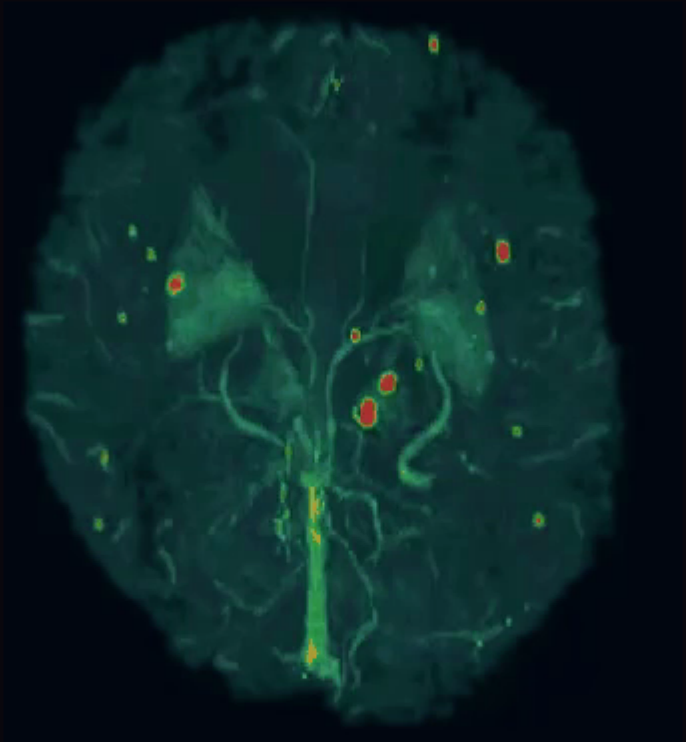
SPINTECH
From image to insight™

Introducing STAGE Imaging:

A new frontier in rapid, quantitative brain MRI



www.spintechimaging.com

Introducing STAGE™:

Quantitative.
Multi-Contrast.
Standardized.
40% Faster Brain Imaging.

Faster Imaging. Enhanced Detection.

40% reduction in brain imaging time with improved detection of key biomarkers.

Experienced Team & Partners

Advanced technology from an experienced, winning team and global partners

Rapid Insights from Automation

Powering AI detection of unseen biomarkers for faster, more accurate diagnoses.

Driving Clinical Value

Meeting rapidly growing market for increased quality and revenue

SPINTECH COMPANY OVERVIEW

Founded
2017

Based in
Detroit, MI

100+
Research papers

10,000+
research references

40+ global
research sites

9 awarded patents
with 1 patent pending,
4 in pipeline

First product
FDA cleared

8,000+
processed cases

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Growing Patient Demand

DEMENTIA — **5 M** U.S. Patients

PARKINSON'S — **1 M** U.S. Patients

STROKE — **800K** Patients/year

MULTIPLE SCLEROSIS — **1 M** U.S. Patients

TRAUMATIC BRAIN INJURY — **2.8 M** U.S. Patients/year

WHAT'S THE PROBLEM?

Radiology Industry Pressures

Still Unsolved

- **Rising** Cost of Care
- **Decreased** Reimbursement
- Need for **Enhanced** Diagnostics
- **Strained** Workflow

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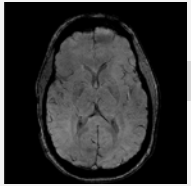
INTRODUCING STAGE™:
A New Frontier in Rapid, Quantitative Brain MRI

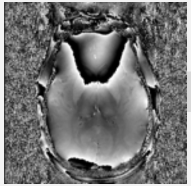
Rapid, 5 Min. Acquisition

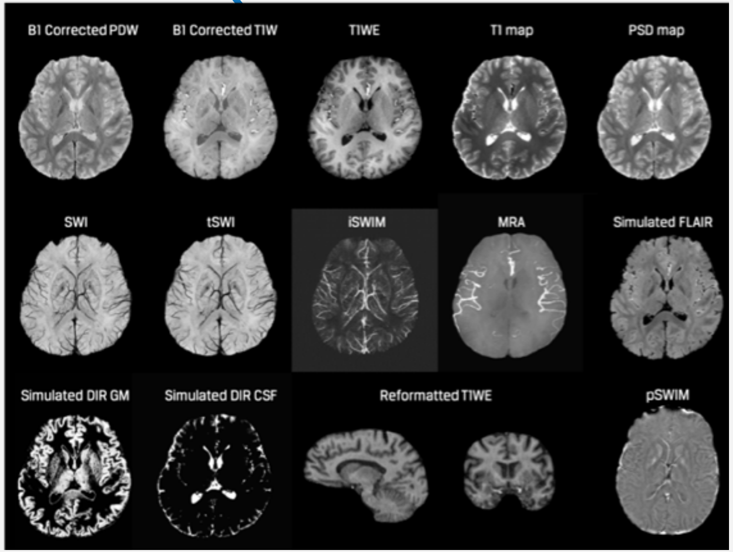
Seamless, Integrated Processing

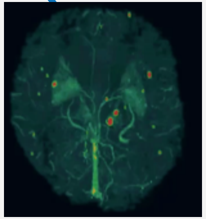
Enhanced, Multi-Contrast, Quantitative Outputs

Automatic Detection and Reporting









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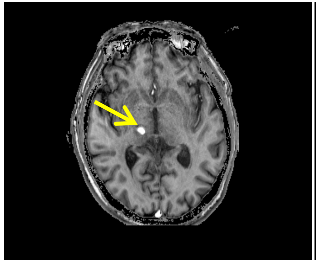
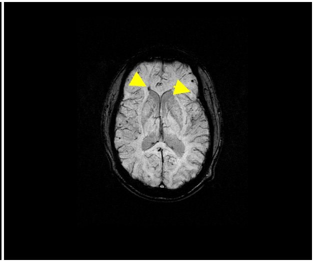
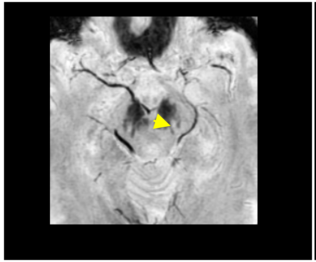
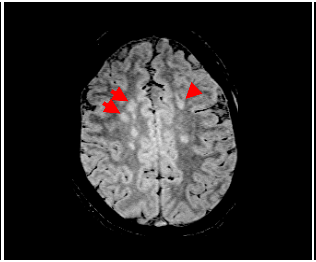
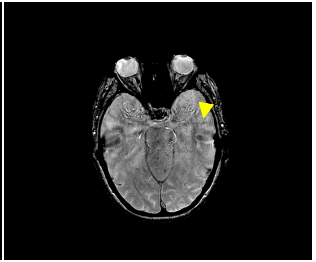
STAGE™ vs. CONVENTIONAL MRI

40% faster brain MRI acquisition time vs. conventional MRI protocols

METHOD	ACQUISITION SEQUENCES	TIME @ 1.5T	TIME @ 3T
SpinTech	STAGE, T2FLAIR, DWI	13:14	9:30
Conventional	T1W, PDW, SWI, DWI, T2FLAIR	22:37	14:27

Increased patient throughput.
Less patient time in scanner.
Improved customer ROI.

ENHANCED DETECTION = BETTER OUTCOMES

DISEASE	Stroke	Traumatic Brain Injury	Parkinson’s	Multiple Sclerosis	Dementia
BIOMARKER	Microbleeds, O2 Saturation	Microbleeds, Vessel Shearing	SN Swallow Tail	FLAIR/SWI Mismatch	Microbleeds
					

- Detect all of these critical biomarkers with one protocol
- Diagnosis and treatment relies on clear detection
- Inaccurate / missed biomarkers mean adverse outcomes
- Drug development relies on reliable biomarkers

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TANGIBLE CLINICAL VALUE

40% Faster Neuro Throughput Means…

ABILITY TO SEE
10-15
MORE PATIENTS EACH WEEK

x

REIMBURSEMENT OF
$750
PER SCAN

=

$500,000
ADDITIONAL REIMBURSEMENT EVERY YEAR

40% Faster Scan Times

Rich, Standardized Data

Lower Costs, Increased Revenue

Improved Workflow

Improved Patient Experience

Improved Outcomes

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Powering the future of AI:

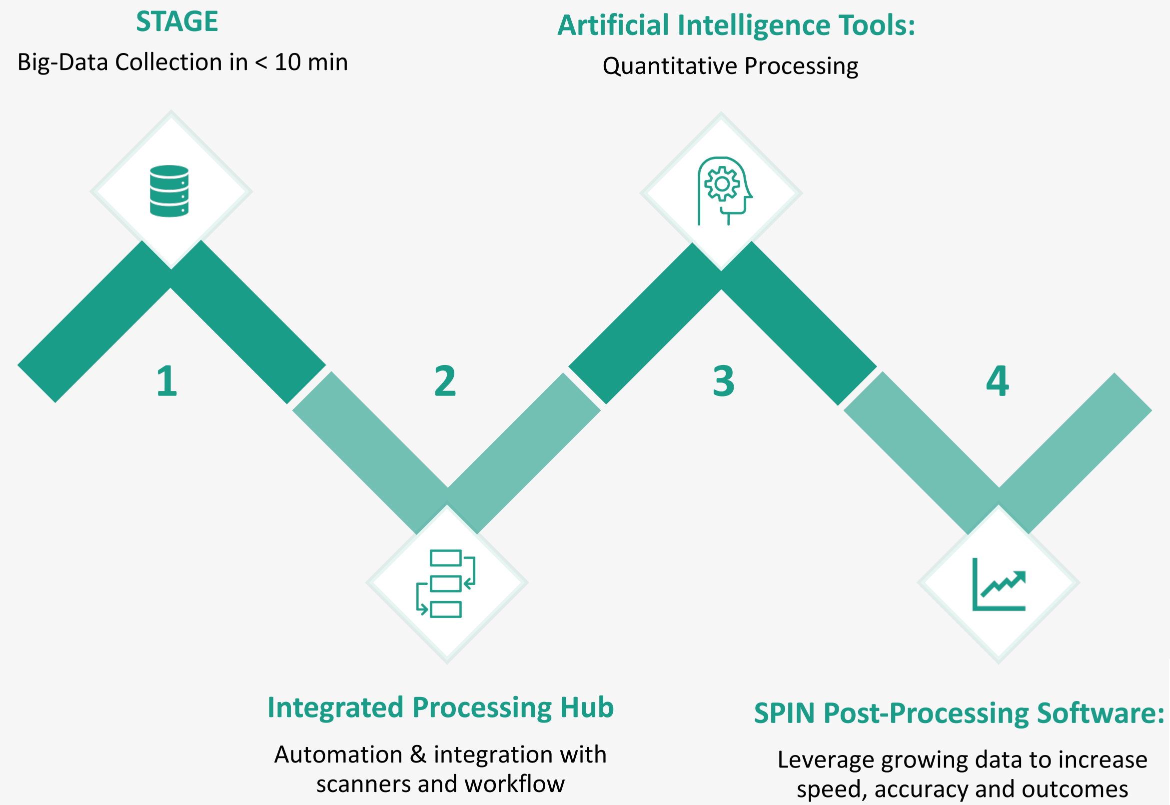
Rapid Insights from Automation

Rich, quantitative, standardized data solving key challenges of clinical AI adoption.

DRIVING AI ADOPTION

Clinical AI adoption requires an imaging data platform with:

- Rich, standardized data
- Quantified biomarkers
- Increased throughput
- Workflow integration
- Tangible clinical value



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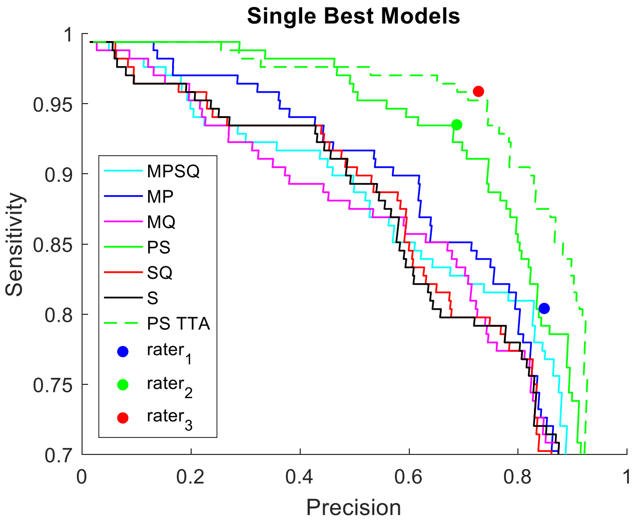
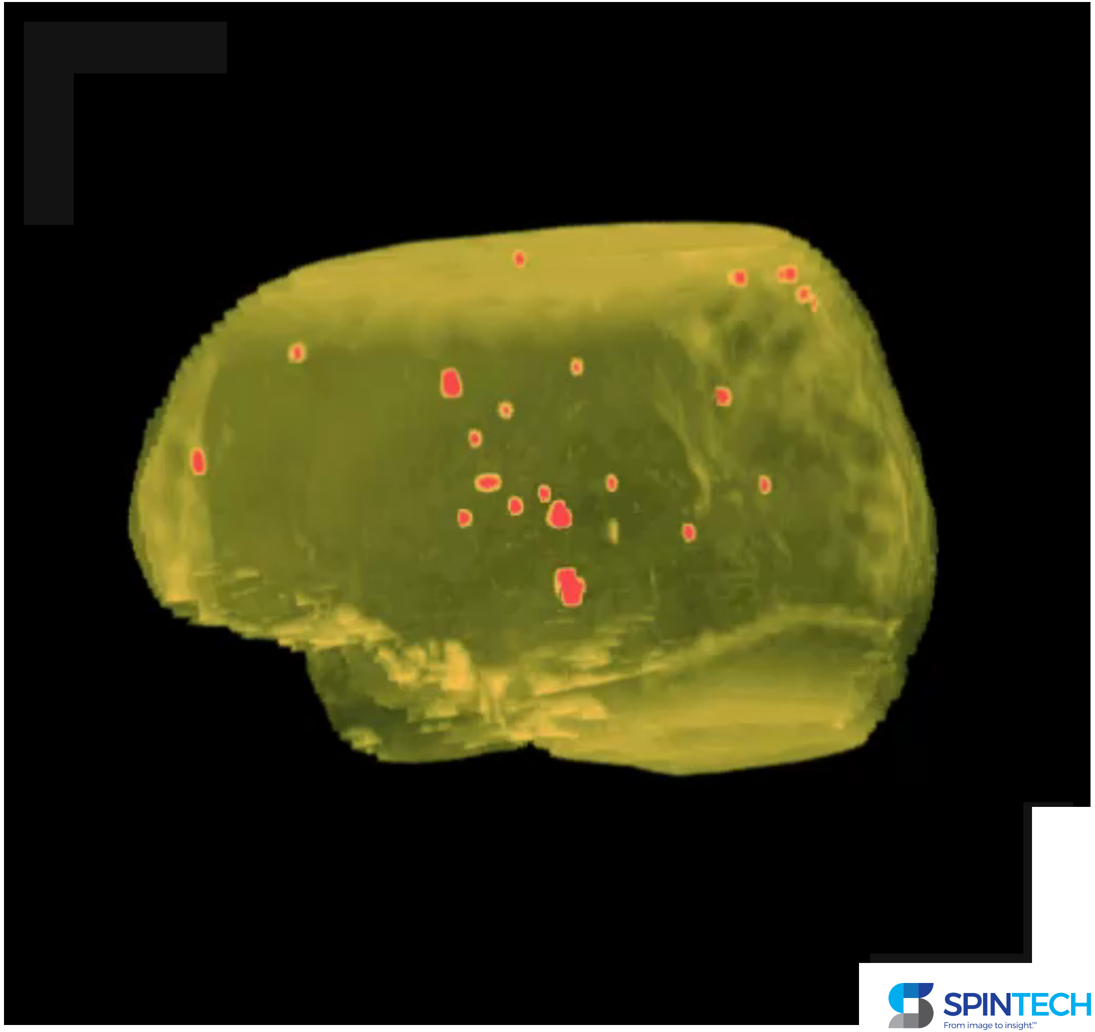
AI IS MAKING A DIFFERENCE

STAGE enables automatic detection of hard to detect cerebral microbleeds that may otherwise be missed



Liu, S et al. *NeuroImage*, 2019. Sep;198:271-282.



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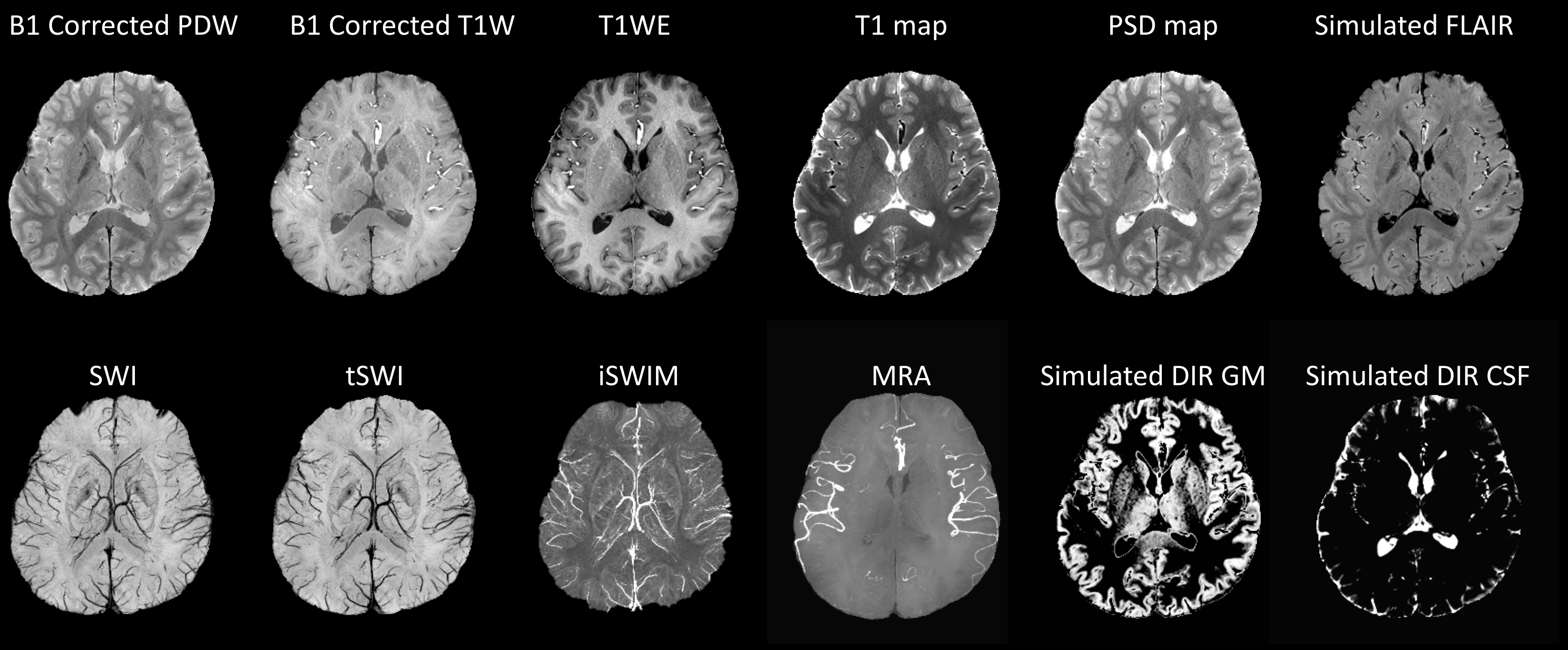
“BIG DATA” FROM A SINGLE PROTOCOL



