

Original Article

Province of Alberta Jurisdictional Standardized Operating Protocol (SOP) for Screening Brain Vascular Malformations

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ABSTRACT: Objective: Hereditary hemorrhagic telangiectasia (HHT) is an autosomal dominant genetic disorder leading to vascular malformations in different organ systems. Approximately 10% of patients with HHT have brain vascular malformations (BVMs). Due to the negative health consequences related to BVMs, screening with MRI is recommended. There are no health jurisdictional standards for medical imaging protocols in North America or elsewhere. The objective of this project is to adopt a provincial standardized operating protocol (SOP) to improve diagnostic accuracy and reduce inappropriate imaging in patients with and without HHT in Alberta. Methods: Multiple fora were held among the five Alberta Health Services zones with stakeholders from urban, suburban and rural radiology groups, neurology, pulmonology and hematology. The consensus process took five years to complete between 2015 and 2020. The content of the fora was approved by all participants. Results: The SOP was implemented in February 2020 and defines that screening for BVMs must include standard unenhanced brain MRI (sagittal T1, axial fluid-attenuated inversion recovery and axial T2) with susceptibility-weighted imaging (SWI), a 3T or 1.5T magnet strength and minimum imaging standards to include 3 mm contiguous slice thickness. Discussion: Incorporation of SWI allowed for the elimination of MR contrast to improve access to the local performance of studies within the province, facilitating virtual care. Conclusion: A provincial SOP for BVM screening in patients with suspected or confirmed HHT was successfully implemented in Alberta. Gadolinium was avoided, as it was felt to be unnecessary for screening purposes and might complicate imaging at more remote sites.

RÉSUMÉ: Protocole opérationnel normalisé de la province de l'Alberta pour le dépistage des malformations vasculaires cérébrales Objectif: La télangiectasie hémorragique héréditaire (THH) est une maladie génétique autosomique dominante qui entraîne des malformations vasculaires dans différents systèmes d'organes. À ce sujet, environ 10 % des patients atteints de THH présentent des malformations vasculaires cérébrales (MVC). En raison des conséquences négatives des MVC sur la santé, un dépistage par IRM est recommandé. Il n'existe cependant aucune norme juridique en matière de protocoles d'imagerie médicale en Amérique du Nord ou ailleurs. L'objectif de ce projet est donc d'adopter un protocole opérationnel normalisé (PON) provincial afin d'améliorer la précision des diagnostics et de réduire le recours inapproprié aux examens d'IRM chez des patients atteints ou non de THH en Alberta. Méthodes: Plusieurs forums ont été organisés entre les cinq zones de services de santé de l'Alberta avec des parties prenantes issues de groupes urbains, suburbains et ruraux dans les domaines de la radiologie, la neurologie, la pneumologie et l'hématologie Le processus d'établissement d'un consensus s'est déroulé pendant cinq ans, entre 2015 et 2020. Le contenu des forums a été approuvé par tous les participants. Résultats: Un PON a été mise en œuvre en février 2020 et stipule que le dépistage des MVC doit inclure un examen cérébral d'IRM standard sans contraste (séquences sagittale T1, de type axial avec atténuation fluidique par inversion-récupération et axiale T2) avec imagerie pondérée en fonction de la susceptibilité, une force magnétique de 3T ou 1,5T ainsi que des normes d'imagerie minimales incluant une épaisseur de coupe contiguë de 3 mm. Discussion : L'intégration de l'imagerie pondérée en fonction de la susceptibilité a permis d'éliminer le recours aux produits de contraste dans les examens d'IRM et d'améliorer l'accès aux études locales dans la province, facilitant ainsi les soins virtuels. Conclusion: Un PON provincial pour le dépistage des MVC chez les patients atteints de THH suspectée ou confirmée a été mis en œuvre avec succès en Alberta. Le gadolinium a été évité, car il a été jugé inutile à des fins de dépistage et susceptible de compliquer les examens d'IRM dans les établissemenst de santé plus

Keywords: brain vascular malformation; hereditary hemorrhagic telangiectasia; jurisdictional standards; medical imaging protocols; brain MRI protocols

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Highlights

- Due to the negative consequences of hereditary hemorrhagic telangiectasia (HHT), screening with MRI is recommended.
- There are no health jurisdictional standards for HHT-related medical imaging protocols in North America or elsewhere.
- A provincial standardized operating protocol for brain vascular malformation screening was implemented in the province of Alberta.

