rarely, death in approximately one in 10,000 patients (4,5). PLB is time consuming, resource intensive, and requires a high degree of technical and interpretive expertise; the results of which require several days for completion. Moreover, studies show significant interobserver variation among the reading pathologists and, notwithstanding adequate technical parameters, liver diseases are often inhomogeneous, introducing staging uncertainty (6,7). Finally, in a predominantly single-payer health care system, such as found in Canada, the direct and indirect costs of PLB, while fully funded by provincial health ministries, are not trivial. Conservative estimates of the direct costs of PLB suggest $1,200 to $1,500 per procedure, with costs of complications approximately $4,500 (8,9).

FibroScan relies on sonic detection of liver stiffness to predict hepatic fibrosis and has been validated in patients with chronic hepatitis (10). It is a safe, noninvasive modality that offers several specific advantages: rapid procedure time; immediate results; and the option of performing the procedure in real time at the bedside or in the outpatient clinic. However, TE has some limitations: the results are to some extent operator and machine dependent but can be mitigated by proper training, experience and machine calibration. In addition, liver stiffness may be overestimated in the presence of confounding factors such as obesity and extrahepatic cholestasis (11,12).

In 2009, FibroScan technology was licensed for use in Canada and has become accepted as a noninvasive marker of fibrosis by clinicians. Provincial funding authorities accept FibroScan results for adjudicating eligibility criteria for the treatment of viral hepatitis; however, access to and uptake of this attractive and accurate modality remains vanishingly rare. Reasons for this are primarily threefold and centre around the lack of access to noninvasive modalities: there are few people trained in its use – training that can be accomplished in a few hours; the capital cost of the hardware is relatively expensive – approximately $100,000 (range $70,000 to $140,000); and, with the exception of Quebec, the test is not currently reimbursed by provincial health care ministries, leaving most patients to pay approximately $100 per test. Without a means to offset the initial capital investment or to spare patient expense, there is further disincentive for clinicians to obtain the technology. Estimates place the number of FibroScan machines in Canada at approximately 40 and, with very few community examples, are primarily concentrated in large academic centers (2).

Review of Canadian clinicians' practice patterns and attitudes toward PLBs and noninvasive modalities of fibrosis assessment reveals that the majority of survey participants – nearly two-thirds of whom were gastroenterologists – required assessment of disease stage, and the greatest demand for fibrosis assessment was for patients with hepatitis C (76.9%) (2). In this same survey, noninvasive fibrosis assessment was ordered more frequently in patients with viral hepatitis than autoimmune hepatitis and, surprisingly, approximately 50% of surveyed physicians continue to use PLB as the primary modality of fibrosis assessment as opposed to FibroScan primarily for the reasons outlined above (2).

Despite the paucity of available FibroScan assessment in Canada, another study found that, where available and due to its introduction, there was a significant reduction in the performance of PLBs; one-half of hepatologists who have access to this diagnostic modality reported a decrease in PLBs of 25% to 50%, while 29% reported a decrease of >50% (3).

The study by Kan et al (1) is particularly telling; an overwhelming majority (95.4%) of patients (two-thirds of whom had viral hepatitis) preferred FibroScan to PLB if both tests were available at no cost to them. This result did not change when only PLB-experienced respondents were considered (95.1%), validating the clear preference of patients for FibroScan over PLB. Seventy-five percent of patients reported being willing to self-pay to undergo FibroScan if only PLB was publicly funded.

These findings confirm that there continues to exist inequitable access to state-of-the art fibrosis testing for the vast majority of Canadians with liver disease. It is a curious paradox that this disproportionately disadvantages individuals infected with chronic hepatitis C for which in most of Canada there now exists public funding for curative therapy.

Furthermore, it cannot escape notice that if noninvasive testing, such as FibroScan, were publicly funded in Canada, the number of PLBs performed would continue to be significantly reduced, along with their limitations and costs. The very cost savings of such a reduction in PLB would, in essence, facilitate a cost-effective strategy for FibroScan procurement. This could occur in as quickly as one to three years depending on the volume of patients requiring a FibroScan assessment vis-à-vis the number of foregone PLBs at the respective centres.

The following example is offered from our centre, where the capital cost in 2013 of a FibroScan FS 502 Step-5 with M probe (with an annual maintenance cost of $1,808) was $114,808. Yearly, between 2011 and 2015, there were 223, 239, 175, 150 and 25 (year to date, projected 100) PLBs performed, respectively. At a conservative cost of $1,365.52 per PLB (adjusted for 2015), 84 biopsies would be required to demonstrate cost-effectiveness of the technology. In the three years before obtaining FibroScan, our facility performed a yearly average of 212 biopsies, suggesting a time horizon of 4.75 months for the investment to have been cost-effective in addition to a 50% reduction in PLBs; targets that have already been achieved at absolutely no cost to our patients.

Admittedly, PLB still has a role to play in the diagnosis and management of certain liver diseases. However, with the advent of accurate, rapid and safer staging of liver fibrosis that FibroScan offers, a compelling case can be made for national funding within provincial health budgets to redress the inequality of its availability, to respect clinician and patient preference, and to bridge the tremendous unmet need of fibrosis staging for a majority of patients for whom access confers untold management benefits.

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