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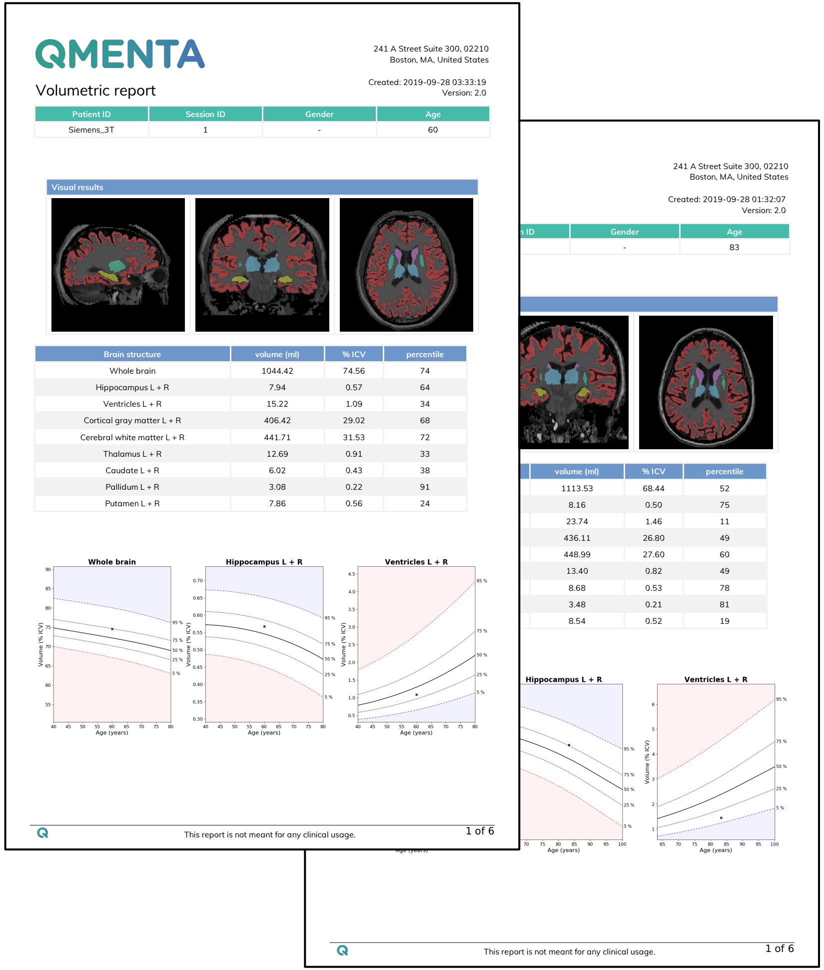

QMENTA

Volumetric report

241 A Street Suite 300, 02210
Boston, MA, United States

Created: 2019-09-28 03:33:19
Version: 2.0

Patient ID	Session ID	Gender	Age
Siemens_3T	1	-	60

Visual results

Brain structure	volume (ml)	% ICV	percentile
Whole brain	1044.42	74.56	74
Hippocampus L + R	7.94	0.57	64
Ventricles L + R	15.22	1.09	34
Cortical gray matter L + R	406.42	29.02	68
Cerebral white matter L + R	441.71	31.53	72
Thalamus L + R	12.69	0.91	33
Caudate L + R	6.02	0.43	38
Pallidum L + R	3.08	0.22	91
Putamen L + R	7.86	0.56	24

Whole brain — Hippocampus L + R — Ventricles L + R

This report is not meant for any clinical usage. 1 of 6

241 A Street Suite 300, 02210
Boston, MA, United States

Created: 2019-09-28 01:32:07
Version: 2.0

... ID	Gender	Age
	-	83

volume (ml)	% ICV	percentile
1113.53	68.44	52
8.16	0.50	75
23.74	1.46	11
436.11	26.80	49
448.99	27.60	60
13.40	0.82	49
8.68	0.53	78
3.48	0.21	81
8.54	0.52	19

Hippocampus L + R — Ventricles L + R

This report is not meant for any clinical usage. 1 of 6

3rd PARTY COMPATABILITY

STAGE Data is compatible with most 3rd party post-processing and reporting tools, integrating with existing workflow and expanding diagnostic capabilities.

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Clinical Applications & Research Findings

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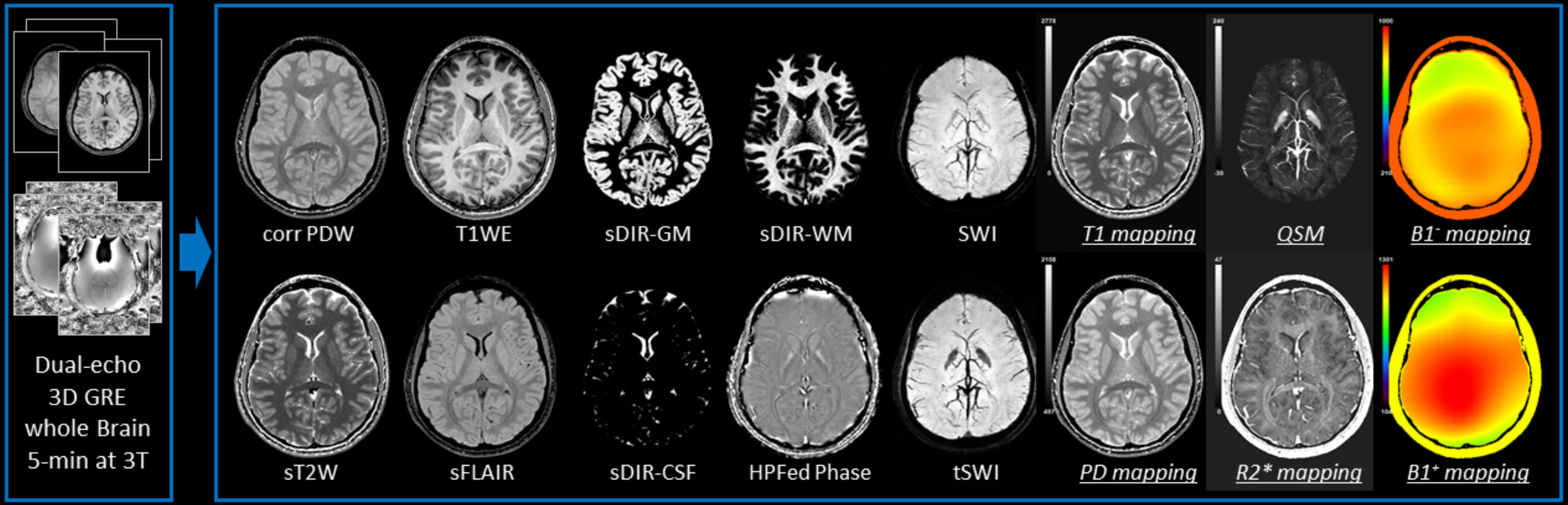
RAPID. STANDARDIZED. QUANTITATIVE. MULTI-CONTRAST IMAGING.

ON AVERAGE, STAGE PROVIDES A NEW TYPE OF IMAGE EVERY 30 SECONDS WITH A TOTAL TIME OF DATA ACQUISITION BEING JUST 5 MINUTES: TEN QUALITATIVE AND SIX QUANTITATIVE IMAGES.



Qualitative Images: corr PDW, T1WE, sDIR for GM, WM and CSF, sT2W, sFLAIR, HPFed Phase, SWI and tSWI

Quantitative Data: T1 and PD mapping, QSM, R2 mapping, B1+ and B1- mapping*

STAGE OVERVIEW

- Rapid MRI brain protocol and post-processing software generating enhanced contrasts and quantitative maps
  - Enhanced GM/WM T1 Contrast, pSWIM, mpSWIM
  - Quantitative maps of T1, Proton Density, R2*, T2*, and Susceptibility
  - Simulated Dual Inversion Recovery
  - SWI
- Reduced imaging time (5-10 minutes)
- B1 field correction
- Data are collected 3D, no spaces
- Offers repeatability and standardization
- Data are comparable across manufacturers and field strengths
- No contrast agent required
- Reduced need for registration
- Automated, workflow-integrated processing

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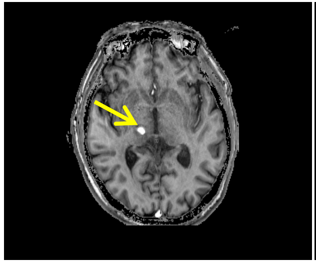
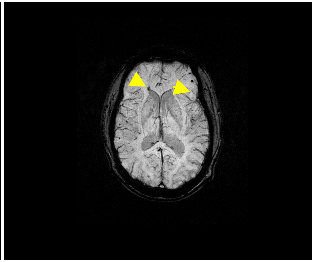
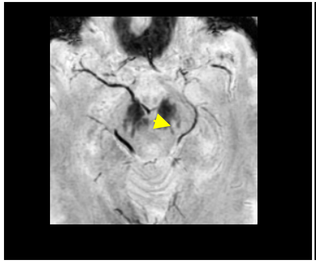
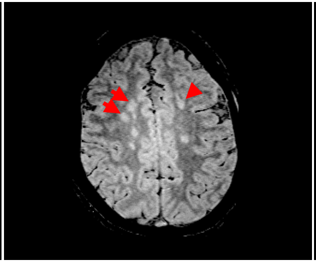
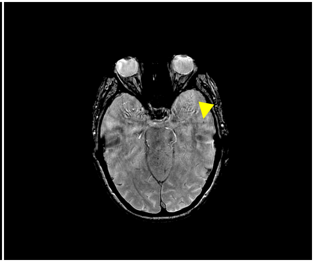
ENHANCED DETECTION = BETTER OUTCOMES

Comprehensive, automated biomarker detection from a single protocol

DISEASE	**Stroke**	**Traumatic Brain Injury**	**Parkinson's**	**Multiple Sclerosis**	**Dementia**
BIOMARKER	Microbleeds, O2 Saturation	Microbleeds, Vessel Shearing	SN Swallow Tail	FLAIR/SWI Mismatch	Microbleeds
					

- ☑ Detect all of these critical biomarkers with one protocol
- ☑ Diagnosis and treatment relies on clear detection
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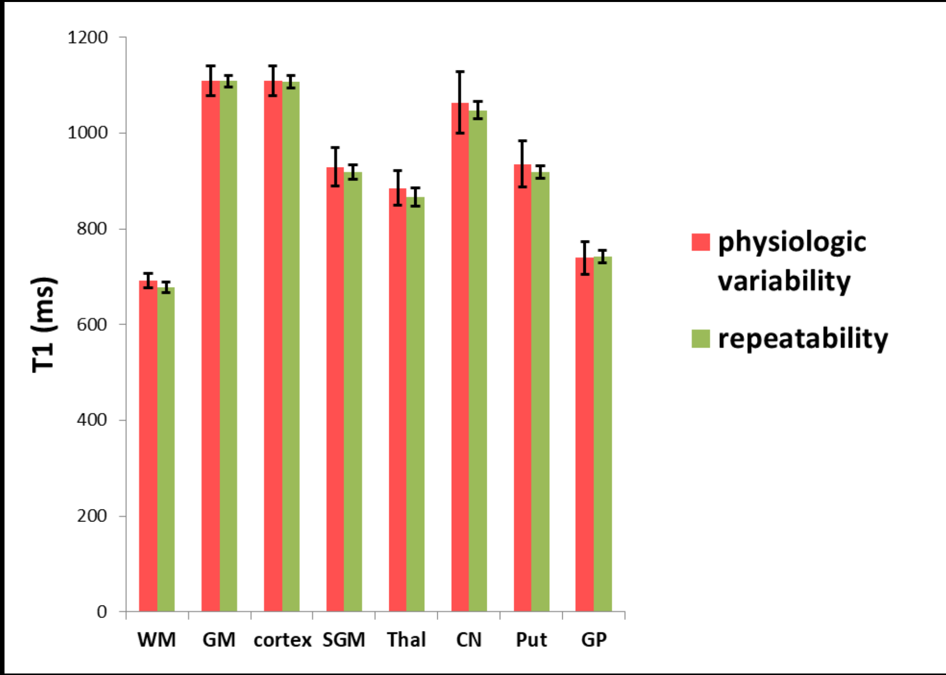
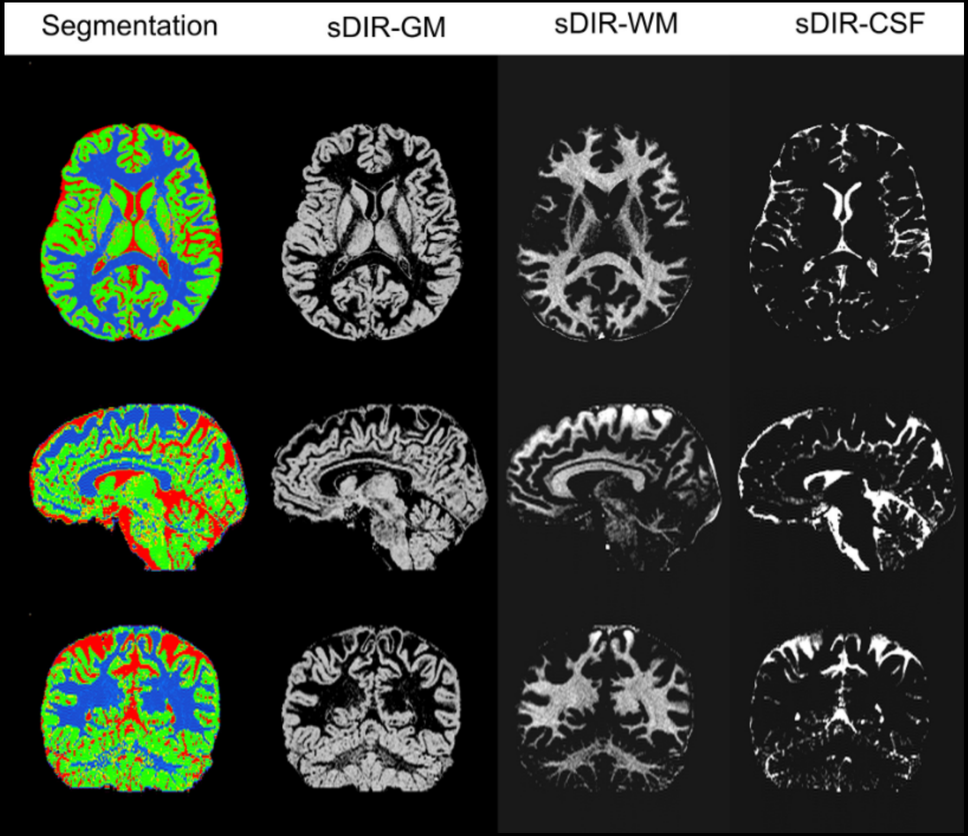
STANDARDIZATION + REPEATABILTY



Haacke, EM, et al. *Mag. Res. Imaging,* 2020. Jan; 65:15-26

Improving Volumetric Segmentation and Beyond



- Representative sDIR images from a STAGE case on a healthy subject. The three sDIR images can be used as naturally segmented data for mapping GM, WM, and CSF and potentially for following brain volumes longitudinally in patients.
- Additionally, in combination with the quantitative maps (T1mapping, R2*map, QSM), structural properties can be quantitatively assessed (i.e. water content, iron content).

Haacke, EM, et al. *Mag. Res. Imaging,* 2020. Jan; 65:15-26

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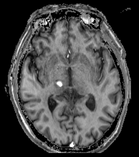
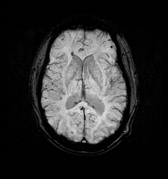
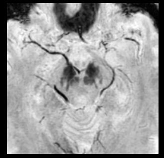
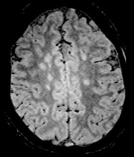
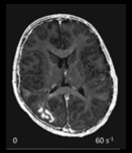
DISEASES AND CONDITIONS

DISEASE	Dementia	Stroke	TBI	Parkinson's	Multiple Sclerosis	Sturge-Weber	Tumor
BIOMARKER	Microbleeds, Volumetrics	Microbleeds, oxygenation	Microbleeds, venous trauma	SN Swallow Tail Neuromelanin	FLAIR/SWI Mismatch	Calcium, bleeding	Vascularization, bleeding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DISEASES AND CONDITIONS

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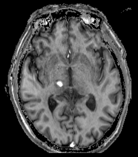
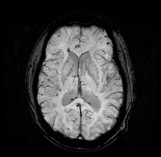
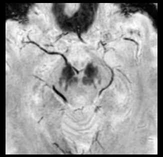
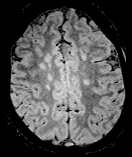
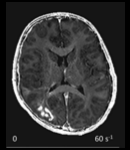


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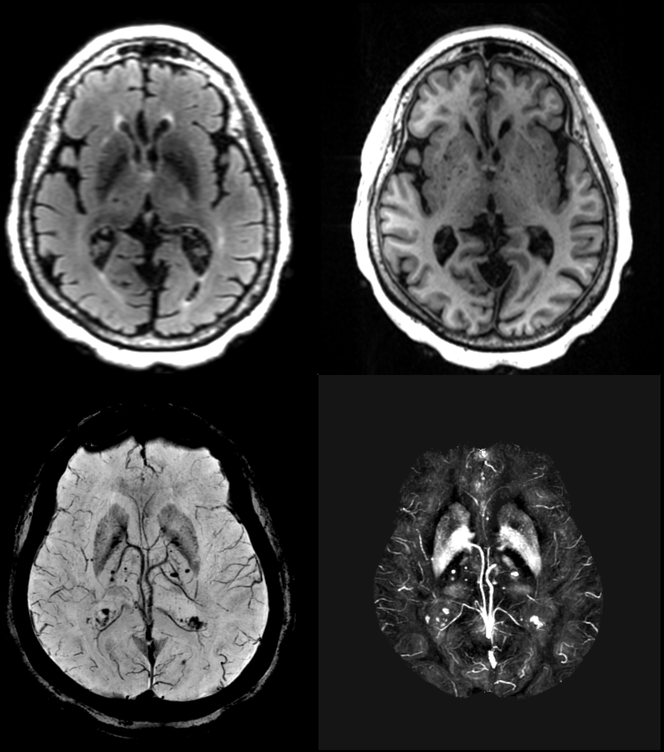
CEREBRAL MICROBLEEDS IN DEEP GM

T2 FLAIR T1WI



STAGE SWI (mIP) STAGE SWIM (MIP)

Differentiating bleeds from calcifications reduces false positives, improves accuracy

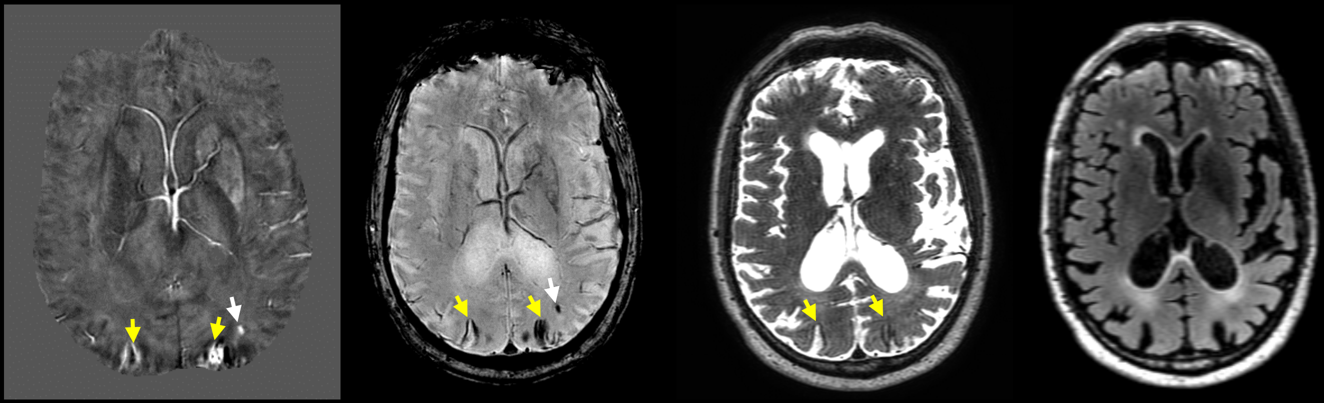
CORTICAL SUPERFICIAL SIDEROSIS

STAGE SWIM

STAGE SWI

T2WI

T2 FLAIR



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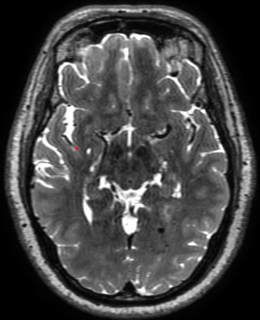
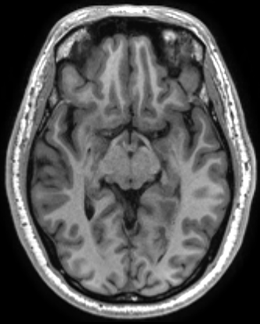
DEMENTIA? OR NORMAL?

