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**CADTH RAPID RESPONSE REPORT:**
**SUMMARY WITH CRITICAL APPRAISAL**

# Portable Stroke Detection Devices for Patients with Stroke Symptoms: A Review of Diagnostic Accuracy and Cost-Effectiveness


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**About CADTH:** CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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**Questions or requests for information about this report can be directed to Requests@CADTH.ca**

## Abbreviations

| | |
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| CRD | Centre for Reviews and Dissemination |
| CT scan | Computed Tomography Scan |
| EMS | Emergency Medical Service |
| FAST | Face, Arm, Speech, and Time |
| LAMS | Los Angeles Motor Scale |
| MeSH | Medical Subject Headings |
| NIHSS | National Institutes of Health Stroke Scale |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
| QALY | Quality-Adjusted Life Year |

## Context and Policy Issues

Stroke is a highly prevalent and potentially life-threatening medical emergency that requires prompt recognition and treatment in order to minimize morbidity and mortality.[1] In Canada, there are an estimated 62,000 stroke events that occur each year.[2] Moreover, stroke is the third leading cause of death in Canada, comprising nearly 14,000 deaths annually.[3] Mortality rates have improved over time, possibly due to the establishment of integrated regional stroke systems, stroke unit care to prevent and manage complications, and decreases in stroke severity as a result of improved risk factor management.[4] Despite this, over 740,000 Canadian adults over the age of 20 years are living with the effects of stroke (e.g., neurologic deficits, such as hemiparesis, aphasia, and sensory and cognitive deficits).[1]

A stroke is the acute neurologic injury that occurs as a consequence of sudden loss of focal brain function due to cell death from poor or interrupted blood flow within the brain.[5,6] There are two broad categories of stroke that have vastly different treatment approaches. Ischemic strokes are the most common type (80% of all stroke events) and are generally caused by a sudden blood vessel blockage.[5] Hemorrhagic strokes are caused by a rupture of an artery in the brain.[5] It is vital to differentiate between these two different types, as the treatment approaches are entirely different. Great efforts are made to minimize time delays in treatment, as delays are associated with worse outcomes, including death.[7]

If an individual experiences a stroke in the community, the Emergency Medical Service (EMS) is usually called to the scene. Currently, EMS workers rely on patient history, physical examination (e.g., a tool that includes components of Face, Arm, Speech, and Time [FAST], such as National Institutes of Health Stroke Scale [NIHSS] or Los Angeles Motor Scale [LAMS]), and some diagnostic testing (e.g., blood glucose) to reach a pre-hospital diagnosis of stroke and to determine stroke severity.[8] A pre-hospital assessment helps to determine what resources are required to appropriately treat the patient and thereby informs next steps, including whether to transport the patient to a stroke centre or the closest medical hospital. A more objective way to diagnose a patient at this stage may be using a portable stroke detection device. A portable stroke detection device is a health technology aimed to detect strokes in the pre-hospital environment by observing changes in blood flow to the brain using alternative ambulatory stroke detection methods (e.g., ultrasound, cranial electrodes.[9,10] The use of portable stroke detection devices may increase the likelihood of pre-hospital diagnoses of stroke, which in turn could facilitate earlier initiation of stroke care (e.g., routing the patient to a stroke centre, earlier neurovascular imaging in-hospital, and definitive stroke therapies with

thrombolysis/endovascular treatment if warranted).[9,10] However, there is a lack of clarity on the diagnostic accuracy and cost-effectiveness of portable stroke detection devices for patients with stroke symptoms.

A previous CADTH report (summary with critical appraisal) examined the diagnostic accuracy and cost-effectiveness of portable stroke detection devices for adults experiencing symptoms of stroke, including: combination of transcranial Doppler ultrasound, robotic headset blood flow monitor, and machine learning; bioimpedance spectroscopy visor (which uses volumetric impedance phase-shift spectroscopy); and microwave tomography system).[10] The current report extends upon this previous report by evaluating the evidence regarding the diagnostic accuracy and cost-effectiveness of alternative ambulatory stroke detection methods for patients with symptoms of stroke (no age restriction) not covered in the previous report.

## Research Questions

1. What is the diagnostic accuracy of portable stroke detection devices for patients with stroke symptoms?
2. What is the cost-effectiveness of portable stroke diagnostic devices for patients with stroke symptoms?