Introduction

Hereditary hemorrhagic telangiectasia (HHT) is an autosomal dominant genetic disorder involving vascular malformations in different organ systems. Vascular malformations may present in the lungs, brain, liver and sometimes other visceral organs (i.e., uterus, spleen) as well as involvement of mucocutaneous membranes including the nasal mucosa, lips and oropharyngeal mucosa, throughout the gastrointestinal tract and elsewhere. The diagnosis of HHT is based on the Curação Diagnostic Criteria, which includes (i) recurrent epistaxis, (ii) mucocutaneous telangiectasia, (iii) visceral arteriovenous malformations (AVMs) (iv) and a family history of HHT in a first-degree relative. Those with three or four of these criteria have definite HHT; two criteria are consistent with possible HHT, and one criterion is unlikely based on the Curacao criteria. HHT has an estimated world prevalence of 1 in 5000.2 However, in Alberta, the reported prevalence is higher at 1 in 3800.3 Populations with Dutch genetic backgrounds appear to have an even higher prevalence of HHT at 1 in 1331, and Alberta is home to many Dutch settlements and rural communities with families affected by HHT.4,5 With an estimated 1200 individuals affected and more with suspected HHT, the demand for BVM screening will continue to grow as these patients interact with the healthcare system. 4,6

The prevalence of brain vascular malformations (BVMs) in patients with HHT is reported to be 10%.⁷ BVMs can result in acute hemorrhage with hemorrhagic strokes and/or chronic bleeding. Embolic strokes, transient ischemic attacks and brain abscesses are seen in patients who have coexistent pulmonary arteriovenous malformations (PAVMs) with right-to-left shunts; blood clots (strokes) or infected material bypass the normal capillary bed architecture allowing for this.^{7,8}

Three subtypes of BVMs exist, including brain arteriovenous fistula, nidus-type AVM and capillary vascular malformation.^{9,10} Capillary-type vascular malformations previously known as "micro-AVMs" do not demonstrate an enlarged artery or vein and simply represent dilated capillary beds as evidenced by a contrast blush on cerebral angiography and likely have a lower risk of hemorrhage. 11 The rate of hemorrhage in HHT-associated BVMs versus sporadic BVMs in the population remains a topic of debate; however, retrospective data have demonstrated a similar bleeding risk of around 2.0% per patient-year. ¹² Capillary-type BVMs are the most prevalent vascular malformation among patients with HHT 11 and do not typically represent a bleeding risk.^{9,10} However, it is important to note that although capillarytype malformations with their low bleeding risk represent the most frequent BVM in patients with HHT, patients with HHT do still demonstrate nidus- and fistulous-type BVMs, and as a result,

the average bleeding rate for the HHT population may be falsely low when compared to sporadic BVMs overall. More importantly, patients with true nidus- or fistulous-type BVMs may present with a catastrophic bleed or seizure as a revealing event. 13,14

Screening results in four possible outcomes for the patient, and these are benefit, no benefit, harm and no harm. 15 The assumption is that a patient benefits from the identification and discussion around the treatment of a BVM. However, whether or not identifying and treating a lesion results in a better outcome for the patient than not detecting a lesion and subsequently no treatment will vary considerably based on the individual and the clinical presentation.¹⁶ Consideration must be given to the potential harm in screening that may be related to treatment, psychological factors, potential lifestyle modification and financial implications related to insurance. 16 There is no conservative management for BVMs, and therefore, treatment options are invasive including surgical resection, arterial embolization and/or stereotactic radiosurgery. 16 Due to the lack of randomized controlled trials showing definitive management for BVMs and the varied nature of the individualized clinical context, the decision to screen should be patient-centered. The North American standard in keeping with the second international HHT guidelines recommends the use of screening MRI in pediatric and adult patients with possible or definite HHT to identify BVMs that may be amenable to