Conventional MRI

T2WI

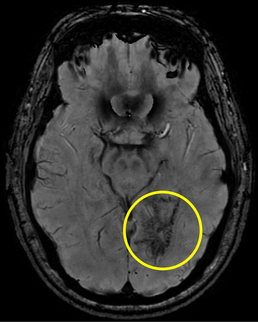




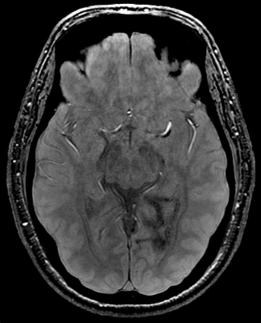
T1WI

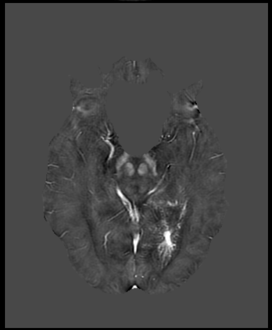
STAGE

SWI

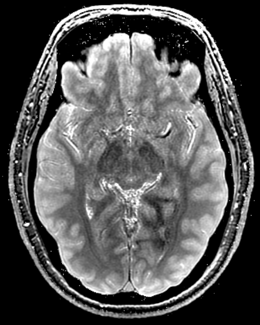


PDW





SWIM



PD MAP

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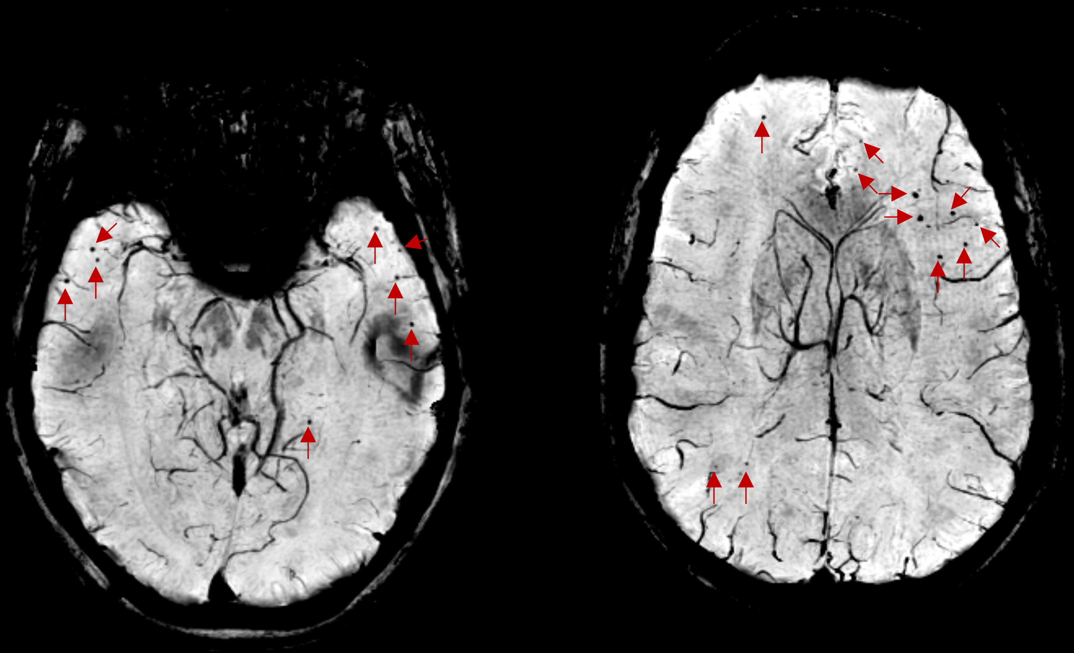
CAA IN COGNITIVELY NORMAL CONTROL

MoCA Score: 27

30+ CMBs in Frontal, Temporal, Parietal Lobes.



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DISEASES AND CONDITIONS

DISEASE	Dementia	Stroke	TBI	Parkinson's	Multiple Sclerosis	Sturge-Weber	Tumor
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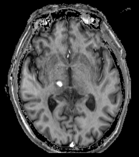

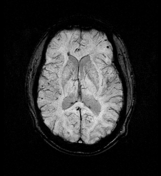

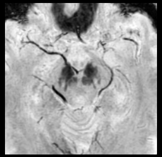

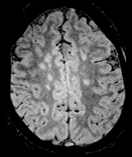

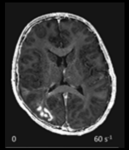

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STAGE FOR STROKE

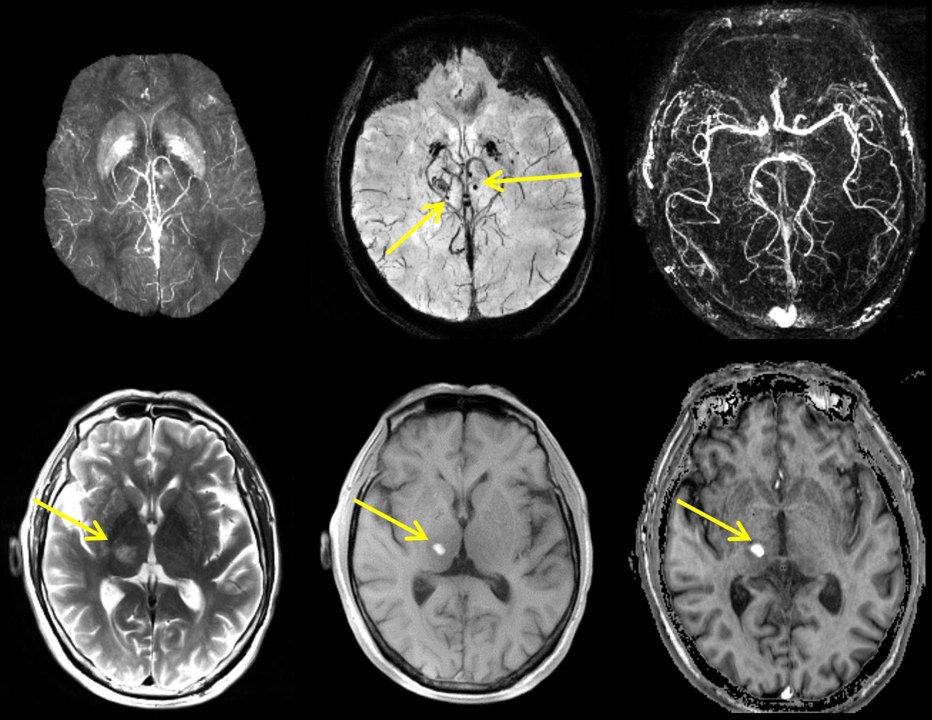
- What do we look for?
  - Cerebral Microbleeds
  - Areas of deoxygenation
  - APCV

- **STAGE** enhances detection of microbleeds, which are critical for proper diagnosis and treatment

- Oxygen saturation, which can be an indicator of perfusion

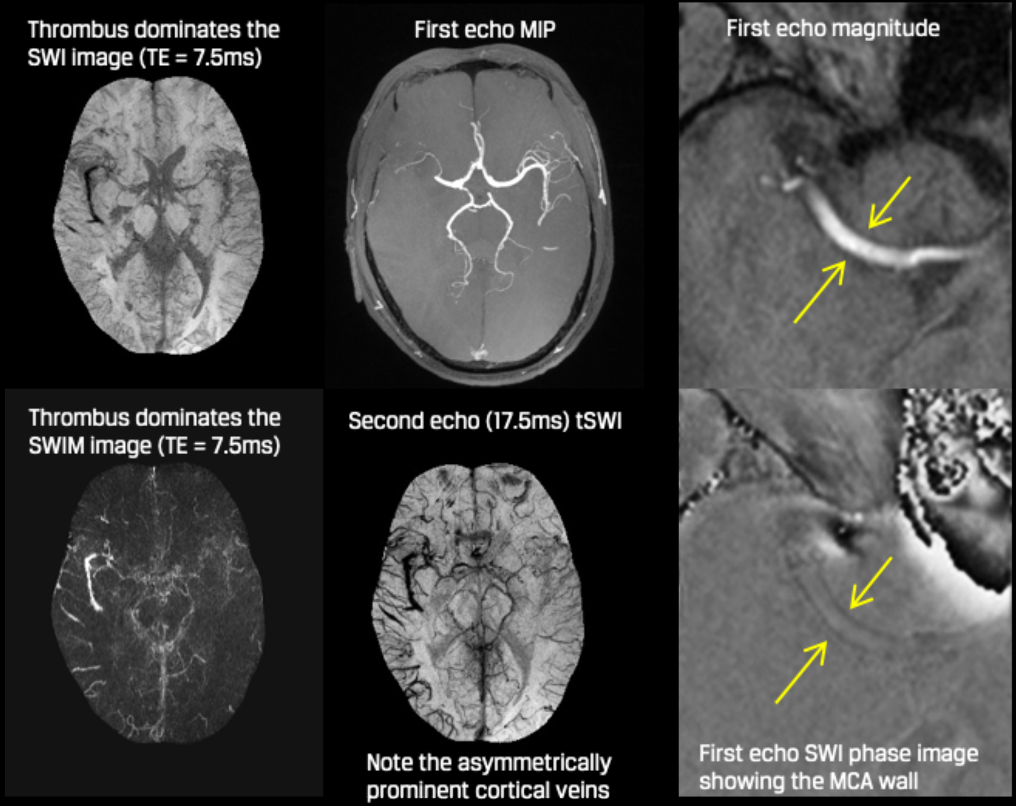
- Non-contrast MRAV

STAGE SWIM MIP | STAGE SWI mIP | STAGE MRAV MIP



Conventional T2WI | Conventional T1WI | STAGE T1WE

IMAGING VEINS AND ARTERIES



Images courtesy of Meiyun Wang, MD, Henan Provincial People's Hospital

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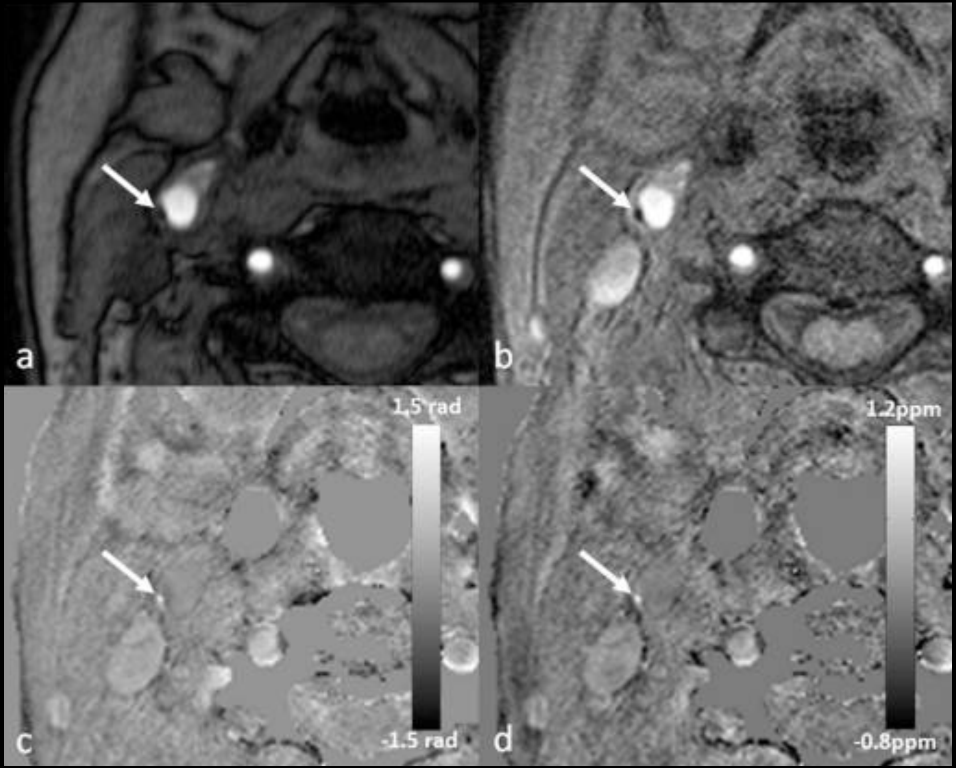
Susceptibility Weighted Imaging: Current Status and Future Directions
Cervical Neck Vessel Imaging



- Eccentric wall thickening (arrow) at the posterolateral aspect of the right common carotid artery on TOF-MRA (**a**). There is a dark spot on the magnitude image (**b**), which appears bright on both the filtered phase image (**c**) and the susceptibility map (**d**). This suggests that this is a tiny foci of intraplaque hemorrhage and may represent an example of vulnerable plaque. The original data for **b**, **c** and **d** were acquired using a multi-echo SWI sequence at 3T, although these images were generated using the data from the shortest echo with TE=5.18ms. Image **c** was generated using a homodyne high-pass filter with k-space window size 64×64, while **d** was generated using a truncated k-space division algorithm with a k-space threshold 0.2.

Liu et al. 2017 NMR Biomed

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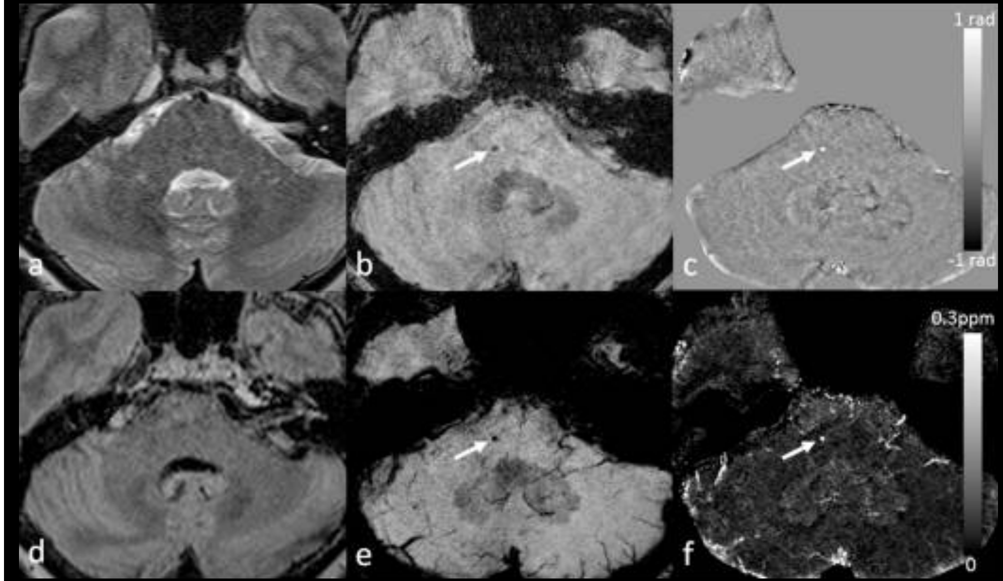
Susceptibility Weighted Imaging: Current Status and Future Directions - microbleeding



- Imaging cerebral microbleeds (CMB) using SWI and QSM. For this patient, there is a single CMB that is not visible in either T2WI (**a**) or FLAIR (**d**), but can be seen in the original magnitude (**b**) and filtered phase images (**c**) in the SWI data (white arrows). The CMB can be better visualized in the minimum intensity projection of SWI data (**e**) and the maximum intensity projection of susceptibility maps (**f**) (white arrows). The CMB appears as hypo-intense in **b** and **e**, while hyper-intense in **c** and **f**, indicating that it is paramagnetic. Note that the phase image shown in **c** was from a left-handed system. There is no connection between the CMB and vessels, as can be seen in both **e** and **f**. Susceptibility maps were generated using the geometry constrained iterative SWIM algorithm. The (effective) slice thickness is 2mm in **a**, 1.5mm in **b** and **c**, 0.5mm in **d**, 12mm in **e** and **f**.

Liu et al. 2017 NMR Biomed

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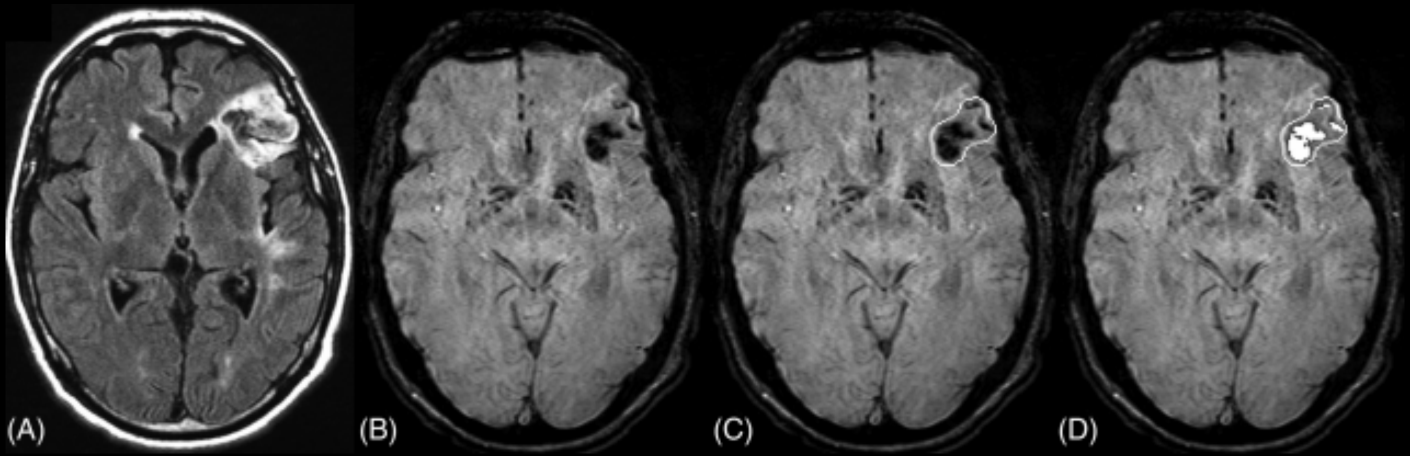
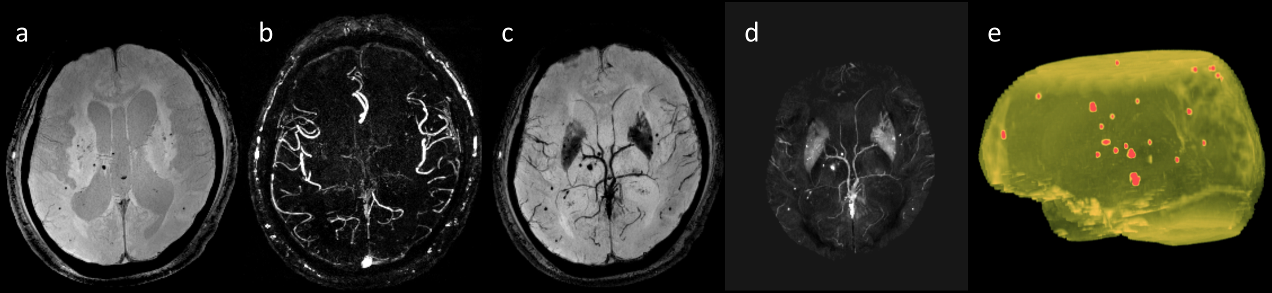
Final Results of the RHAPSODY Trial: A Multi-Center, Phase 2 Trial Using a Continual Reassessment Method to Determine the Safety and Tolerability of 3K3A-APC, A Recombinant Variant of Human Activated Protein C, in Combination with Tissue Plasminogen Activator, Mechanical Thrombectomy or both in Moderate to Severe Acute Ischemic Stroke

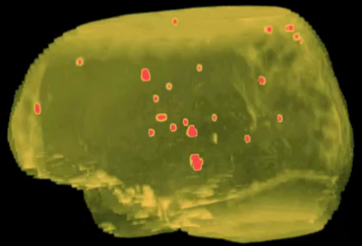


- Image analysis method for hemorrhage volume quantification. The analyst (unaware of treatment assignment) identified the infarct region using FLAIR (A), then reviewed the susceptibility sequence (B). An object was drawn around abnormal findings (C), and a threshold was applied within the object to outline any hemorrhage (D). The number of pixels lower than the threshold was (Spintech Inc., Bingham Farms, MI). FLAIR = fluid-attenuated inversion injury.

