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Brief Communication

Evaluation of Commercially Available Seizure Detection Wearables in Canada: Current Evidence

Yassine Lamrani[1], Amirhossein Jahani[1,2], Laura Gagliano[1], Dang Khoa Nguyen[1,2,3] and Elie Bou Assi[1,2]

[1]University of Montreal Hospital Research Center (CRCHUM), Montreal, QC, Canada, [2]Department of Neuroscience, University of Montreal, Montreal, QC, Canada and [3]Division of Neurology, University of Montreal Hospital Center (CHUM), Montreal, QC, Canada

ABSTRACT: Wearable-based seizure detection devices hold promise in reducing seizure-related adverse events and relieving the daily stress experienced by people with epilepsy. In this work, we present the latest evidence regarding the performance of three seizure detection wearables (eight studies) commercially available in Canada to provide guidance to clinicians. Overall, their ability to detect focal-to-bilateral and/or generalized tonic-clonic seizures ranges between 21.0% and 98.15% in sensitivity, with the 24h false alarm rates ranging from 0 to 1.28. While performance in epilepsy monitoring units show promise, the lack of evidence in outpatient settings precludes strong recommendations for their use in daily life.

RÉSUMÉ : Évaluation de détecteurs portatifs de crises d'épilepsie, vendus dans le commerce, au Canada : état de données récentes. Des dispositifs portatifs de détection de crises d'épilepsie se montrent prometteurs dans la diminution des événements défavorables liés à ces crises, et soulagent l'anxiété vécue tous les jours par les personnes atteintes d'épilepsie. Nous présentons, dans l'article, les données les plus récentes (provenant de 8 études) sur la performance de trois de ces détecteurs portatifs vendus dans le commerce au Canada afin de guider les médecins cliniciens en la matière. Dans l'ensemble, la capacité de ces dispositifs à détecter les crises d'épilepsie focales à évolution bilatérale et celles de type tonicoclonique généralisé varie de 21,0 % à 98,15 % en ce qui concerne la sensibilité, et le taux de fausses alarmes sur 24 h varie de 0 à 1,28. Bien que ces dispositifs de surveillance des crises d'épilepsie soient prometteurs, l'insuffisance de données recueillies en milieu non hospitalier nous empêche, pour le moment, de préconiser leur port dans la vie de tous les jours.

Keywords: epilepsy; refractory epilepsy; seizure detection; SUDEP; wearables

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Introduction

Epilepsy is a chronic neurological condition that affects about 300,000 Canadians.[1] Despite the availability of numerous antiseizure medications, up to 30% of people with epilepsy (PWE) continue to experience uncontrolled seizures[2] putting them at increased risk of complications such as burns, fractures, head injury and sudden unexpected death in epilepsy (SUDEP).[3] The epilepsy research community has made significant efforts toward the development of wearable-based seizure detection devices, with the aim of generating alarms to alert relatives or members of the medical staff, thus reducing intervention time and therefore limiting seizure-related injuries and death. In addition, these devices could provide clinicians with a more reliable assessment of PWE's seizure frequency, and thus lead to better epilepsy management. Because PWE and/or their caregivers enquire more and more about these devices to their physicians, we sought to provide a comprehensive overview of commercially available devices in Canada.

There are currently three seizure detection wearable devices available in Canada. Their performances were covered in eight articles (summarized in Table 1). A detailed description of those articles (methods, results) can be found in sections 1 and 2 respectively of the supplementary material, respectively. These articles all met criteria of a phase 2 study or higher according to standards of evaluation for seizure detection wearables proposed by Beniczky et al. 2018 (single or multicentric study with a minimum of 10 patients with seizures and a minimum of 15 recorded seizures; real-time seizure detection was optional).[4] A detailed description of criteria for study phases (phase 3 and 4) as well as a detailed methodology of our review of literature can be found in section 1.2 of the supplementary material.