## Key Findings

No relevant literature was identified regarding the diagnostic accuracy of portable stroke detection devices for patients with stroke symptoms. Additionally, no evidence regarding the cost-effectiveness of the portable stroke detection devices of interest was identified. Thus, the diagnostic accuracy and cost-effectiveness of portable stroke detection devices for patients with symptoms of stroke remains unclear.

## Methods

### Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including Ovid Medline, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were portable ultrasound devices and stroke. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2014 and July 5, 2019.

### Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

## Table 1: Selection Criteria

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| **Population** | Any patient with stroke symptoms (no restriction on age) |
| **Intervention** | Portable ultrasound devices for stroke detection/treatment/monitoring (proprietary names: SONAS™) and to identify stroke and triage patients to the right hospital (proprietary name: Alphastroke™) |
| **Comparator** | Q1-Q2: Any comparator (e.g., Computed Tomography scan, Los Angeles Motor Scale) |
| **Outcomes** | Q1: Diagnostic accuracy (e.g., specificity, sensitivity, area under the curve, positive or negative predictive values, accurate triage decision)<br>Q2: Cost-effectiveness (e.g., cost per quality-adjusted life year) |
| **Study Designs** | Q1: Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, and non-randomized studies<br>Q2: Economic evaluations |

### Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2014. A previous CADTH report summarized the diagnostic accuracy and cost-effectiveness of the following portable stroke detection devices for adults with stroke symptoms: combination of transcranial Doppler ultrasound, robotic headset blood flow monitor, and machine learning; bioimpedance spectroscopy visor (which uses volumetric impedance phase-shift spectroscopy); and microwave tomography system.[10] These portable stroke detection devices were excluded from this report to prevent duplication of findings.

### Critical Appraisal of Individual Studies

No relevant evidence regarding the diagnostic accuracy and cost-effectiveness of portable stroke detection devices for patients with stroke symptoms was identified; therefore, critical appraisal was not conducted.

## Summary of Evidence

### Quantity of Research Available

A total of 190 citations were identified in the literature search. Following screening of titles and abstracts, 173 citations were excluded and 17 potentially relevant reports from the electronic search were retrieved for full-text review. In addition, two potentially relevant publications were retrieved from the grey literature search for full-text review. Of these 19 potentially relevant articles, all 19 publications were excluded for various reasons, and no publications met the inclusion criteria and were included in this report. Appendix 1 presents the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[11] flowchart of the study selection. Additional references of potential interest are provided in Appendix 2.

### Summary of Study Characteristics

No relevant studies (health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic evaluations) were identified regarding the diagnostic accuracy or cost-effectiveness of portable stroke

detection devices for patients with symptoms of stroke; therefore, no summary can be provided.

### Limitations

The primary limitation of this report was that there was no relevant evidence identified to answer either research question. The literature search conducted to inform this report was limited to five years (from 2014 to 2019). It is possible that relevant literature exists but was published more than five years ago and, therefore, excluded by the date-limited search. However, portable stroke detection devices are a relatively novel technology, so it is more likely that studies regarding diagnostic accuracy and cost-effectiveness of these devices are ongoing[12,13] or yet to be conducted.

## Conclusions and Implications for Decision or Policy Making

No relevant literature was identified regarding the diagnostic accuracy or cost-effectiveness of portable stroke detection devices for patients with symptoms of stroke; therefore, no conclusions can be made. Moreover, the previous CADTH report identified one non-randomized study regarding diagnostic accuracy of bioimpedance spectroscopy visors for adults with stroke symptoms, but no evidence regarding the cost-effectiveness of the portable stroke diagnostic devices of interest was identified.[10] This further highlights the lack of evidence regarding portable stroke detection devices. Future studies addressing the diagnostic accuracy and cost-effectiveness of portable stroke detection devices for patients with symptoms of stroke are needed to help reduce this uncertainty and inform clinical practice.