It is recommended in international guidelines that individuals with possible or definite HHT obtain a screen for BVMs. In Alberta, the absence of a neuroimaging standardized operating protocol (SOP) to screen for BVMs resulted in a myriad of screening modalities and protocols, some of which were nondiagnostic and ultimately led to duplicate testing. The reference standard for the identification of BVMs is invasive digital subtraction angiography (DSA); however, any invasive procedure is associated with risk, and therefore, DSA is not used for screening.¹⁸ CT has excellent spatial resolution, and with the addition of IV contrast, CT angiograms can detect BVMs; however, it is still not as sensitive or specific as MRI with the addition of susceptibility-weighted imaging (SWI).^{18,19} CT also includes radiation to the patient and the added risk of a contrast reaction, neither of which is relevant to screening using noncontrast MRI with SWI. MRI is widely available and, although costly and time-consuming, is the most sensitive and specific noninvasive diagnostic imaging modality available for the detection of BVMs.

Alberta is a single healthcare jurisdiction, which makes it opportune for screening. In Alberta, neuroimaging may be performed internally at Alberta Health Services (AHS) facilities or externally at private for-profit facilities. AHS is the provincial health authority that represents a province-wide integrated health system that is further subdivided into 5 health regions operating 106 acute care facilities (Figure 1).²⁰ Any one of the 106 acute care facilities operated by AHS or an external privately run facility may be the first interaction with diagnostic imaging for a patient with suspected or confirmed HHT; therefore, a standardized protocol is critically important to ensure the accuracy of the screening exam.²⁰ The larger urban hospitals in

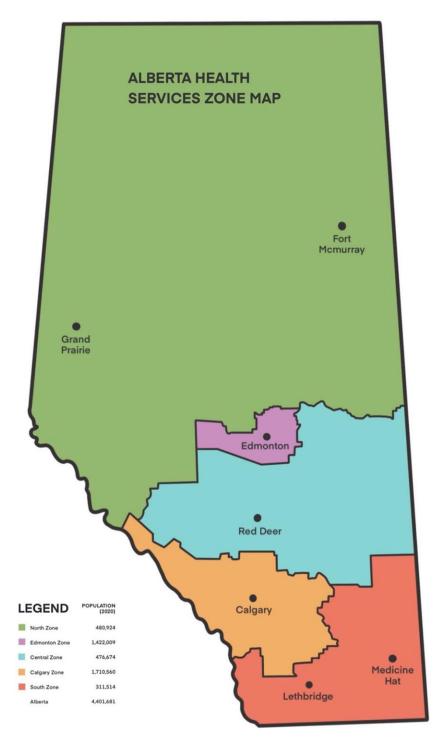


Figure 1. Alberta Health Services zones. Population statistics retrieved from https://www.albertahealthservices.ca/assets/about/publications/ahs-ar-2021 on December 4, 2022.

the province have subspecialty-trained neuroradiologists who are responsible for the appropriate protocolling of screening MRIs for patients with HHT; however, many acute care facilities and private for-profit centers within the province are small and remote without dedicated neuroradiologists or MRI scanners. Subsequently, patients referred to smaller acute care or private facilities would often be incorrectly protocolled and undergo nondiagnostic exams. These exams varied considerably depending on the study location. Inappropriate screening studies performed included CT heads, portable MRI and MRI

protocolled without the use of highly sensitive and specific sequences for arteriovenous shunting such as SWI.^{19,21} Inappropriate screening studies resulted in repeat imaging, increasing the workload to radiology departments and subsequently the cost to the healthcare system. Edmonton is an accredited HHT center of excellence, and given the increased prevalence of patients with HHT in the province and the potential for negative health outcomes, it was imperative to develop an SOP that would be both accessible and sensitive for the detection of BVMs.²²

Methods

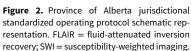
The SOP was developed through a consensus-building process over a five-year period, engaging different neuroimaging and nonimaging clinical groups across the province (telephone, email, inperson). Multiple Fora were held with representation from various stakeholders involved in the care of patients with HHT from all five AHS zones. Stakeholders included representatives from stroke neurology, pulmonary medicine, general internal medicine, hematology, neurosurgery, pediatrics, neuroradiology, interventional radiology and general radiology, as well as rural and remote radiology groups in the province. Fora were conducted via email, telephone and virtual meetings. The content of the Fora was compiled for approval by all participants.