The first of the three identified wearables, the Embrace2 by Empatica (Cambridge, Massachusetts, USA), is a wrist-worn device that has been cleared by the Federal Drug Administration (class II) in 2018 for the detection of generalized tonic-clonic (GTCS) seizures during rest in individuals over 6 years of age. It relies only on accelerometry and electrodermal activity data to

Corresponding author: Yassine Lamrani; Email: yassine.lamrani@umontreal.ca

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Table 1. Summary of current evidence regarding commercially available seizure detection devices in Canada

Seizure detection devices	Mechanism	Seizure types	Regulatory approval	Study	Performance Data	Price
Embrace2 by Empatica	Wrist-worn; accelerometry and electrodermal activity data to detect seizures	Individuals > 6 years of age with FBTCS or GTCS that last > 20 s.	FDA-cleared (2018, 2019)	Onorati et al., 2017 (phase 2, FDA-clearance)[5]	31 patients (54 GTCS); ages ranging 6–63 years old; 98.15% sensitivity for GTCS (53/54); 1.25/24h FAR	249.00 USD (~ 330.00 CAD); monthly subscription ranging from 9.90 USD (~ 13.00 CAD) to 44.90 USD (~ 60.00 CAD) based on the chosen plan. *prescription is only required in the US to purchase the device.
				Onorati et al., 2021 (Phase 3, FDA safety and effectiveness) [6]	36 patients (18 pediatrics) with 66 GTCS (35 from pediatric patients); ages ranging 5–41 years old; 94.0% sensitivity (92.0% in pediatric population); 0.57/24h FAR in adults (1.26 in pediatric population); 37.46 s detection latency (37.76 s in pediatric population)	
Inspyre Mobile by SmartMonitor	Mobile application; has to be paired with a wrist-worn watch (Apple or Android); detection of repetitive shaking motions	Seizures associated with rhythmic upper extremity movements (e.g. GTCS, FBTCS, hyperkinetic seizures)	U.S Patent (10,595,766) for "Abnormal Motion Detector and Monitor"	Patterson et al., 2015 (Phase 2) [7]	41 patients (51 GTCS and 140 seizures of other types); ages ranging 5–41 years old; 31% sensitivity for GTCS (13/51); no FAR reported	20.00 USD (~ 27.00 CAD) activation cost; monthly plan ranging from 14.95 to 49.95 USD/month (~ 20.00-65.00 CAD) for Apple devices and 9.95 to 39.95 USD (~ 13.00-53.00 CAD) per month for Android ones. *Wrist-worn wearable must be bought separately
				Velez et al., 2016 (Phase 2) [8]	10 patients (with 13 GTCS); ages ranging 19–66 years old; 92.3% sensitivity (12/13); 1.8/24h FAR	
EmfitMM by Emfit	Piezoelectric sensor sensitive to pressure changes; emits local alarm when fast rhythmic movements (3–20 Hz) are detected for > 13 s (default setting)	GTCS, FBTCS	No	Narechania et al., 2013 (Phase 2) [9]	51 patients (13 patients with 18 GTCS); ages ranging 18–81 years old; 89% sensitivity (16/18); 0.13/24h FAR	594 USD (~ 790.00 CAD) *Optional remote wireless alarm (up to 500 ft) can be purchased separately for 45.00 USD (~ 60.00 CAD)
				Anderson et al., 2017 (Phase 2) [10]	85 adult patients (61 GTCS recorded, with 50 being included); 84% sensitivity (42/50); no FAR reported; 23s mean detection latency	
				Arends et al., 2018 (Phase 2) [11]	14 patients with intellectual disability (508 major seizures); mean age = 29.1 years old; median sensitivity 21%; median FAR 0.03 per night	
				Nouboue et al., 2023 (Phase 2) [12]	55 adult patients (23 convulsive seizures); 69.6% sensitivity; 0.0007/24h FAR; 74s mean detection latency (10s when considering onset of clonic movements)	

CAD = Canadian Dollar; FAR = false alarm rate; FBTCS = focal to bilateral tonic-clonic seizures; FDA = The United States Food and Drug Administration; GTCS = generalized tonic-clonic seizures; USD = United States Dollar