Lyden et al. 2018 Annals of Neurology,

STAGE FOR STROKE AND DETECTION OF CMBS



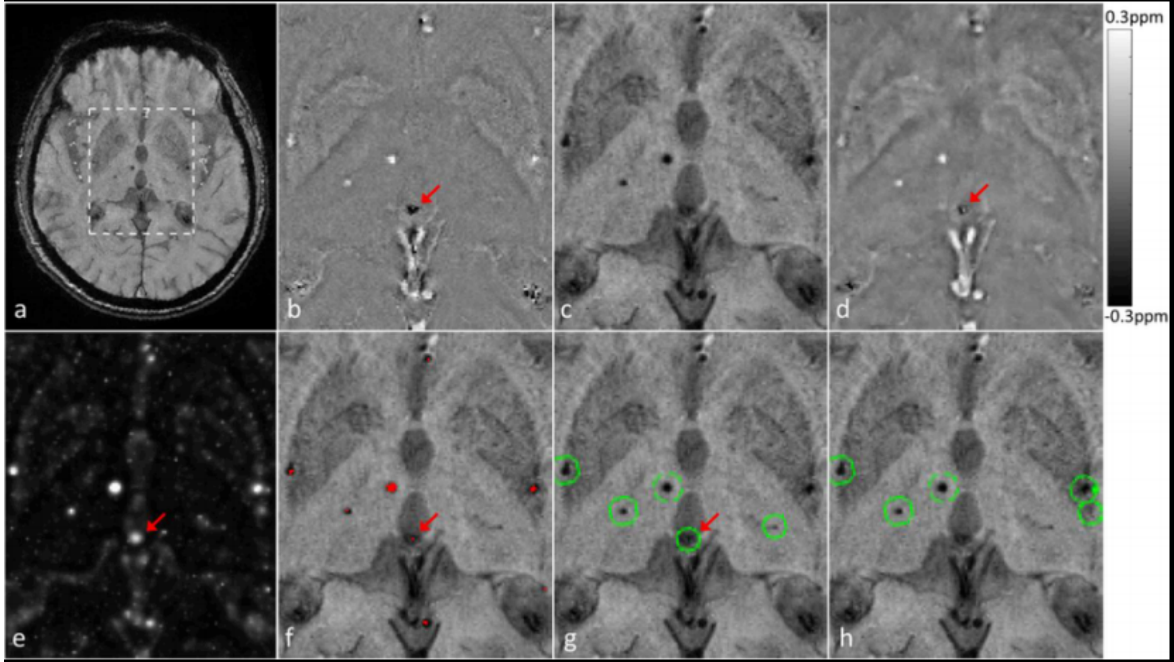


Preliminary results of segmenting and quantifying CMBs using STAGE data. PDW magnitude image (a); MRAV (b); SWI (c); QSM (d); A 3D rendering (e) of segmented CMBs.

Images (a to d) are maximum/minimum intensity projection over 8 slices with an effective slice thickness of 16 mm.

Y. Chen, S. Xia, et al., ASNR 2018, Vancouver, Canada

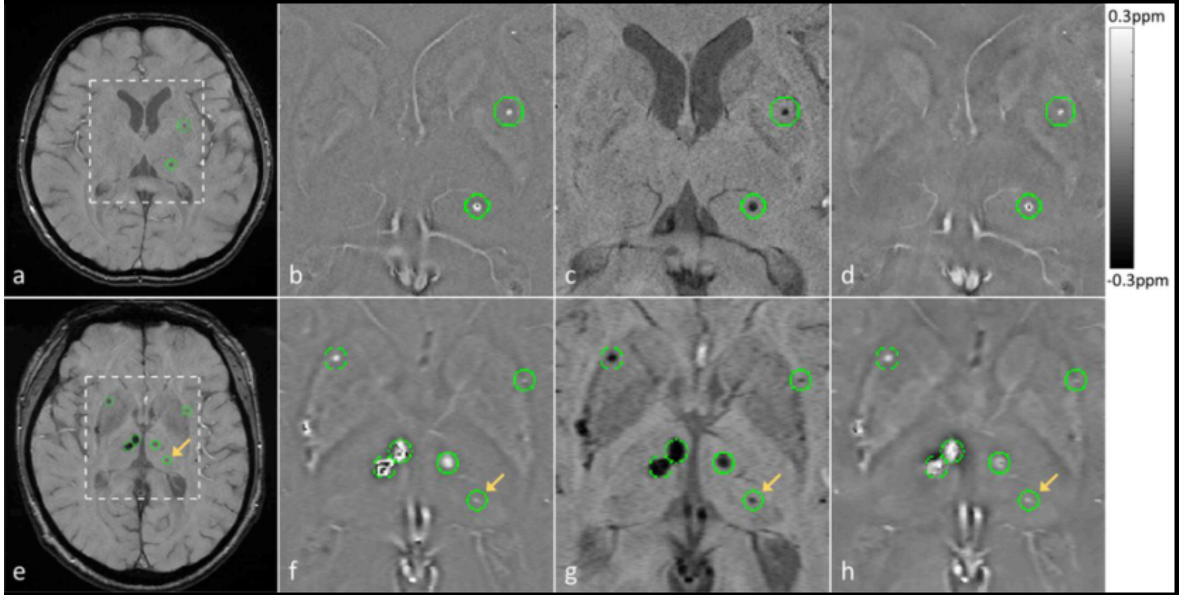
CEREBRAL MICROBLEED DETECTION USING SUSCEPTIBILITY WEIGHTED IMAGING AND DEEP LEARNING



- Differentiation of calcification from CMBs using phase and SWI images. (a) Magnitude image. (b) Phase image. The calcification (red arrow) is negative on phase images, while CMBs are positive. (c) SWI image. (d) Quantitative susceptibility map. The scale bar is for (d) only. (e) 3D-FRST transformed SWI image. (f) SWI image with detected CMB candidates (red regions). Both CMBs and calcification (red arrow) were detected. (g) The model using SWI images alone failed to eliminate the false positive caused by the calcification (red arrow). (h) The model using phase and SWI images eliminated the one false positive successfully. (b) to (h) correspond to the dashed box region in (a).

Liu et al. 2019 Neuroimage,

CEREBRAL MICROBLEED DETECTION USING SUSCEPTIBILITY WEIGHTED IMAGING AND DEEP LEARNING



- Detected CMBs in subjects affected by hemodialysis (a to d) and stroke (e to h). (a) and (e): magnitude images. (b) and (f): phase images. (c) and (g): SWI images. (d) and (h): quantitative susceptibility maps. The scale bar is for (d) and (h) only. (b) to (d) and (f) to (h) correspond to the dashed box regions in (a) and (b), respectively. The CMBs are indicated by the green circles. The small lesion indicated by the yellow arrows in (e) to (h) was missed by all three raters.

Liu et al. 2019 Neuroimage,

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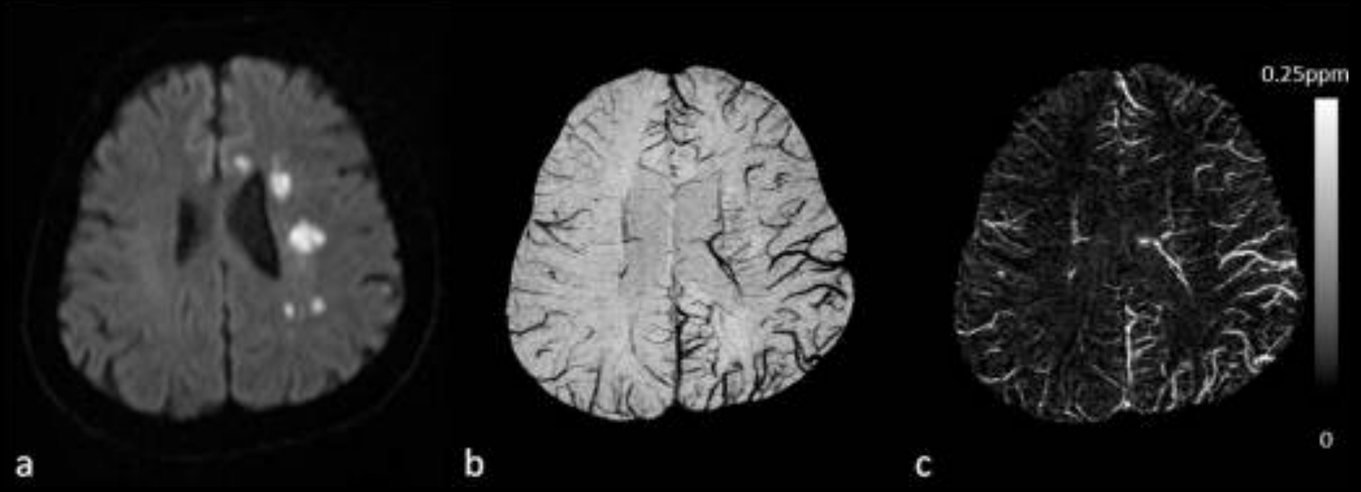
SUSCEPTIBILITY WEIGHTED IMAGING: CURRENT STATUS AND FUTURE DIRECTIONS - APCV



- Visualization and quantification of asymmetrically prominent cortical veins (APCV) in an ischemic stroke patient using SWI and QSM. **a.** DWI showed multiple high signal regions in the centrum semiovale and in the genu of the corpus callosum. **b.** Visualization of the APCV in the left hemisphere in the minimum intensity projection of SWI data. **c.** Maximum intensity projection of susceptibility maps showing cortical veins with increased susceptibility in the ischemic hemisphere, compared to those in the contralateral hemisphere. Susceptibility maps were generated using the geometry constrained iterative SWIM algorithm .

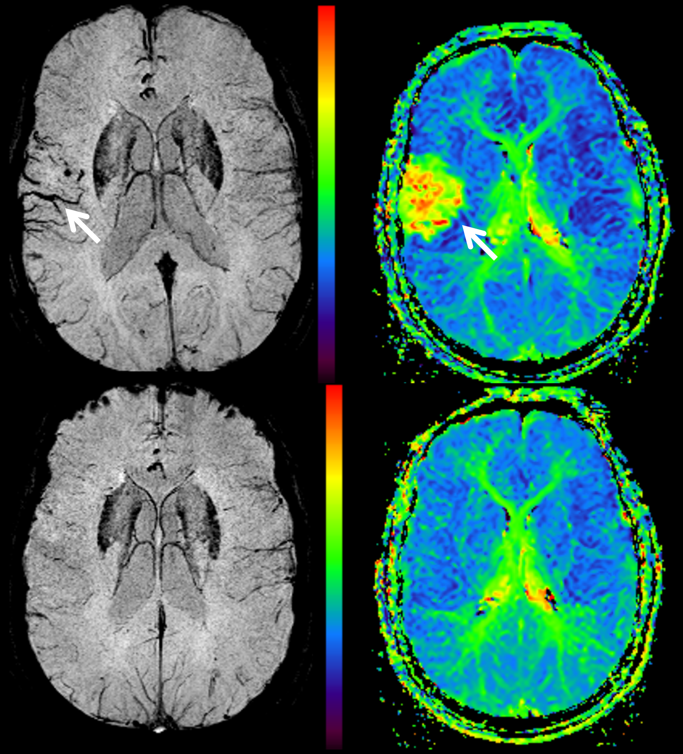
Liu et al. 2017 NMR Biomed

TWO SCANS FROM SAME STROKE PATIENT

At initial scanning

Asymmetrically Prominent Cortical Veins (APCV, arrows) may indicate the tissue is still viable.

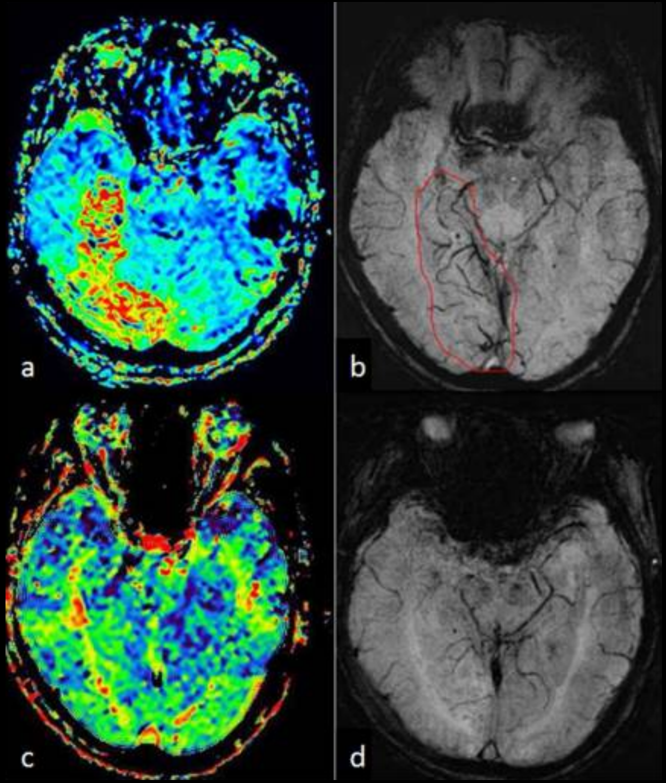
SWI



MTT

One week later

SUSCEPTIBILITY WEIGHTED IMAGING: CURRENT STATUS AND FUTURE DIRECTIONS - APCV



- A 77-year-old male who suddenly had left limb weakness and paresthesia underwent an MR scan with PWI and SWI 3 hours after stroke. MTT (**a**) showed a large hypo-perfused region in the right lateral hippocampus and occipital lobe, while SWI (**b**) showed asymmetrically prominent cortical veins (APCV) in the corresponding region, as indicated by the red contour in **b**. Six days after intravenous rTPA treatment, with improved neurological symptoms, the patient underwent a second MR scan with PWI-MTT (**c**) and SWI (**d**), in which both MTT and SWI appeared normal.

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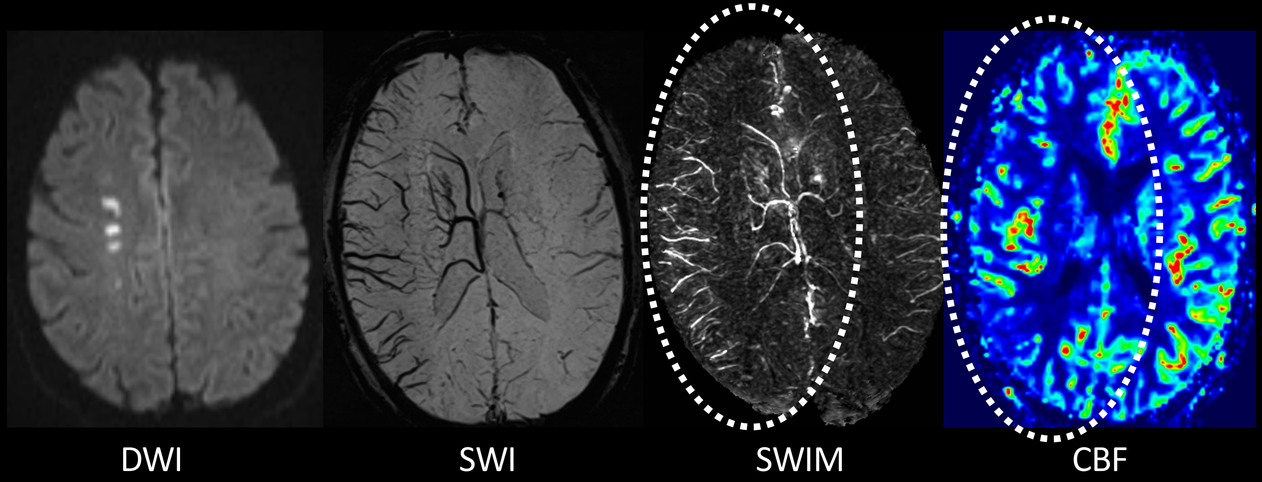
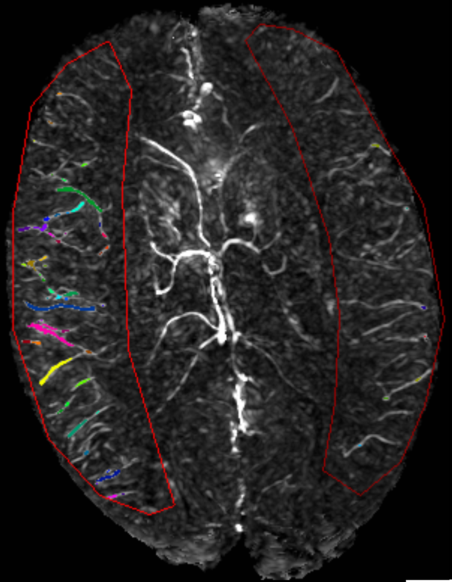
APCV AND STROKE



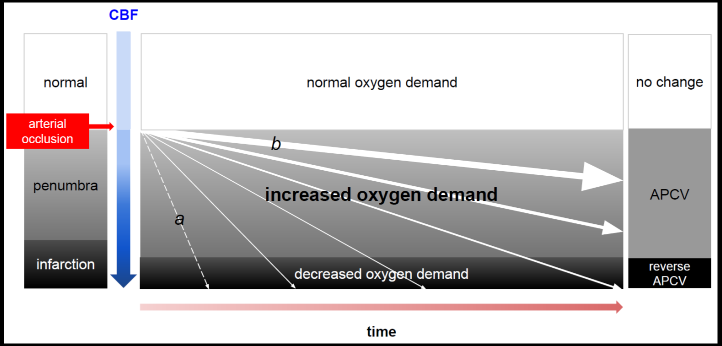


ΔY of about 30%

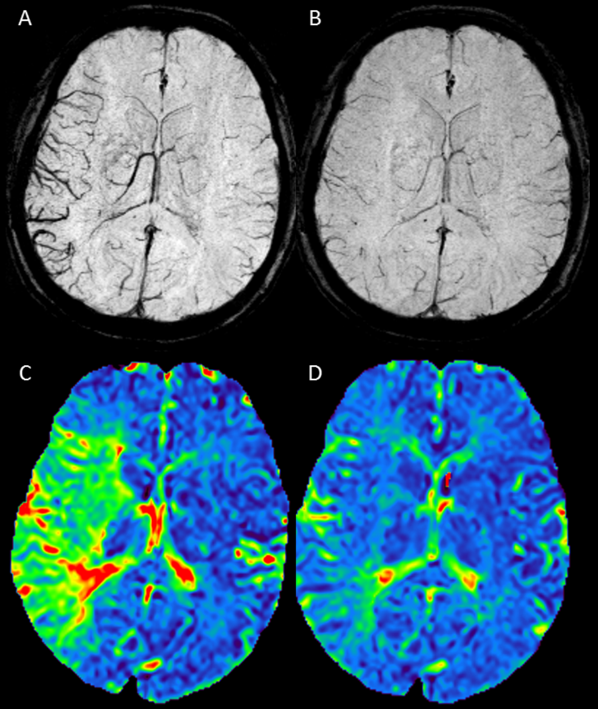
A 57-year-male stroke patient with weakness of left limb was scanned MRI **144 hours after the event**. Multi-lacunar infarctions on DWI.

