Ontario
Health Quality Ontario

Transient Elastography for Assessment of Liver Fibrosis and Steatosis: OHTAC Recommendation

ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE RECOMMENDATIONS

- OHTAC recommends that transient elastography be publicly funded to diagnose and assess the degree of liver fibrosis.
- OHTAC recommends against publicly funding controlled attenuation parameter for the diagnosis of steatosis (fatty liver).

BACKGROUND

Liver fibrosis is a sign of advanced liver disease and is often an indication for treatment. The current standard for diagnosing liver fibrosis and steatosis (fatty liver) is biopsy, but noninvasive alternatives are available; one of the most common is transient elastography (FibroScan).

REVIEW OF THE EVIDENCE

Research Questions

Evidence-Based Analysis

Health Quality Ontario conducted an evidence-based analysis (1) to answer the following research questions:

Clinical Utility

- What is the clinical utility, with respect to the impact on diagnosis, therapeutic decision or patient outcomes, of transient elastography (TE) versus liver biopsy when used for the assessment of liver fibrosis in one or more of the disease areas of interest[1]?
- What is the clinical utility, with respect to the impact on diagnosis, therapeutic decision or patient outcomes, of TE with controlled attenuation parameter (CAP) versus liver biopsy when used for the assessment of steatosis in one or more of the disease areas of interest[1]?

Diagnostic Accuracy

- What is the diagnostic accuracy of TE versus liver biopsy for the assessment of liver fibrosis in one or more of the disease areas of interest[1]?
- What is the diagnostic accuracy of TE versus FibroTest for the assessment of liver fibrosis in one or more of the disease areas of interest[1]?
- What is the diagnostic accuracy of TE versus acoustic radiation force impulse imaging for the assessment of liver fibrosis in one or more of the disease areas of interest[2]?
- What is the diagnostic accuracy of TE with CAP versus liver biopsy for the assessment of steatosis in one or more of the disease areas of interest[1]?

[1]Liver disease areas of interest (see evidence-based analysis for more detail): hepatitis C virus, hepatitis B virus, nonalcoholic fatty liver disease, alcoholic liver disease, cholestatic diseases.

Economic Analysis
HQO also commissioned the Ottawa Hospital Research Institute to evaluate the cost-effectiveness and budget impact of TE with and without CAP compared with liver biopsy for the diagnosis of liver fibrosis or steatosis in patients living with hepatitis B, hepatitis C, alcoholic liver disease (ALD), or nonalcoholic fatty liver disease (NAFLD). (2)

- What is the cost-effectiveness and 1-year budget impact of TE compared to liver biopsy for the diagnosis of liver fibrosis in patients living with hepatitis B, hepatitis C, ALD, or NAFLD?
- What is the cost-effectiveness and 1-year budget impact of TE with CAP compared to liver biopsy for the diagnosis of hepatic steatosis in patients living with chronic liver diseases?

Main Findings
Transient elastography with and without controlled attenuation parameter offers a noninvasive and cost-effective alternative to biopsy for the assessment of liver fibrosis and steatosis, given its comparable diagnostic accuracy.

- There was evidence to support the diagnostic accuracy of TE compared to liver biopsy for assessing liver fibrosis in the disease areas of interest.
- There was evidence that the diagnostic accuracy of FibroTest and acoustic force radiation impulse were not significantly different from TE for assessing liver fibrosis in the disease areas of interest.
- There was evidence to support the diagnostic accuracy of CAP compared to liver biopsy for assessing steatosis in the disease areas of interest.
- No evidence was found that assessed the clinical utility of TE (with or without CAP) versus biopsy, as measured by a change in clinical diagnosis, treatment, or patient outcomes. Beneficial impact could be presumed, given that the accuracy of TE is comparable to that of a biopsy and would have an impact as a noninvasive alternative to diagnose. The clinical utility of CAP is less certain given that treatment for this condition generally consists of providing advice about healthy behaviours.
- There was evidence that TE was cost-effective for the diagnosis of liver fibrosis in patients with hepatitis B, hepatitis C, ALD, and NAFLD.
- Compared to liver biopsy, TE with CAP was associated with lower costs, but also with a reduced number of cases correctly identified with steatosis.
- Replacing liver biopsy with TE (without and with CAP) would result in cost savings. The net annual budget impacts would range from $219,875 to $879,502 for TE without CAP and from $17,498 to $69,992 for TE with CAP.