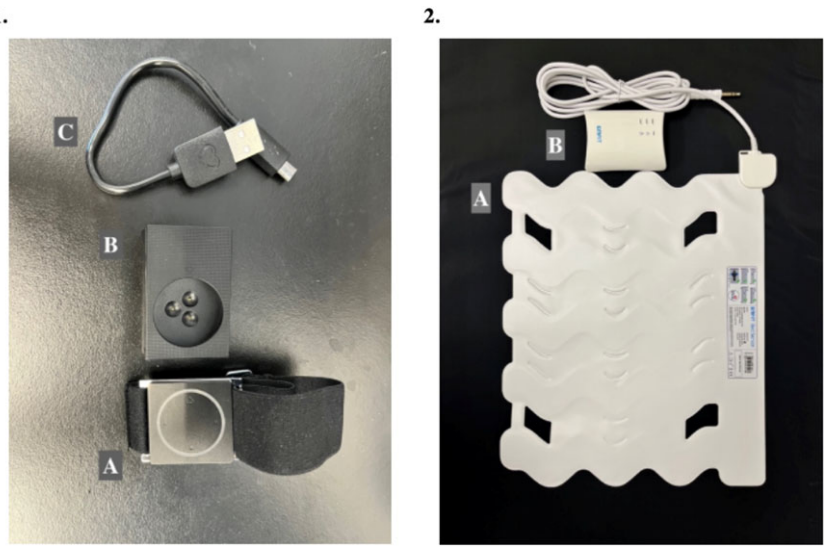

Figure 1. Illustrations of the commercially available wearable devices. 1) Embrace2 by Empatica wrist-worn device (A) Wrist-worn device (B) Charging dock (C) Charging cable; 2) EmfitMM by Emfit Corp. (A) Movement piezoelectric sensor (B) Control unit.

detect seizures; alarms are sent to caregivers through a mobile application (Alert App). The Embrace2 costs 249.00 USD (~ 330.00 CAD) and requires a monthly subscription ranging from 9.90 USD (~ 13.00 CAD) to 44.90 USD (~ 60.00 CAD) based on the chosen plan (exclusive of taxes and delivery). Two studies using this device were conducted. A 2017 phase 2 study performed on 141 PWE (80 children) with over 409 days of total recording time yielded a sensitivity of 98.15% (53/54 GTCS) and a 24h false alarm rate (FAR) of 1.25 (0.67 for patients over the age of 21).[5] A 2021 phase 3 multicenter prospective continuous study in multiple epilepsy monitoring units (EMUs) on 152 individuals over the age of six years yielded a 94.0% sensitivity, a 0.57 24h FAR and a 37.46s mean detection latency on 66 FBTCS/GTCS. No false alarms were reported during rest periods.[6] A picture of this device can be found in Figure 1.

The second wrist-worn seizure detection technology, the Inspyre mobile application by SmartMonitor (San Jose, California, USA), is a mobile application that can be paired with a wrist-worn wearable (Apple Watch series 3 and above or any Android smartwatch running WearOS). Seizure detection is based on the detection of repetitive wrist motion to detect seizures associated with rhythmic upper extremity movements. Caregivers can be alerted by a mobile text or call, with the GPS location of the person who had a seizure being sent to them.

Cost for purchasing this mobile app includes a 20.00 USD (~ 27.00 CAD) activation cost and a monthly subscription ranging from 9.95 USD to 49.95 USD (~ 13.00-65.00 CAD) per month (exclusive of taxes and delivery) depending on the type of watch used (Apple or Android). The wrist-worn watch must be bought separately. Two phase 2 studies assessed the seizure detection performances of this mobile application. The first study, performed in 2015 by Patterson et al., yielded sensitivities of 31 and 16% respectively on a total of 51 GTCS and 140 other seizure types (11 myoclonic, 21 tonic, 45 focal-onset hypermotor and 63 focal-onset with minimal motor component) in a cohort of 41 patients aged between 5 and 41 years admitted to the EMU.[7] The second study was conducted in 2016 by Velez et al. in an EMU on 30 patients aged between 19 and 66 years old and with a history of tonic-clonic movements in more than one limb. From this group, 27 patients experienced 62 seizures (13 GTCS, 1 myoclonic, 17 hypermotor, 31 focal non-motor seizures). Authors reported a 92% sensitivity (12/13 GTCS), while no focal non-motor seizures or hypermotor seizures were detected (device placed on wrist while hypermotor movements were seen in lower limbs and the trunk for 17 seizures). Eighty-one false alarms were recorded by the watch during 45 total days of recording (1.8/24h FAR). Only one false alarm occurred during sleep.[8]