Images courtesy of Dr. Xia Shuang

USING PERFUSION WEIGHTED IMAGING TO AID IN DRAWING PROMINENT VEINS ON QUANTITATIVE SUSCEPTIBILITY MAPPING

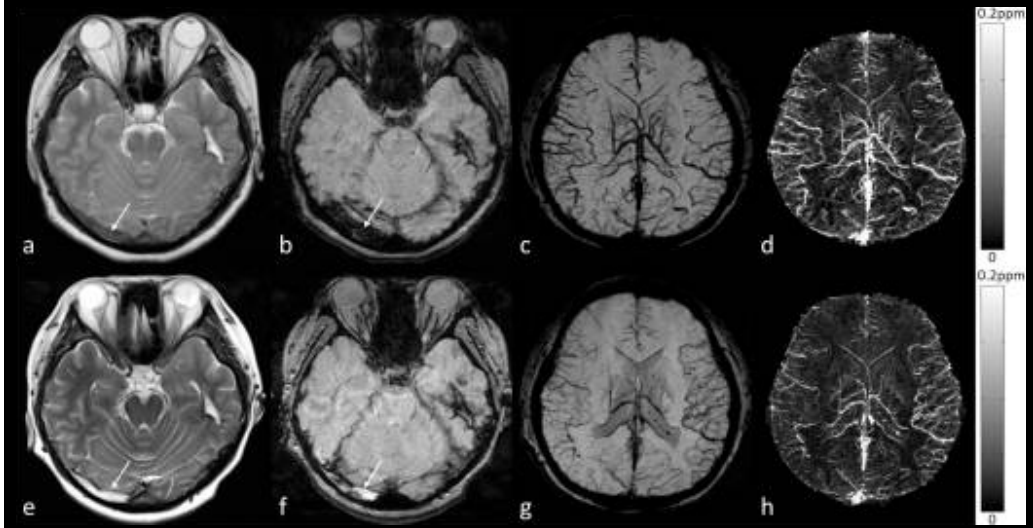


- Asymmetrically Prominent Cortical Veins (APCV) are a valid imaging marker, but identification is user dependent. With the help of PWI, we create a stepping stone for automatic APCV segmentation – a reliable identifier for ischemic penumbra from SWI data.



Fawaz et al. 2019 ISMRM

SUSCEPTIBILITY WEIGHTED IMAGING: CURRENT STATUS AND FUTURE DIRECTIONS – DV THROMBUS



- Visualization and quantification of the susceptibility of bilateral cortical veins in a 19-year-old female patient with right transverse sinus thrombosis.
- The right transverse sinus is less hypo-intense than normal on T2WI (**a**) and markedly hypo-intense and dilated on SWI (**b**), suggestive of early thrombosis. Bilateral cortical veins were dilated and increased levels of deoxyhemoglobin were indicated on the minimum intensity projection (mIP) of the SWI data (**c**) and the maximum intensity projection (MIP) of the QSM data (**d**).
- In the follow-up scan, both the T2WI (**e**) and the original magnitude image in the SWI data (**f**) showed hyper-intensity in the right transverse sinus, possibly due to evolving blood products in the thrombus (white arrows). Although a normal flow void did not return on T2WI, the increased oxygen saturation of the cortical veins may suggest early recanalization or collateral venous drainage in the brain, as indicated by both the mIP of SWI data (**g**) and the MIP of QSM data (**h**).

Liu et al. 2017 NMR Biomed

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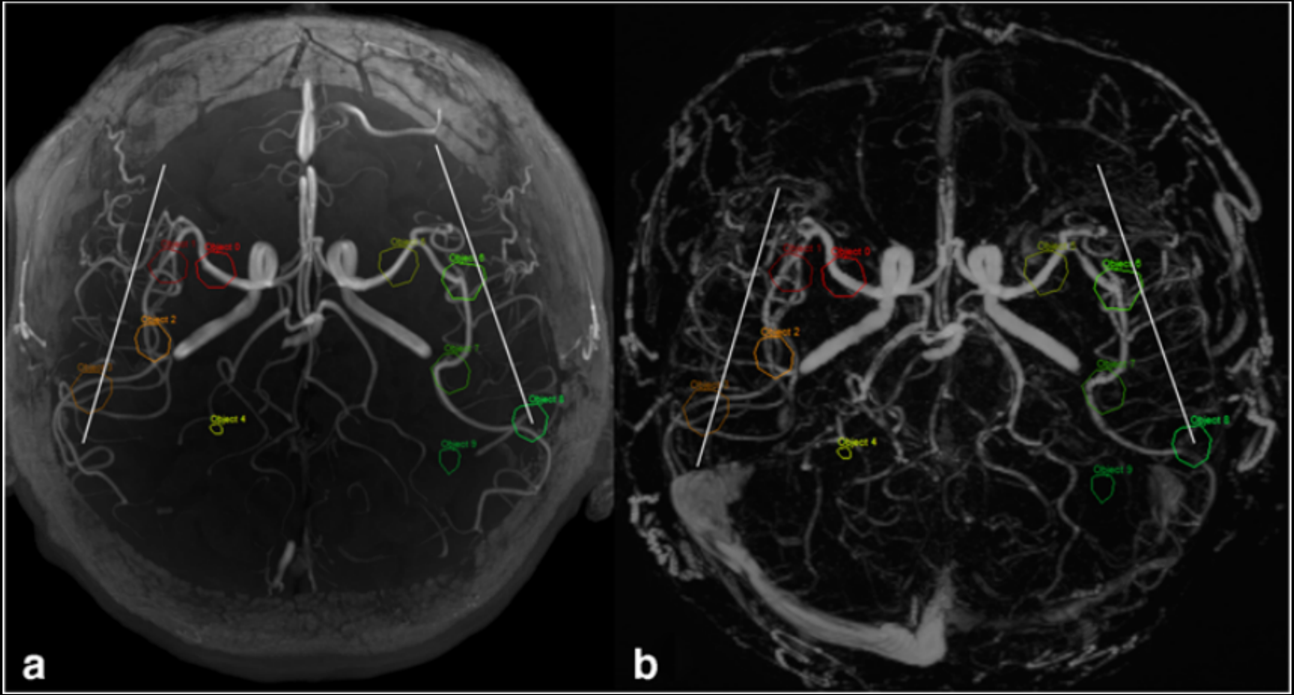
CLINICAL USE COMPARISON: STAGE-MRA AND 3D TOF MRA



- Study of 75 participants
- Uses interleaved double echo rephase / dephase STAGE MRAV.
- CNR measures of M1-4 segments and number of leptomeningeal collaterals (LMCs)
- CNRs in the M1–4 segments were significantly higher in STAGE-MRA than in TOF MRA
- When referred to digital subtraction angiography (DSA) in 25 ICAD patients, STAGE-MRA showed higher qualitative scores only at LMCs

Tang et al. European Radiology 2020

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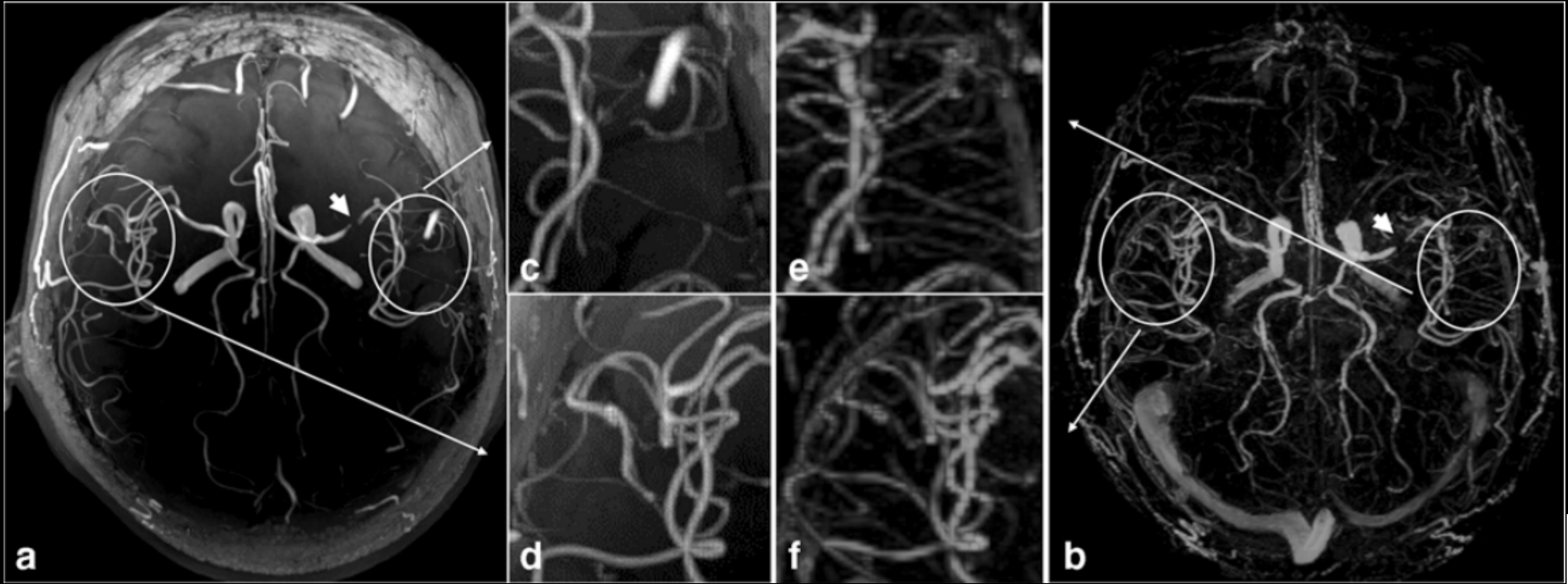
CLINICAL USE COMPARISON: STAGE-MRA AND 3D TOF MRA



"STAGE-MRA might be superior to TOF-MRA in qualitative and quantitative assessment of LMCs in both healthy volunteers and ICAD patients; thus, it may serve as an alternative method in evaluating LMC." Tang et al. European Radiology 2020

Tang et al. European Radiology 2020

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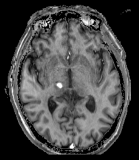
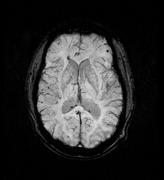
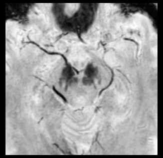
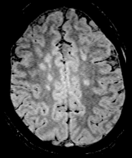
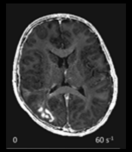
DISEASES AND CONDITIONS

DISEASE	Dementia	Stroke	TBI	Parkinson's	Multiple Sclerosis	Sturge-Weber	Tumor
BIOMARKER	Microbleeds, Volumetrics	CMB, oxygenation	CMB, venous trauma	SN Swallow Tail Neuromelanin	FLAIR/SWI Mismatch	Calcium, bleeding	Vascularization, bleeding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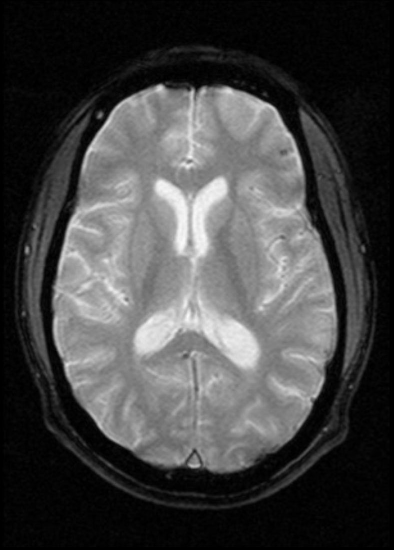
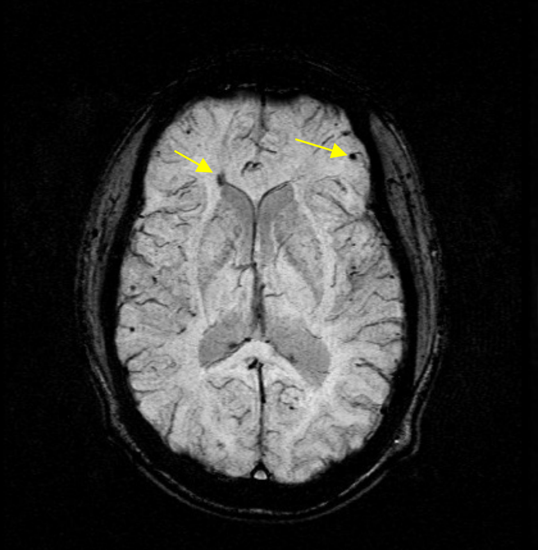
TRAUMATIC BRAIN INJURY WITH STAGE

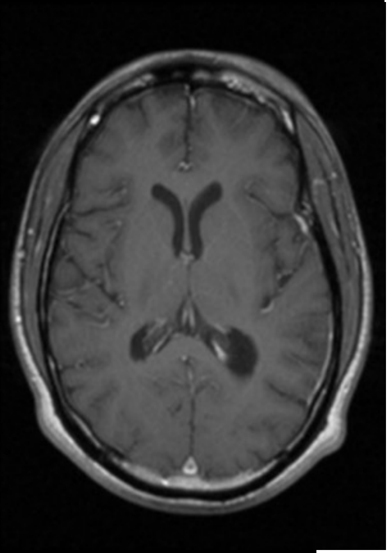
T2



STAGE SWI



T1 CE



What do we look for?

- Cerebral Microbleeds
- Shearing damage
- Subarachnoid Hemorrhage

- **STAGE SWI** clearly shows findings that conventional T2 and T1 data missed

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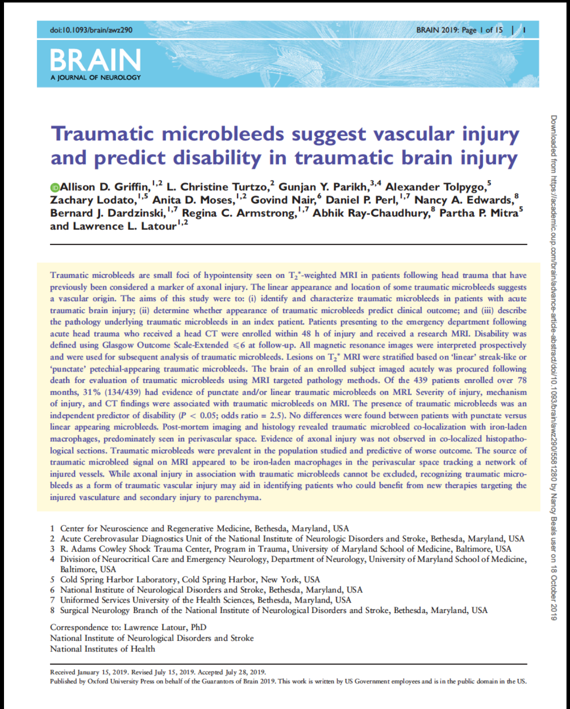
CEREBRAL MICROBLEEDS:
A PREDICTOR OF DISABILITY IN TBI

"Traumatic microbleeds suggest vascular injury and predict disability in traumatic brain injury"

-Brain, October 2019

Accurate quantification of number, size, and location of bleeds is important and proper diagnosis and treatment.



doi:10.1093/brain/awz290 BRAIN 2019: Page 1 of 15 | 1

BRAIN
A JOURNAL OF NEUROLOGY

Traumatic microbleeds suggest vascular injury and predict disability in traumatic brain injury

Allison D. Griffin,[1,2] L. Christine Turtzo,[2] Gunjan Y. Parikh,[3,4] Alexander Tolpygo,[5] Zachary Lodato,[1,5] Anita D. Moses,[1,2] Govind Nair,[6] Daniel P. Perl,[1,7] Nancy A. Edwards,[8] Bernard J. Dardzinski,[1,7] Regina C. Armstrong,[1,7] Abhik Ray-Chaudhury,[8] Partha P. Mitra[5] and Lawrence L. Latour[1,2]

Traumatic microbleeds are small foci of hypointensity seen on T_2*-weighted MRI in patients following head trauma that have previously been considered a marker of axonal injury. The linear appearance and location of some traumatic microbleeds suggests a vascular origin. The aims of this study were to: (i) identify and characterize traumatic microbleeds in patients with acute traumatic brain injury; (ii) determine whether appearance of traumatic microbleeds predict clinical outcome; and (iii) describe the pathology underlying traumatic microbleeds in an index patient. Patients presenting to the emergency department following acute head trauma who received a head CT were enrolled within 48 h of injury and received a research MRI. Disability was defined using Glasgow Outcome Scale-Extended $\leqslant 6$ at follow-up. All magnetic resonance images were interpreted prospectively and were used for subsequent analysis of traumatic microbleeds. Lesions on T_2* MRI were stratified based on 'linear' streak-like or 'punctate' petechial-appearing traumatic microbleeds. The brain of an enrolled subject imaged acutely was procured following death for evaluation of traumatic microbleeds using MRI targeted pathology methods. Of the 439 patients enrolled over 78 months, 31% (134/439) had evidence of punctate and/or linear traumatic microbleeds on MRI. Severity of injury, mechanism of injury, and CT findings were associated with traumatic microbleeds on MRI. The presence of traumatic microbleeds was an independent predictor of disability ($P < 0.05$; odds ratio = 2.5). No differences were found between patients with punctate versus linear appearing microbleeds. Post-mortem imaging and histology revealed traumatic microbleed co-localization with iron-laden macrophages, predominately seen in perivascular space. Evidence of axonal injury was not observed in co-localized histopathological sections. Traumatic microbleeds were prevalent in the population studied and predictive of worse outcome. The source of traumatic microbleed signal on MRI appeared to be iron-laden macrophages in the perivascular space tracking a network of injured vessels. While axonal injury in association with traumatic microbleeds cannot be excluded, recognizing traumatic microbleeds as a form of traumatic vascular injury may aid in identifying patients who could benefit from new therapies targeting the injured vasculature and secondary injury to parenchyma.

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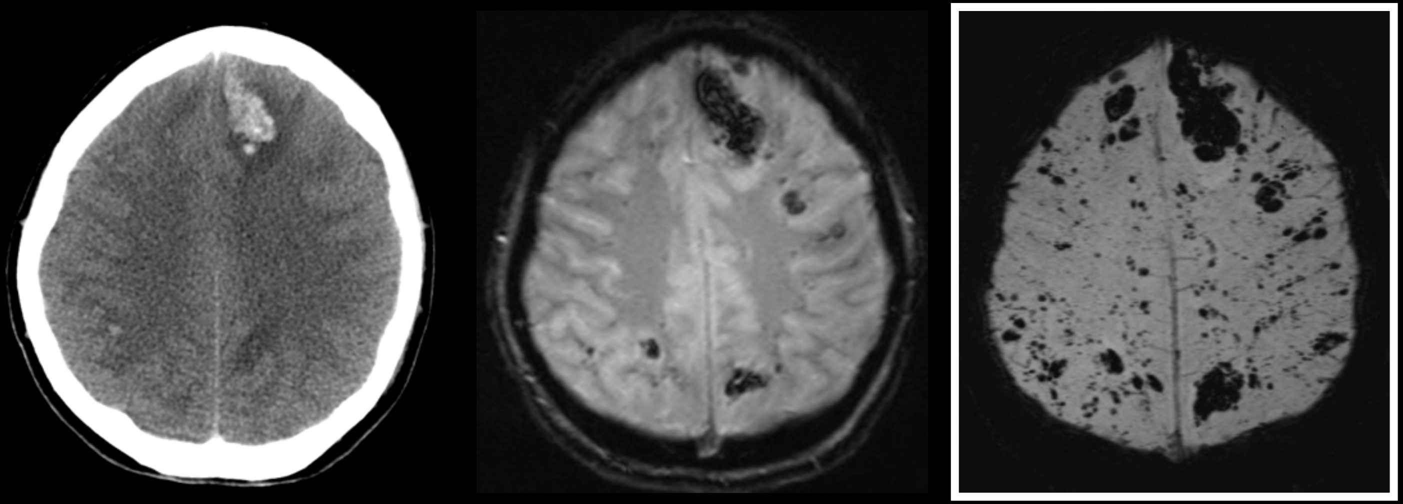
National Institute of Neurological Disorders and Stroke
National Institutes of Health

Received January 15, 2019. Revised July 15, 2019. Accepted July 28, 2019.