OHTAC DELIBERATIONS
HQO has developed a decision-making framework to help guide deliberation and support the development of OHTAC recommendations regarding the uptake, diffusion, distribution, or removal of health interventions in Ontario. Appendix 1 provides a summary of the decision determinants for this recommendation.

OHTAC members accepted that TE and CAP offer diagnostic accuracy and cost-effectiveness that is comparable to liver biopsy. OHTAC came to a consensus that it could presume a beneficial impact of TE for the assessment of liver fibrosis. OHTAC felt it could not presume a beneficial impact of TE with CAP for the assessment of steatosis, given that treatment for steatosis generally consists of providing advice about healthy behaviours.

APPENDICES

APPENDIX 1: DECISION DETERMINANTS

Table A1: Decision Determinants for Liver Fibrosis Scanning

Decision Criteria	Subcriteria	Decision Determinants Considerations
Overall clinical benefit How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	**Effectiveness** How effective is the health technology/intervention likely to be (taking into account any variability)?	TE has good diagnostic accuracy for assessing liver fibrosis, and (with CAP) for assessing steatosis, but clinical utility is uncertain. Among patients with viral hepatitis, a diagnosis of fibrosis may impact access to antiviral therapies, and there could be presumed clinical utility given that it is a noninvasive alternative to biopsy with comparable accuracy
	Safety How safe is the health technology/intervention likely to be?	There is no potential harm in using TE; the only potential harm is in misdiagnosis, but the risk of this is limited given its good diagnostic accuracy
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	There are hundreds of thousands of Ontarians with diseases that require liver fibrosis assessment
	Need How large is the need for this health technology/intervention?	The current standard for assessment is biopsy. There is limited access to biopsy because it is invasive and costly. It must also be performed in a hospital setting (as an outpatient procedure) TE offers an easier, faster, noninvasive alternative
Consistency with expected societal and ethical values[a] How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	**Societal values** How likely is the adoption of the health technology/intervention to be congruent with expected societal values?	TE is already disseminated in Ontario academic hospitals and paid for by the centres or by patients
	Ethical values How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	Very likely: the technology has already been well accepted throughout Ontario. As well, experts have told us there is great pressure to make TE more widely available so that patients can have access to liver fibrosis assessment in remote areas, where neither biopsy nor TE are currently accessible
Value for money How efficient is the health technology likely to be?	**Economic evaluation** How efficient is the health technology/intervention likely to be?	TE lowers costs but also offers slightly fewer correctly identified cases When long-term costs and outcomes are considered, TE is likely to be cost-effective from the perspective of the Ontario Ministry of Health and Long-Term Care
Feasibility of adoption into health system How feasible is it to adopt the health technology/intervention into the Ontario health care system?	**Economic feasibility** How economically feasible is the health technology/intervention?	Implementing TE as an alternative to biopsy would lead to cost savings for the Ontario health care system
	Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	Very feasible: TE requires very little room; it has been considered comparable to an ultrasound machine. It can be conducted in any centre, unlike biopsy, which must be done in a hospital setting. As well, training can be offered so that a technician could provide the service and results could be interpreted by a health care provider

[a]The anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

REFERENCES

REFERENCES

(1) Brener S. Transient elastography for assessment of liver fibrosis and steatosis: an evidence-based analysis. Ont Health Technol Assess Ser [Internet]. 2015 November;15(18):1–45. Available from: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/transient-elastography-eba.

(2) Thavorn K, Coyle D. Transient Elastography and Controlled Attenuation Parameter for Diagnosing Liver Fibrosis and Steatosis in Ontario: an economic analysis. Ont Health Technol Assess Ser [Internet]. 2015 November;15(19):1–58. Available from: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations/ontario-health-technology-assessment-series/transient-elastography-econ.

DISCLAIMER

The analysis may not have captured every relevant publication and relevant scientific findings may have been reported since the development of this recommendation. This report may be superseded by an updated publication on the same topic.

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