The third available device, the Emfit Movement Monitor (EmfitMM) by EmfitCorp (Austin, Texas, USA), utilizes a piezoelectric movement sensor placed under a mattress to detect pressure changes that last more than 13 s (default setting). This device can interface with most nurse call systems, wireless transmitters and personal emergency phones to allow for prompt intervention. The device can be purchased for 594 USD (~ 790.00 CAD) (exclusive of taxes and delivery). Four studies have been conducted using this device. A 2013 phase 2 study conducted in an EMU for 15 months (3741 h of recording) on 79 patients (mean age = 37.6 years; range 18-81 years), yielded a sensitivity of 89.0% (16/18) for the detection of GTCS and a FAR of 0.13/24h. Both non-detected seizures were during wakefulness.[9] A 2017 phase 2 study retrospectively assessed the EmfitMM's sensitivity for seizure detection and staff response time to GTCS[10] in the Scottish Epilepsy Centre EMU on 85 adult patients (61 GTCS) for 9 months (no total recording time reported). Fifty of the 61 GTCS occurred in bed and were therefore included. The study yielded a sensitivity of 84.0% (42/50). Mean staff response time to EmfitMM alarms was 23 s (range 0–69 s). In a 2018 phase 2 multicentric prospective cohort study,[11] the device was used during sleep by 14 patients (mean age = 29.1 years) with intellectual disability and epilepsy (i.e., West syndrome, Lennox-Gastaut syndrome, Dravet syndrome and other unspecified etiology). A total of 508 "major" seizures (GTCS, generalized tonic seizures lasting more than 30 s, hyperkinetic seizures and clusters (> 30 minutes) of short myoclonic/tonic seizures) during 1097 nights were recorded. A median sensitivity of 21% and a median FAR of 0.03 per night were reported. More recently, a phase 2 study (55 adult patients; mean age = 37 years old) performed in Amiens University Hospital's EMU, reported a sensitivity of 69.6% for the detection of convulsive seizures (FBTCS, GTCS, focal seizures with prominent clonic movements) and a FAR of 0.0007/24h. Mean detection latency was 74 s from electrical seizure onset (5 s for GTCS, 98.5 s for FBTCS and 60 s for focal seizures with prominent clonic

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movements). However, mean detection latency was shorter when calculating only from the onset of clonic movements (10 s for FBTCS and 15 s for focal seizures with prominent clonic movements).[12] A picture of this device can be found in Figure 1.

Patients who enquire about such devices should thus be informed about the limitations of current evidence to manage patient expectations: (1) While there is high-quality evidence these devices can detect GTCS/FBTCS in the EMU, they have not been sufficiently tested outside the hospital; (2) Though capable of detecting most GTCS/FBTCS, they are not reliable for other types of seizures; (3) While they could potentially reduce the risk of seizure-related complications (including SUDEP), this has not yet been formally demonstrated; (4) While they could potentially aid with seizure count, superiority over patient recall has not yet been proven. Furthermore, devices are not without cost (prices ranging between 249 and 594 USD or ~ 330-790 CAD). This is an important factor, considering that PWE frequently have a more precarious socioeconomic status. A survey conducted by our group in 2020 on needs and preferences of 221 patients and 171 caregivers from Canada revealed that 38% of responders had yet to purchase a seizure detection device due to cost, with 40% of surveyed PWE wanting to spend less than 200 CAD on a multimodal device (much below current prices).[13]

In summary, this work informs physicians on how to respond to patient queries regarding seizure detection devices. Phase 2 and phase 3 studies show promising results for the detection of FBTCS and GTCS in a controlled EMU setting for wearables available in Canada. However, due to the lack of studies in an outpatient setting (phase 4), it is difficult to make strong recommendations regarding their use outside the EMU. Outpatient prospective studies assessing real-life performance and impact as well as cost-effectiveness studies are needed to increase confidence in these seizure detection devices and their wider acceptance by patients and clinicians.

Supplementary material. For supplementary material accompanying this paper visit https://doi.org/10.1017/cjn.2024.58

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