STAGE-SWI VS. CONVENTIONAL



Standard CT
Computerized Axial Tomography

Standard MRI
Gradient Recalled Echo

STAGE-SWI
Susceptibility Weighted Imaging

Images courtesy of Karen A. Tong, MD, Loma Linda University

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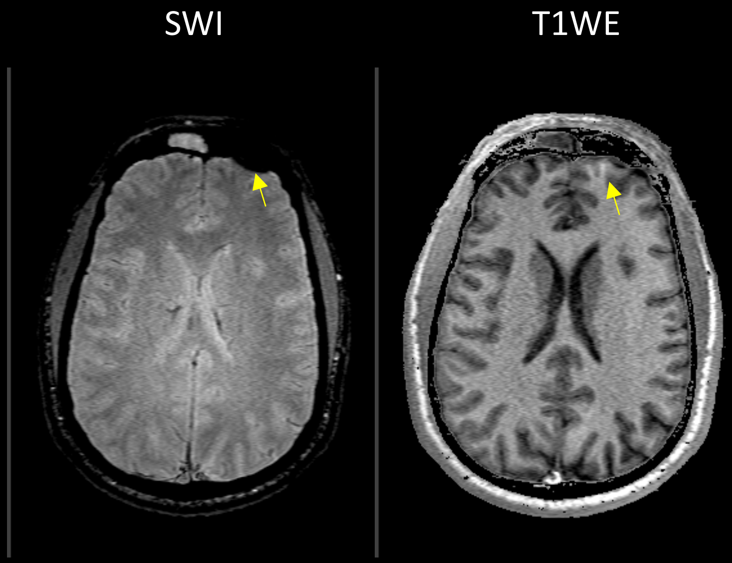
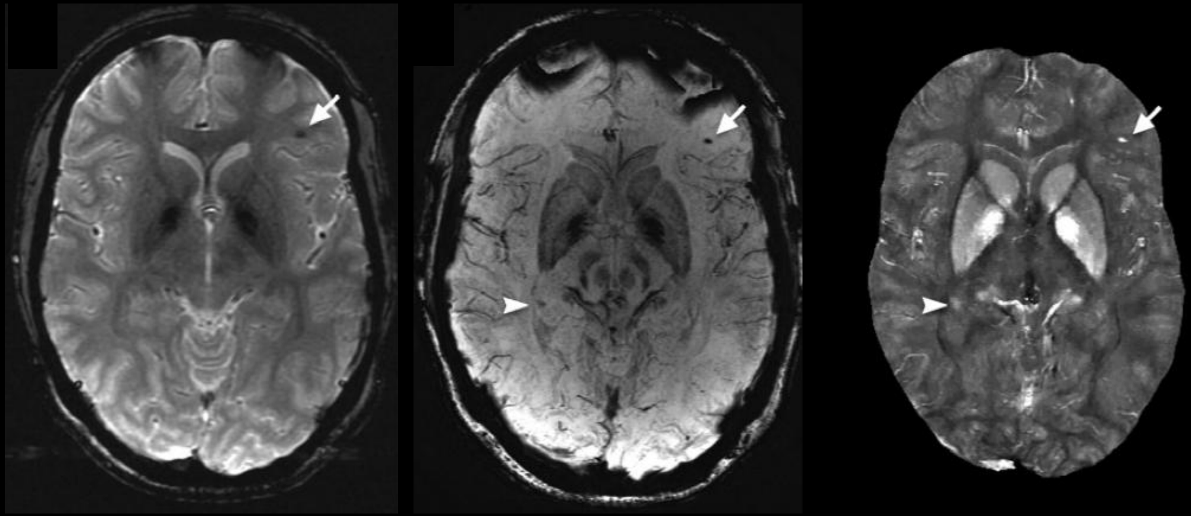
TBI: CLINICAL USE CASE



- No imaging abnormalities in original patient scan
- STAGE imaging shows signal loss in the left frontal lobe with subtle enhancement of the signal in the T1W enhanced image

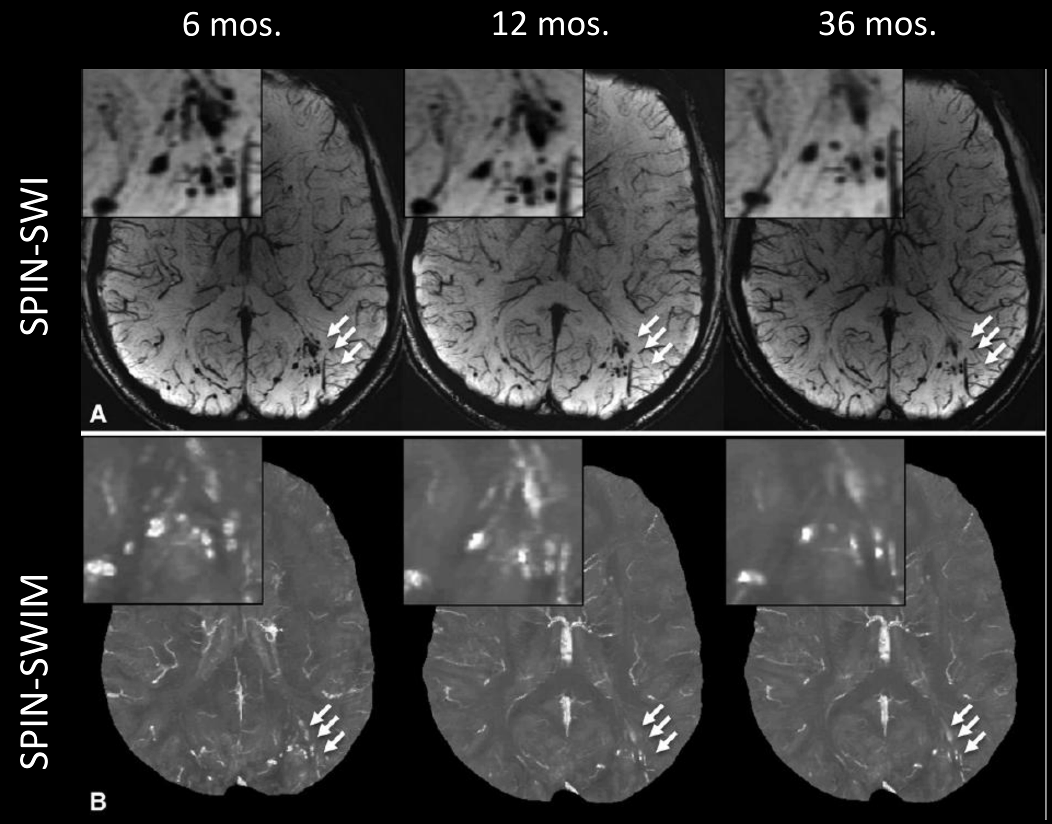
TBI: MILITARY CASE STUDY

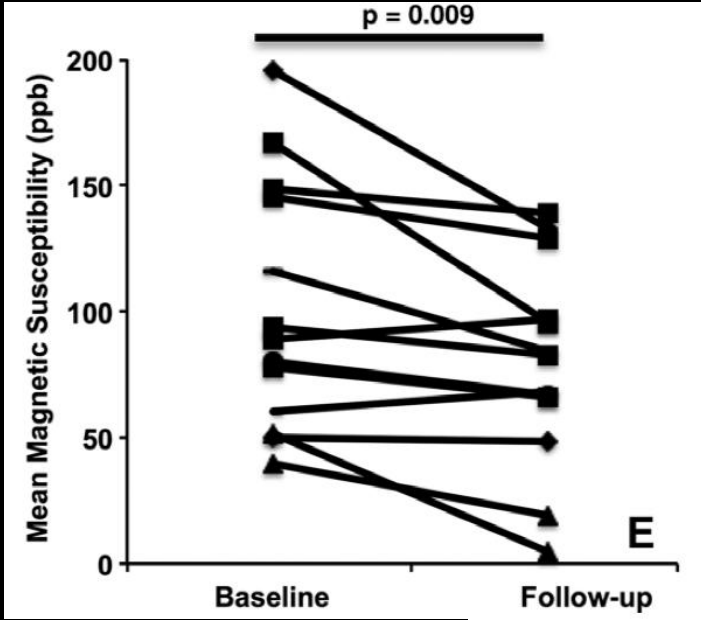
- Longitudinal study in *Radiology* evaluating cerebral microhemorrhages in a cohort of US military service members w/ chronic TBI
- *SPIN-SWI showed higher sensitivity at detecting bleeds compared to the GRE data (585 hemorrhages detected vs. 362)*



GRE SPIN-SWI SPIN-SWIM

TBI: MONITORING CMBs OVER TIME





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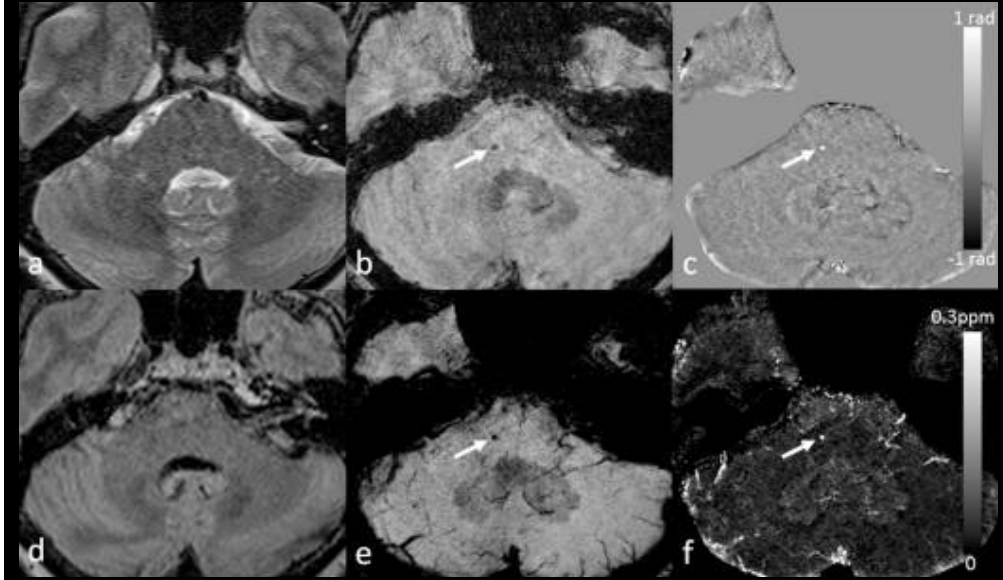
SUSCEPTIBILITY WEIGHTED IMAGING: CURRENT STATUS AND FUTURE DIRECTIONS - MICROBLEEDING



- Imaging cerebral microbleeds (CMB) using SWI and QSM. For this patient, there is a single CMB that is not visible in either T2WI (**a**) or FLAIR (**d**), but can be seen in the original magnitude (**b**) and filtered phase images (**c**) in the SWI data (white arrows). The CMB can be better visualized in the minimum intensity projection of SWI data (**e**) and the maximum intensity projection of susceptibility maps (**f**) (white arrows). The CMB appears as hypo-intense in **b** and **e**, while hyper-intense in **c** and **f**, indicating that it is paramagnetic. Note that the phase image shown in **c** was from a left-handed system. There is no connection between the CMB and vessels, as can be seen in both **e** and **f**. Susceptibility maps were generated using the geometry constrained iterative SWIM algorithm. The (effective) slice thickness is 2mm in **a**, 1.5mm in **b** and **c**, 0.5mm in **d**, 12mm in **e** and **f**.

Liu et al. 2017 NMR Biomed

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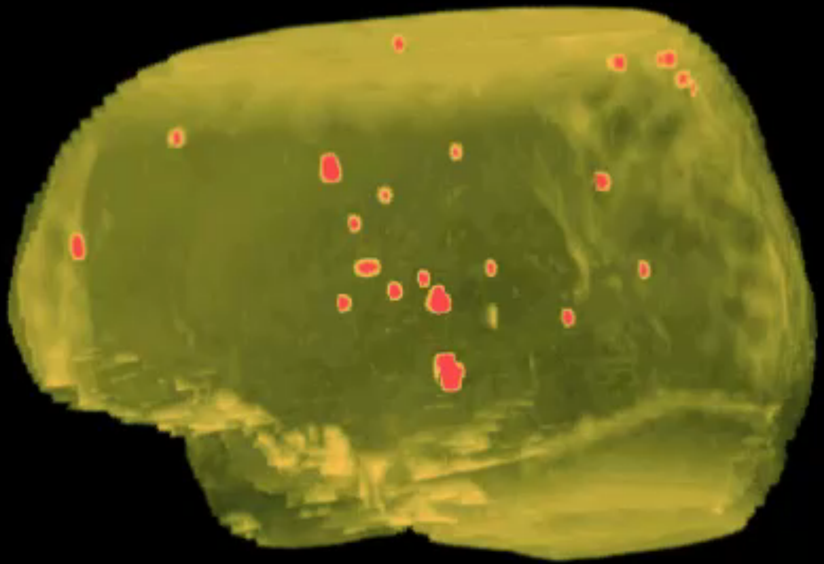
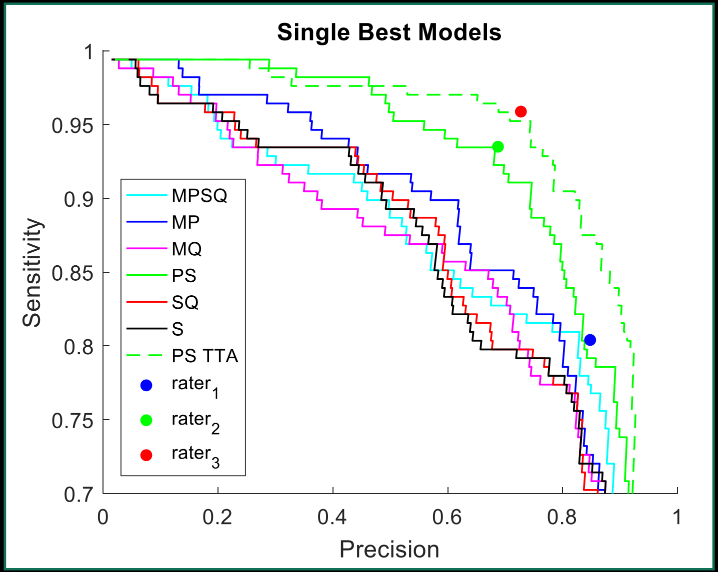
AUTOMATIC CMB DETECTION



STAGE enables automatic detection of hard to detect cerebral microbleeds that may otherwise be missed



Liu, S et al. *NeuroImage*, 2019. Sep;198:271-282.

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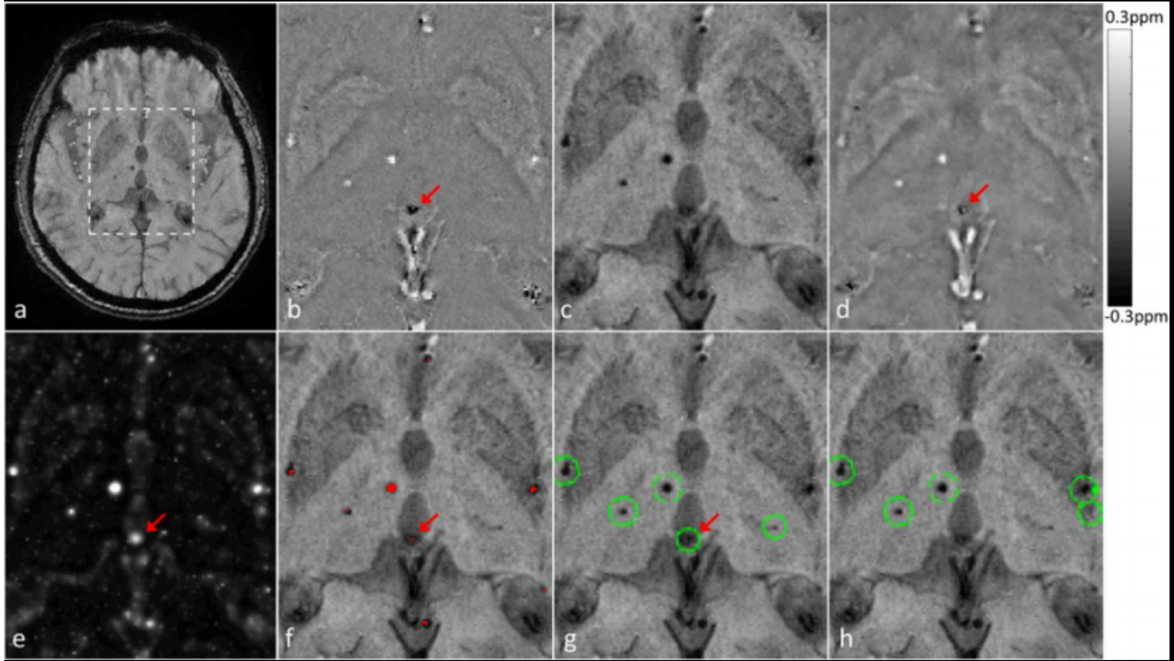
CEREBRAL MICROBLEED DETECTION USING SUSCEPTIBILITY WEIGHTED IMAGING AND DEEP LEARNING



- Differentiation of calcification from CMBs using phase and SWI images. (a) Magnitude image. (b) Phase image. The calcification (red arrow) is negative on phase images, while CMBs are positive. (c) SWI image. (d) Quantitative susceptibility map. The scale bar is for (d) only. (e) 3D-FRST transformed SWI image. (f) SWI image with detected CMB candidates (red regions). Both CMBs and calcification (red arrow) were detected. (g) The model using SWI images alone failed to eliminate the false positive caused by the calcification (red arrow). (h) The model using phase and SWI images eliminated the one false positive successfully. (b) to (h) correspond to the dashed box region in (a).

