RACGP

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29 March 2016

Ms Mary Warner
Director, Medical Services Section
Medical Specialist Services Branch
Department of Health
Canberra ACT 2601

Dear Ms Warner,

RE: Medical Services Advisory Committee (MSAC)'s application 1366 – *Transient Elastography (TE) at 50Hz for the diagnosis of liver fibrosis in patients with confirmed hepatitis B or C.*

The RACGP is pleased to provide feedback to the Department of Health on the Medical Services Advisory Committee (MSAC)'s application 1366 – *Transient Elastography (TE) at 50Hz for the diagnosis of liver fibrosis in patients with confirmed hepatitis B or C.*

As requested, we have provided advice on the following questions posed by the Department of Health outlined below.

Clinical utility of TE for patients with hepatitis B or C

General practitioners are critical in clinical management with early detection, follow-up and monitoring of chronic hepatitis B and C progression. TE has clear benefits for both patients and GPs:

- For many individuals, the invasive nature of liver biopsies pose a barrier for engaging in appropriate care. TE is a safe, non-invasive procedure that requires no venous access, minimal patient preparation and therefore has less impact on the patient's personal or work life.
- TE reduce the risk of bleeding in comparison with a liver biopsy.
- TE only requires electricity to be operational. Portable TE machines allow access to rural and regional areas in outreach clinics, enhancing equity and access to people living with hepatitis B and C in these locations.

The RACGP believe Medicare supported TE would assists GPs in determining the severity of liver disease, establishing treatment priorities and making treatment decisions for patients living with chronic liver disease.

Diagnostic information offered by TE in comparison to other available diagnostic services

The *Australian recommendations for the management of HCV infection: a consensus statement 2016*[1] advocate for a fibrosis assessment in all people being considered for hepatitis C infection. TE is listed as one of the options for this assessment. Other tests/biomarkers listed as options include the calculation of the APRI score, Hepascore, Fibrogene and other scores.

These pathology tests provide result for AST and platelet count which are required as part of the pre-treatment test. GPs are being encouraged to use TE results along with these clinical findings to best assess for the likelihood of significant fibrosis and cirrhosis.

[1] *Australian recommendations for the management of HCV infection: a consensus statement 2016.* Gastroenterological Society of Australia, 2016. Available from*:* https://www.asid.net.au/documents/item/1208

Furthermore, the World Health Organization (WHO) *Guidelines for the screening, care and treatment of persons with hepatitis C infection* reports TE sensitivity of 89 (95% confidence level 84-92) and a specificity of 91 (95% confidence level 89-93) for a cut-off point of 11-14kPa, correlating to cirrhosis (METAVIR F4).[2]

Dissemination of TE in general practice

Hepatitis C

The new PBS-listed direct-acting antiviral medication (DAA) provide people living with hepatitis C greater access to treatment. One of the requirements for accessing the type and length of treatment is to assess whether the patient has cirrhosis. This is also very important in determining the need for ongoing monitoring of these patients and surveillance for hepatocellular carcinoma. To ensure the new PBS-listed DAAs to reach their potential, increased access to TE will be required.

Hepatitis B

In the treatment of chronic hepatitis B, the ultimate goal is preventing the development of associated hepatitis B- virus diseases, including hepatocellular carcinoma. Consequently, assessing whether or not a patient with chronic hepatitis B has fibrosis is important in guiding the decision to commence treatment, treatment timing and ongoing cancer surveillance.

Barriers for implementation

Currently there is a need for increased access to TE for people living with viral hepatitis. Access to TE via portable machines in general practices has the potential to significantly enhance efforts to eradicate hepatitis C, particularly in rural and remote areas. However, the cost of machines and their maintenance serve as barriers to general practices purchasing them.

In addition to cost barriers, there is also an issue of access. In many areas of Australia, TE tests are available in a very restricted number of public and private hospitals. It is not uncommon for individuals who want to have the test done to attend a private gastroenterologist, which may be unaffordable to a number of patients. Furthermore, many patients who have chronic hepatitis B and C are marginalised or from low socioeconomic backgrounds (PWID, refugee and CALD backgrounds, ATSI), limiting their access to best practice care.

The availability of a Medicare item for performing a TE test will increase the likelihood of high caseload general practices being able to incorporate this into standard practice. There are a number of benefits, including:

- potential for opportunistic testing of patients that are traditionally difficult to engage in care, especially those who are reluctant to or have difficulty attending booked appointments in tertiary centres.
- decrease on demand for TEs performed at tertiary services, reducing the waiting times for the assessment of people with more advanced disease which may require more close monitoring.

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[2] *Guidelines for the screening, care and treatment of persons with hepatitis C infection*. World Health Organisation, 2014. Available from: http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755_eng.pdf?ua=1&ua=1

A Medicare rebate has the potential to initiative public regional hospitals' interest to mount a business case for purchase of TEs, increasing scan availability to individuals living in remote and rural areas. Other options to increase access to TE test include making it available at accredited radiology practices in areas with high prevalence of hepatitis B or C, helping GPs to perform this initial assessment prior to making a decision relating to treatment or referral.

Other comments

The RACGP believe a Medicare item for performing a TE would contribute to the financial viability of community based hepatitis B and C management. The ability of GPs to assist their specialist colleagues in the management of patients with chronic hepatitis B and C would be increased if TE were more readily available and affordable. As the majority of people living with hepatitis C have mild disease, there is a scope for it to be assessed and treated in the community by general practice teams.

Yours sincerely,

Dr Frank R Jones
President