Results

The SOP was implemented in February 2020, and the finalized protocol was sent out to all representative zone leaders via email. The SOP has been implemented in all five AHS zones with an extension into Saskatchewan as many patients are shared among the provinces. The SOP defines the appropriate imaging modality and protocol that should be utilized for the screening of BVMs in patients with possible or definite HHT. These include (1) a standard unenhanced brain MRI, (2) additional T1 sagittal reformats and axial T2 reformats, (3) an axial fluid-attenuated inversion recovery (FLAIR) sequence, (4) an axial SWI sequence, (5) a minimum 1.5T field strength and (6) minimum imaging standards to include 3 mm contiguous slice thickness (Figure 2). Currently, the province of Alberta is undergoing a phased rollout of a new province-wide clinical information system called Connect Care that will provide a central access point for up-to-date patient information and best practices, and the SOP will be integrated into Connect Care for ease of access for all zones.²³

Discussion

This health jurisdictional protocol is the first that we are aware of in North America to ensure appropriate neuroimaging to screen for BVMs - not limited to HHT, but other genetic populations where BVMs are seen. The neuroimaging protocol includes the necessary sequences and post-processing to accurately identify and characterize BVMs. T1 (longitudinal relaxation time) sagittal and T2 (transverse relaxation time) axial reformats are included in the protocol to localize pathology in three-dimensional space. The axial FLAIR sequence is included to detect the presence or absence of edema to help differentiate unruptured BVMs from other pathologies such as vascular or glial tumors.²⁴ The decision to exclude the use of gadolinium-based contrast in the standardized protocol was multifactorial. Accessibility was the first factor given that many rural and remote centers do not have the same access to gadolinium-based contrast agents that urban centers do. Depending on local expertise, technologists at more remote sites may or may not be familiar with the administration of MR contrast. Finally, the addition of contrast is an added cost to the screening study. The use of SWI was included to improve the sensitivity and specificity for the detection of BVMs in the absence of IV contrast. SWI is an MRI sequence with phase postprocessing that accentuates the intrinsic properties of paramagnetic compounds found in blood products like deoxyhemoglobin and hemosiderin, allowing for exquisite sensitivity to venous vasculature.^{25,26} SWI typically depicts draining veins in BVMs as a signal void (Figure 3). Modern MRI scanners can support SWI imaging with the appropriate phase post-processing



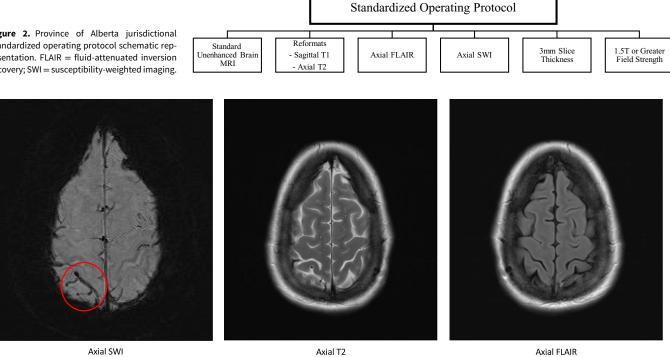


Figure 3. A single axial susceptibility-weighted imaging (SWI) image demonstrating a small nidus-type brain vascular malformation within the medial aspect of the right parietal lobe not readily apparent on T2 and fluid-attenuated inversion recovery (FLAIR) imaging.

software. A 1.5T field strength and 3 mm slice thickness were determined to be the minimum acceptable standards to produce high-quality diagnostic images that would be appropriate for screening. Locally at Edmonton AHS facilities, all MRI scanners are at least 1.5T field strength with several 3T scanners in use. Using MRI scanners of 1.5T or 3T field strength, SWI acquisition occurs as a single 72-slice slab ranging in thickness from 1.8 to 2 mm with a 20% slice gap (0.36–0.4 mm). This thin slice acquisition minimizes the possibility of missing small T2* sensitive lesions (like small BVMs), which can occur when using thicker slice gaps.