Liu et al. 2019 Neuroimage,

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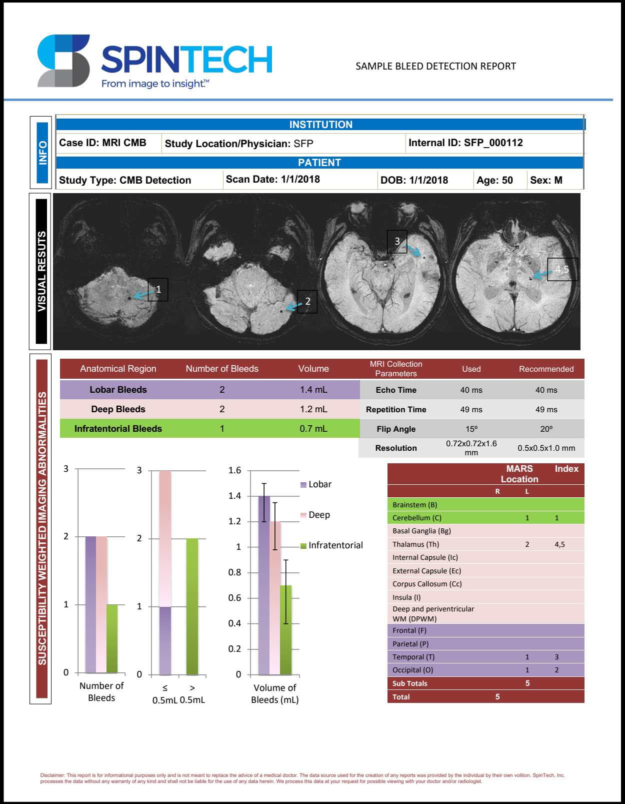
QUANTITATIVE TBI REPORTING



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SAMPLE BLEED DETECTION REPORT

INFO

INSTITUTION		
Case ID: MRI CMB	**Study Location/Physician:** SFP	**Internal ID: SFP_000112**

PATIENT				
Study Type: CMB Detection	**Scan Date: 1/1/2018**	**DOB: 1/1/2018**	**Age: 50**	**Sex: M**

VISUAL RESUTS

SUSCEPTIBILITY WEIGHTED IMAGING ABNORMALITIES

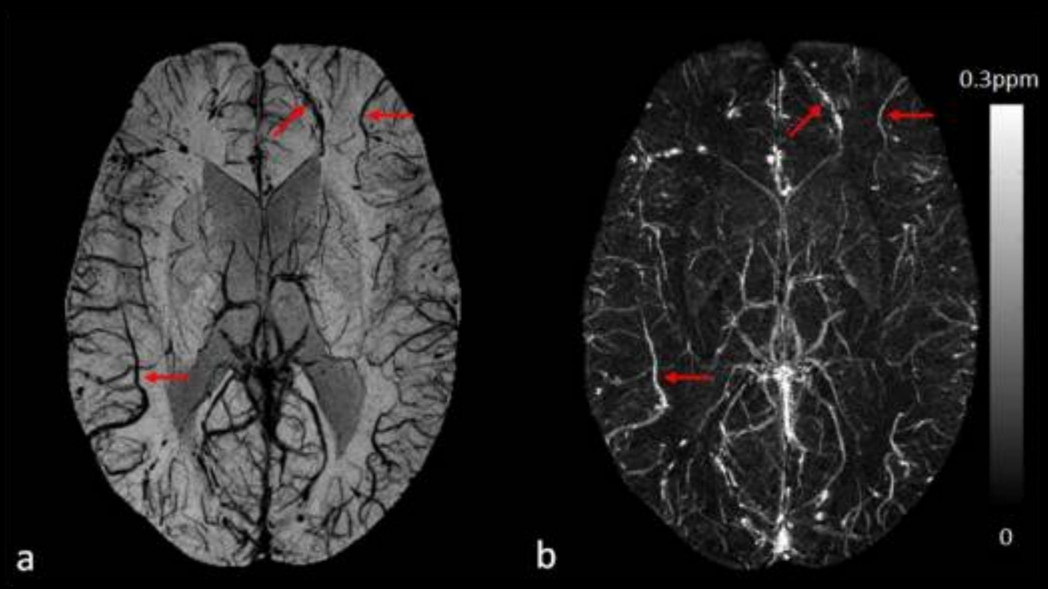
Anatomical Region	Number of Bleeds	Volume
Lobar Bleeds	2	1.4 mL
Deep Bleeds	2	1.2 mL
Infratentorial Bleeds	1	0.7 mL

MRI Collection Parameters	Used	Recommended
Echo Time	40 ms	40 ms
Repetition Time	49 ms	49 ms
Flip Angle	15º	20º
Resolution	0.72x0.72x1.6 mm	0.5x0.5x1.0 mm

	MARS Location		Index
	R	L	
Brainstem (B)			
Cerebellum (C)		1	1
Basal Ganglia (Bg)			
Thalamus (Th)		2	4,5
Internal Capsule (Ic)			
External Capsule (Ec)			
Corpus Callosum (Cc)			
Insula (I)			
Deep and periventricular WM (DPWM)			
Frontal (F)			
Parietal (P)			
Temporal (T)		1	3
Occipital (O)		1	2
Sub Totals		**5**	
Total	**5**		

- Comprehensive quantitative reporting for TBI powered by STAGE data
- Identification, quantification, and location of bleeds & venous damage

SUSCEPTIBILITY WEIGHTED IMAGING: CURRENT STATUS AND FUTURE DIRECTIONS - TBI



- Visualization and quantification of cortical veins on SWI (**a**) and QSM (**b**) in a 32-year-old male patient with diffuse axonal injury due to a traffic accident. The cortical veins near the cerebral microbleeds can be clearly seen in the frontal and parietal lobes (red arrows). Susceptibility maps were generated using the geometry constrained iterative SWIM algorithm.

Liu et al. 2017 NMR Biomed

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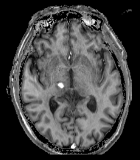
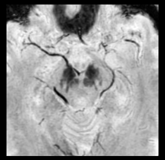
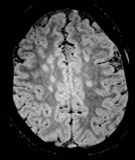
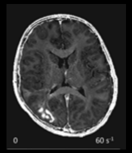
DISEASES AND CONDITIONS

DISEASE	Dementia	Stroke	TBI	Parkinson's	Multiple Sclerosis	Sturge-Weber	Tumor
BIOMARKER	Microbleeds, Volumetrics	CMB, oxygenation	CMB, venous trauma	SN Swallow Tail Neuromelanin	FLAIR/SWI Mismatch	Calcium, bleeding	Vascularization, bleeding

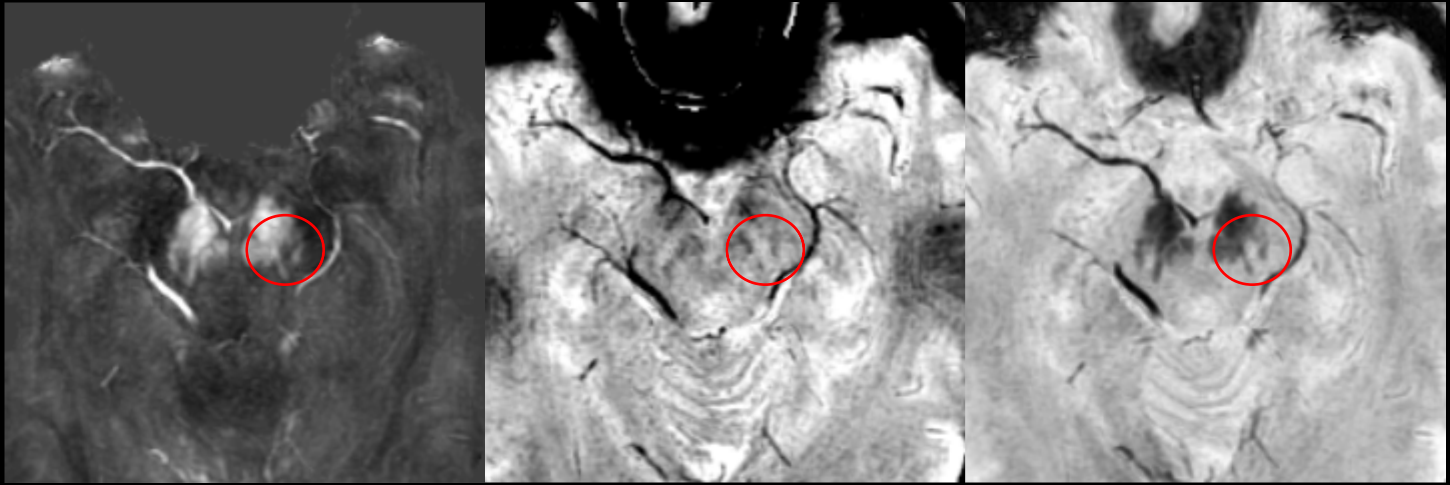




PARKINSON'S DISEASE WITH STAGE

- What do we look for?
  - Iron in the basal ganglia
  - "Swallow Tail" sign

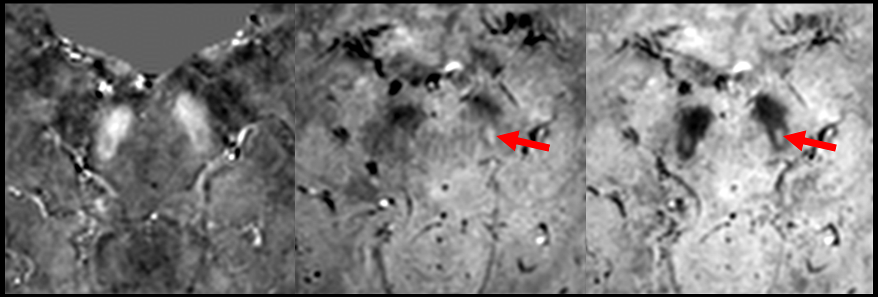
The "swallow tail" or nigrosome 1 (N1) sign in a normal individual seen with **STAGE tSWI**. Absence of the N1 sign is a potential biomarker for Parkinson's Disease.



STAGE SWIM | STAGE SWI | STAGE tSWI

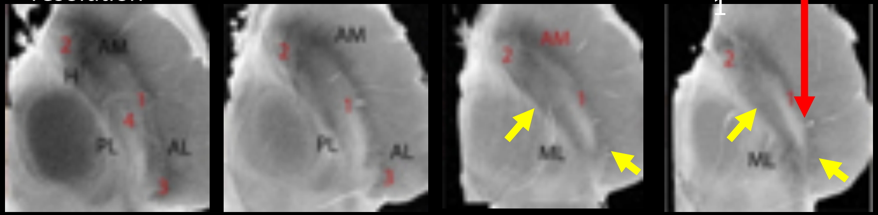
CREATING NEW BIOMARKERS WITH STAGE: IMAGING OF THE NIGROSOME 1 SIGN IN PD

QSM Magnitude tSWI



SWI 0.67mm isotropic resolution

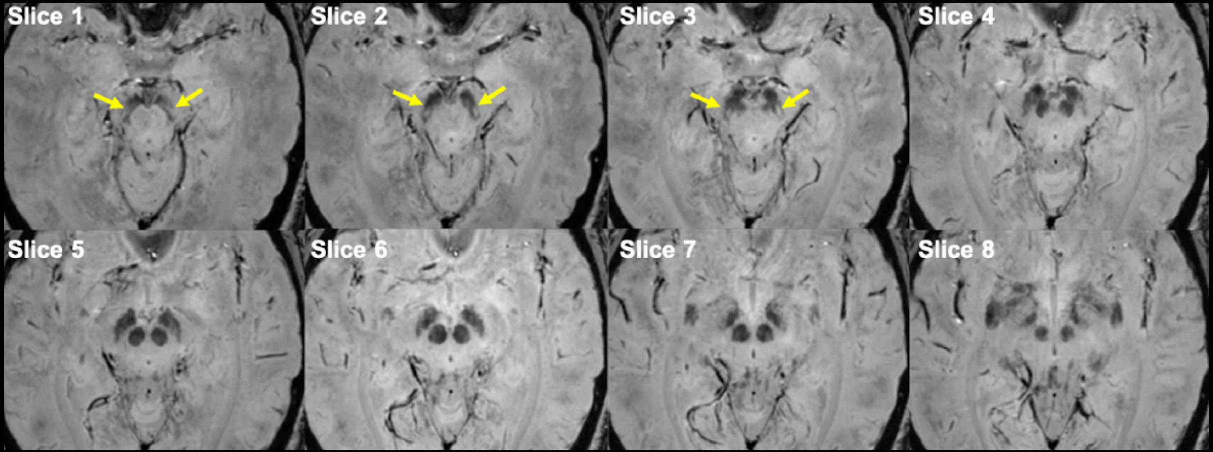
Nigrosome 1



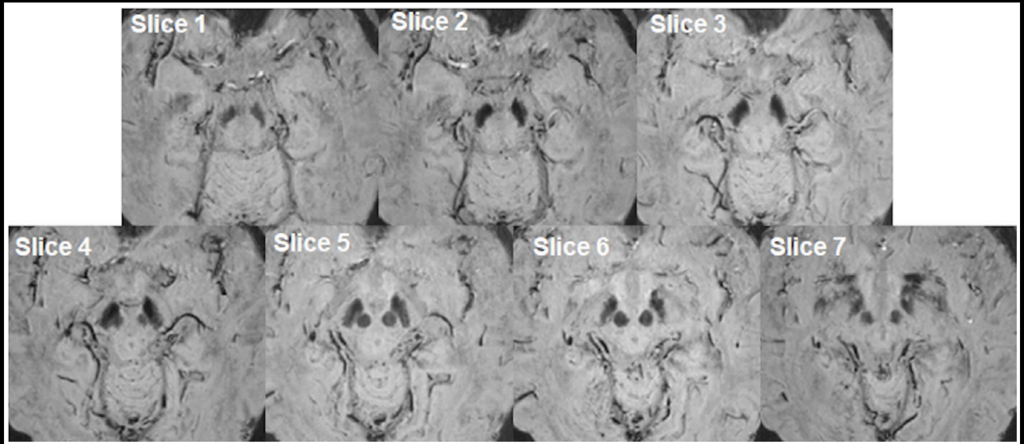
9.4T cadaver brain imaging from: L.A. Massey et al. NeuroImage: Clinical 13:154;2017

SN FROM CAUDAL TO CRANIAL TO THE STN

HC



PD



Cheng et al., *NeuroImage Clinical, 2020*

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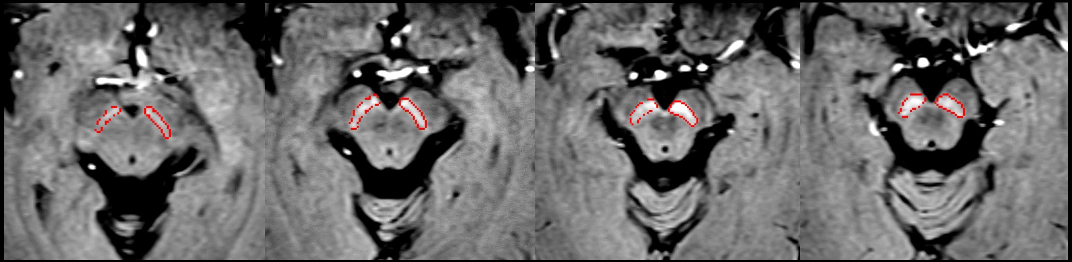
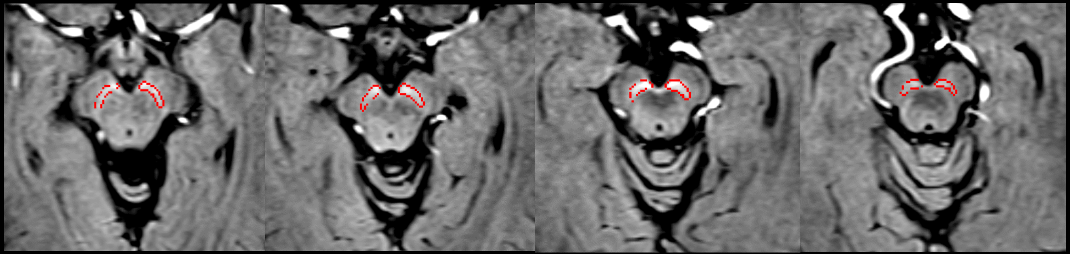
NEUROMELANIN LOSS CORRELATES WITH PARKINSON'S DISEASE

Cranial → Caudal slices
Red ROIs: Neuromelanin traced on MTC magnitude

Normal control

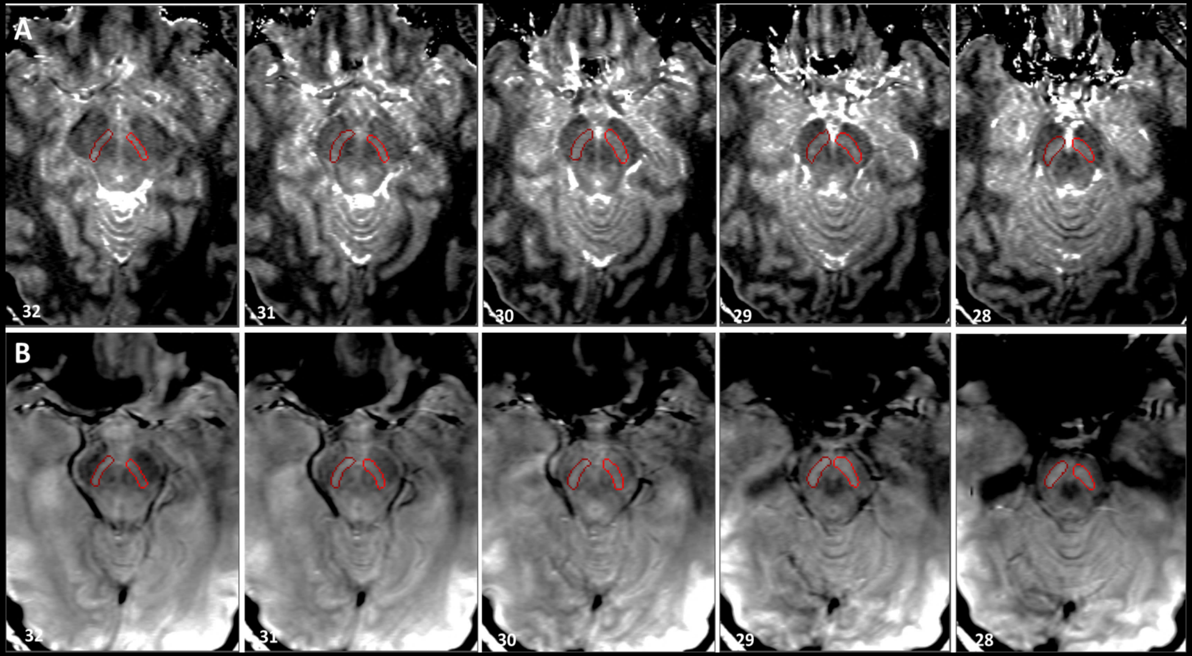


PD case



A 25-50% loss of NM is expected even in early PD.

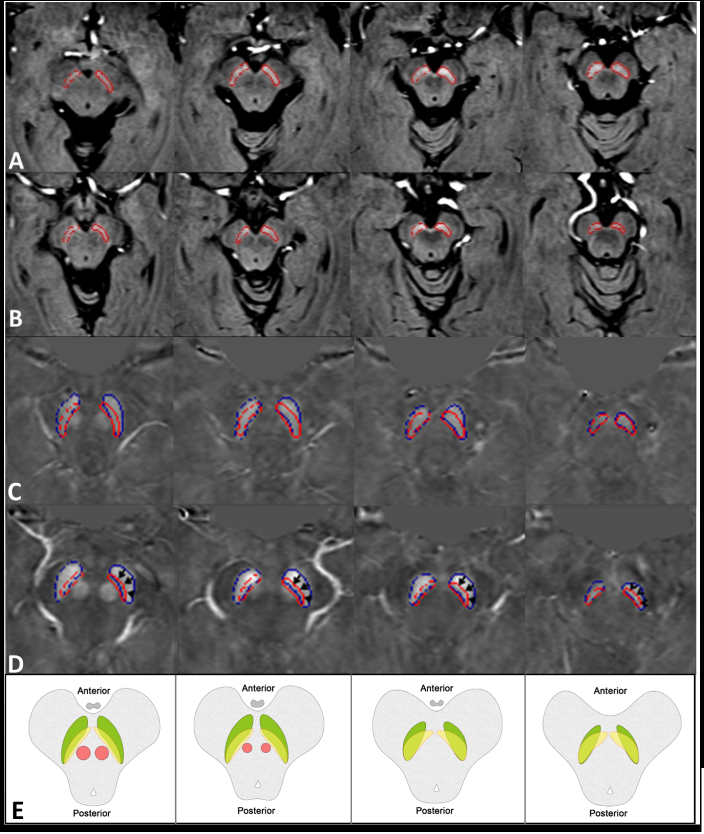
STAGE: CREATING KEY NEW CONTRASTS
CAN PSD MAPS REPLACE MTC?



3D regions of interest representing neuromelanin content on proton density maps (A) and MTC images (B) in the midbrain of a healthy control, with more than 85% overlap between the two datasets.
The images start cranially at the top of the red nucleus and proceed caudally to just under the red nucleus.