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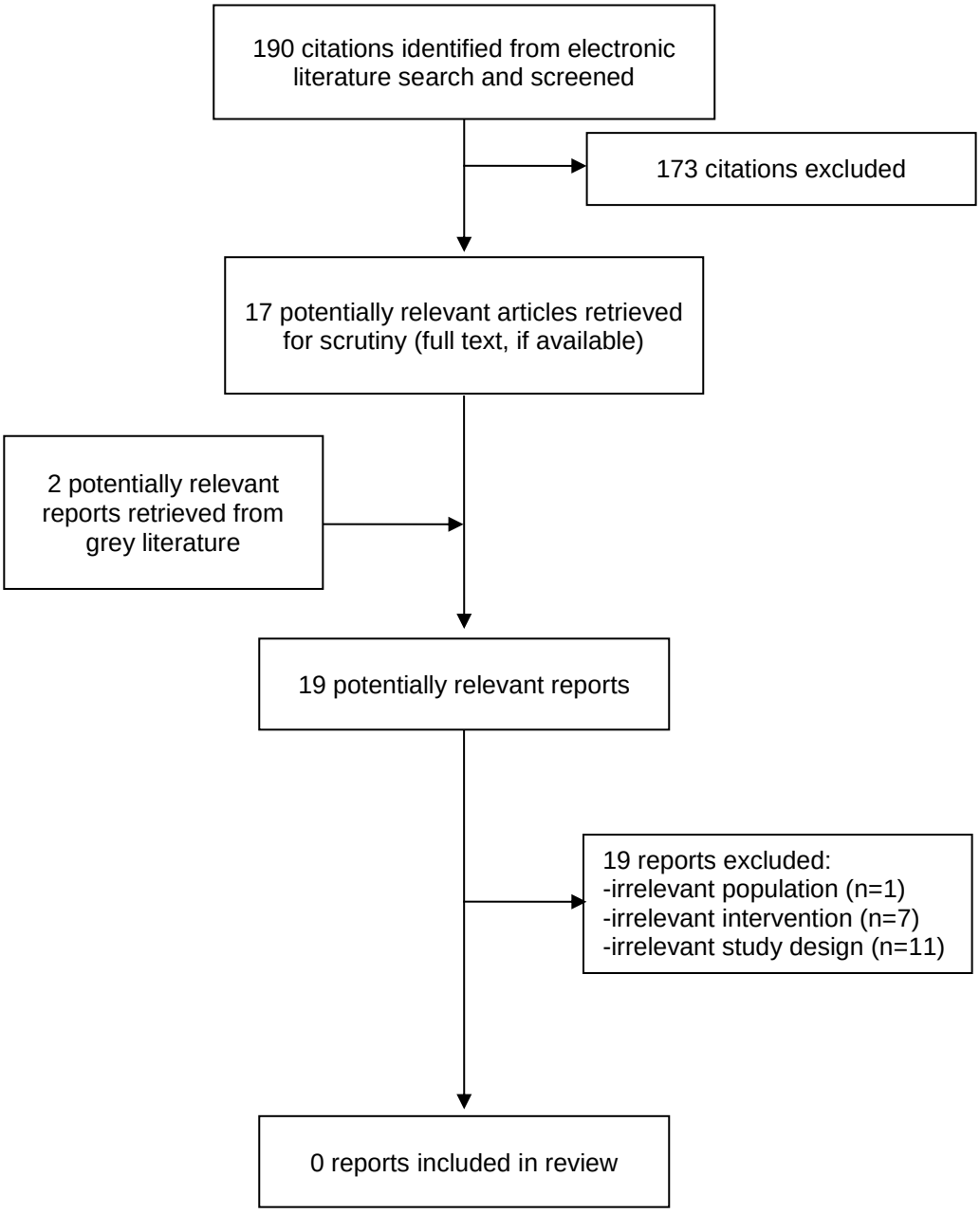
## Appendix 1: Selection of Included Studies



# Appendix 2: Additional References of Potential Interest

## Ongoing Clinical Trials (single-group assignment)

Evaluation of the SONAS® Ultrasound Device for the Assessment of Bilateral Cerebral Perfusion in Subjects With Acute Stroke. NCT03897153 https://clinicaltrials.gov/ct2/show/NCT03897153

Study: SONAS Ultrasound for Detecting Stroke SONAS Ultrasound for Detecting Stroke. NCT03296852. https://clinicaltrials.gov/ct2/show/NCT03296852

## Previous CADTH Reports

Mobile stroke units for prehospital care of ischemic stroke. *(CADTH issues in emerging health technologies no. 154)*. Ottawa (ON): CADTH; 2017: https://www.cadth.ca/sites/default/files/pdf/eh0047_mobile_stroke_units_for_prehospital_care_of_ischemic_stroke.pdf. Accessed 2019 Jul 14.

Computed tomography angiography for diagnosis of stroke or transient ischemic attack: clinical effectiveness. *(CADTH rapid response report: summary with critical appraisal)*. Ottawa (ON): CADTH; 2016: https://www.cadth.ca/sites/default/files/pdf/htis/2016/RC0827%20CTA%20for%20Stroke%20Final.pdf. Accessed 2019 Jul 14.