The consensus-building process took five years in total due to the complexity involved in organizing a province-wide initiative among all five health zones. Holding Fora through virtual means such as videoconferencing allowed for greater participation from the various stakeholders involved in the development of the SOP. Challenges were encountered when attempting to get timely responses from radiologists and radiology groups from rural and remote settings within the province.

Recognizing healthcare disparities related to imaging is an ever-increasing focus for diagnostic imaging departments.²⁷ Choosing Wisely is a Canadian clinician-led campaign focused on identifying unnecessary and inappropriate testing and providing recommendations for the most efficient and safe use of medical testing.²⁸ The Canadian Association of Radiologists contributed five recommendations regarding the appropriate use of commonly ordered imaging modalities in the emergency department for the Choosing Wisely campaign.²⁸ Although these provided recommendations are not directly related to BVM screening, the principles that govern the appropriate use of imaging within the Choosing Wisely campaign mirror the ideology behind this SOP. The lack of an SOP was impacting the quality of screening performed in the province of Alberta. Disparities in the quality of screening, evidenced by inappropriate protocols and/or modalities, were present based on the geographical location within the province. Inequitable access to high-quality screening leads to unnecessary and repeat imaging, an increased workload for the radiology department and ultimately poor patient care. With these considerations in mind, the SOP was developed to screen patients with suspected or confirmed HHT appropriately and efficiently.

For patients found to have unruptured BVMs on screening exams, conflicting opinions exist regarding the most appropriate management as the decision to treat comes with the risk of hemorrhage, neurological deficits and infection.^{29,30} The ARUBA trial proposed that medical management alone is superior to medical management with interventional therapy in patients with unruptured BVMs, suggesting that unruptured BVMs may be best left untreated.³¹ Importantly, patients with HHT were excluded from the ARUBA trial, and the trial result may not be generalizable to the HHT population.32-35 The topic of BVM screening continues to evolve, and irrespective of the controversy around the management of unruptured BVMs, the North American standard is to screen patients with suspected or definite HHT with MRI to detect lesions that may be amenable to treatment.¹⁷ Patients with positive screening MRIs should be seen at an HHT center of excellence to be evaluated by a multidisciplinary team of experts to determine the most appropriate management.¹⁷ The standardization and implementation of a province-wide BVM screening protocol for patients with suspected or confirmed HHT are crucial steps in providing high-quality care to this patient population.

With the provincial AHS platform of Connect Care, this allows for a more streamlined process for many clinicians to order although not all individuals have access to this large Electronic Medical Record (EMR) outside of AHS. However, both within this EMR and Alberta Netcare and Picture Archiving and Communication System (PACS) across the province, there are methods for a unified access point to gather medical imaging data that are being developed, which will allow future quality improvement and other medical imaging research related to health policies and health economics for screening. We have yet to determine the impact of the SOP on avoiding negative consequences of BVMs for HHT and other patients who are at higher risk of BVMs, as well as health service indices to evaluate diagnostic imaging workload reduction from duplicate tests.

If performed, a screening brain MRI should be done according to established SOPs to ensure value to the health system and the patients involved. Successful implementation within Alberta has now been translated to the neighboring province of Saskatchewan, with plans to expand this to other health jurisdictions after further internal review. A follow-up programmatic approach to review and adherence is planned.

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Patents planned, issues or pending:

- US Patent 62/086,077 Licensed to Circle NVI
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Participation on a Data Safety Monitoring Board or Advisory Board:

- DSMC Chair: Oncovir Hiltonel trial (end 2023)
- DSMC Chair: DUMAS trial (end 2023)
- DSMB Member: ARTESIA trial (end 2023)
- DSMB Member: BRAIN-AF trial (end 2023)
- DSMB Member: LAAOS-4 trial (ongoing)

Leadership roles:

• President of CNSF (Canadian Neurological Sciences Federation)

Stock or stock options:

- Circle Inc: Private stock ownership
- Basking Biosciences: Private stock ownership

Jeremy Rempel:

Leadership roles:

• President of CING (Canadian Interventional Neuro Group).

Richard Owen:

Leadership roles:

• President of EZMSA (Edmonton Zone Medical Staffing Association).

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