NEUROMELANIN/IRON OVERLAP IN THE SN CORRELATES WITH THE PRESENCE OF PD

- Cranial → Caudal slices
- Red ROIs: Neuromelanin traced on MTC magnitude
- Blue ROIs: SN-Iron drawn on QSM from the MTC phase data
- NM and SN tracings superimposed on the MTC-QSM data for a normal (A,C) and a PD (B,D) case
- The overlapping regions indicate SNpc anatomical location.
- PD will show significantly less overlap between NM and Iron.
- Neuromelanin overall and overlapping volume loss in the ventral lateral tier of the SNpc in PD (arrow heads in D)



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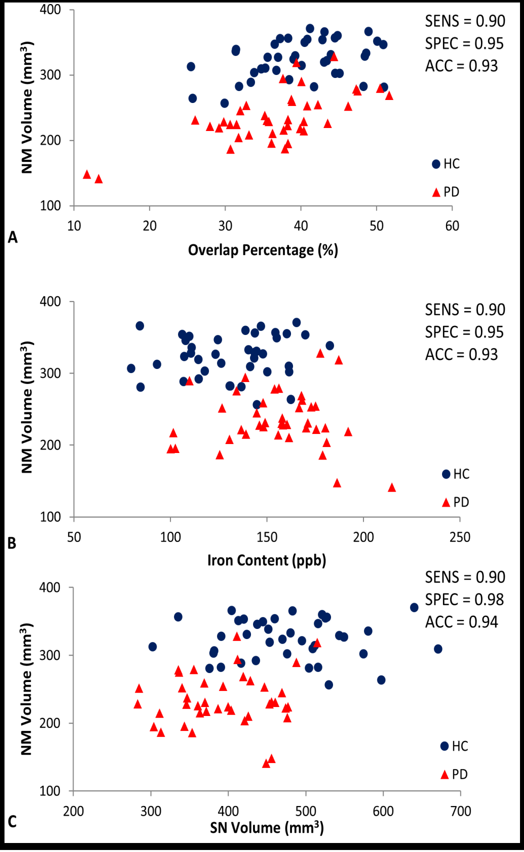
NEUROMELANIN/IRON OVERLAP IN THE SN CORRELATES WITH THE PRESENCE OF PD

- Figures showing neuromelanin volume as a function of SN volume, SN iron content and the normalized overlap percentage in 40 HC and 40 early PD cases.
- The NM provides the best single parameter differentiating normal and PD cohorts.
- Integration of NM and other parameters can provide a new set of biomarkers with superior diagnostic accuracy in early PD



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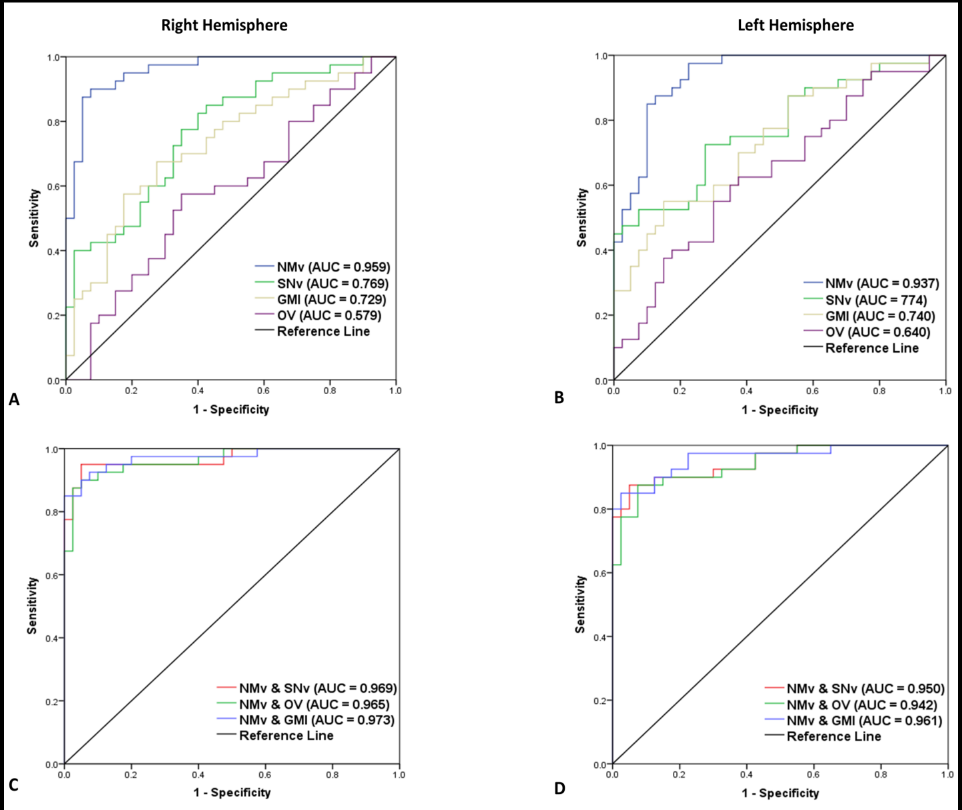
ROC FOR IRON, NM VOLUME AND IRON/NM OVERLAP VOLUME



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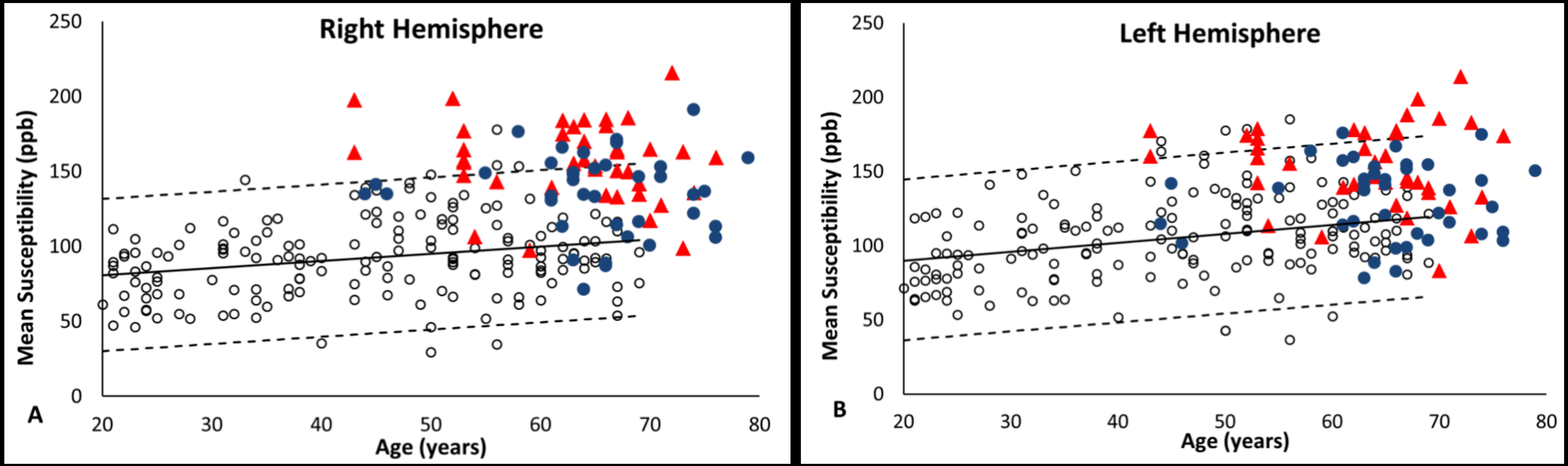
SN IRON IN PD COMPARED TO NORMATIVE DATABASE



CIRCLES = CONTROLS, TRIANGLES = PD

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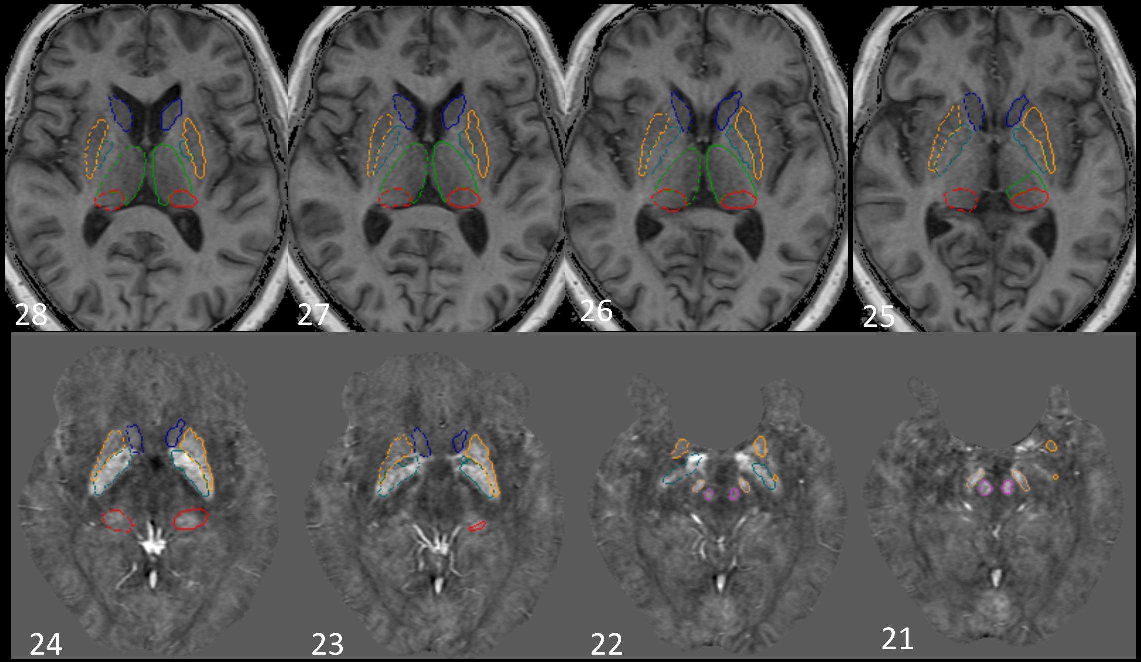
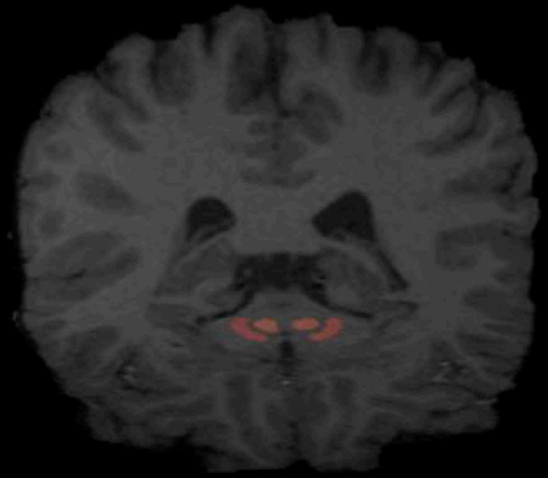
AUTO-SEGMENTATION OF DGM FOR PD



Automatic segmentation of deep grey matter combined with auto-iron quantification allows for accurate quantitative reporting of iron deposition in the substantia nigra

AUTO-DGM SEGMENTATION IN ACTION



- Enhanced contrast STAGE images allow for precise DGM segmentation
- Enables accurate iron quantification by region for measurement of PD progression
- Helpful for precise implantation of Deep Brain Stimulation devices for therapy

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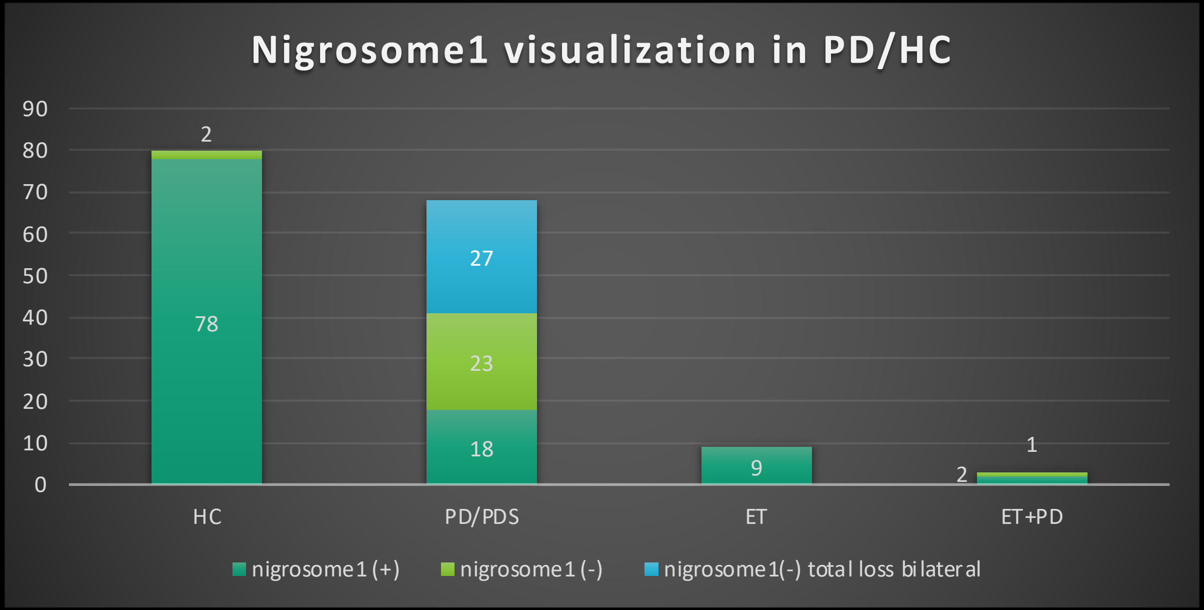
Initial Analysis of 80 HCs and 80 PDs



Nigrosome1 (+) implies >=2 continuous slices showing STS/LOOP;
Nigrosome1 (-) in red implies <=1 slice showing STS/LOOP;
Nigrosome1 (-) in green implies total loss of N1 bilaterally

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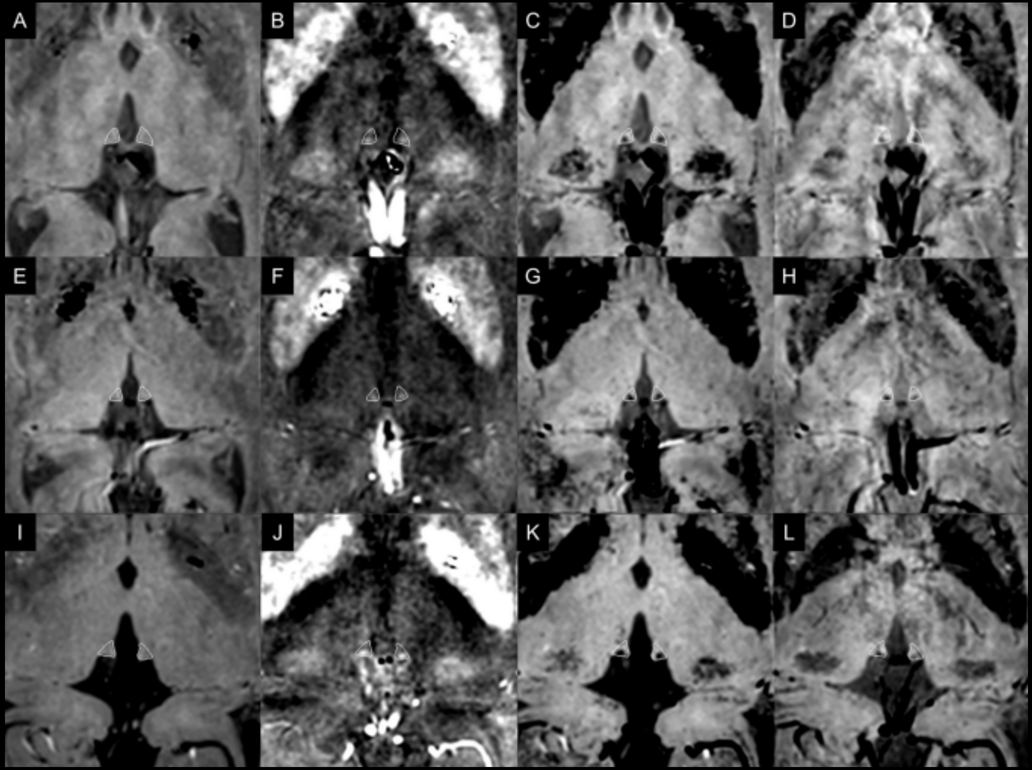
MR Imaging of DBS Candidate Targets: Lateral Habenula



- Examples of the traced Lateral Habenula (Lhb) denoted by the white boundaries on the TE1 magnitude images (A, E, I). Image resolution: 0.67 mm × 0.67 mm × 1.34 mm. Increased contrast in the Lhb is depicted in quantitative susceptibility mapping (QSM) (B, F, J), true susceptibility weighted imaging (tSWI) (C, G, K), and susceptibility weighted imaging (SWI) (D, H, L).

He and Sethi, et. al, *MRI 2019*

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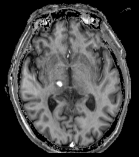
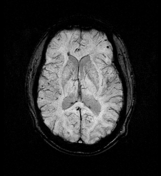
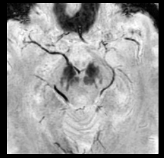
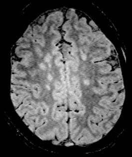
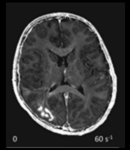
DISEASES AND CONDITIONS

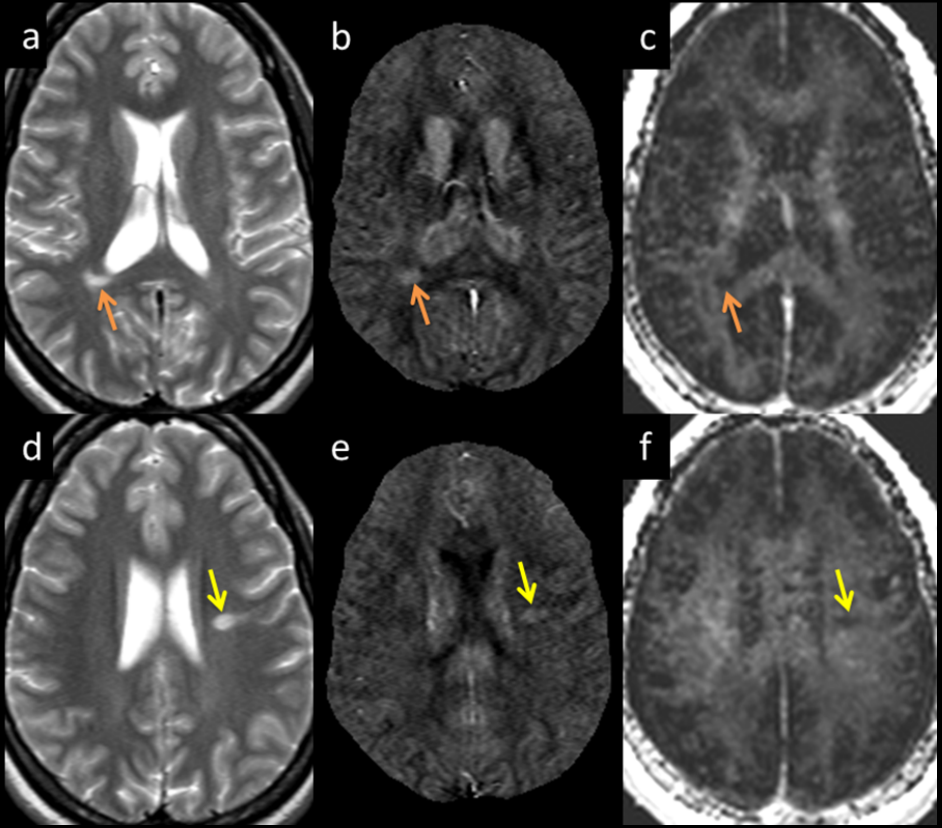
DISEASE	Dementia	Stroke	TBI	Parkinson's	Multiple Sclerosis	Sturge-Weber	Tumor
BIOMARKER	Microbleeds, Volumetrics	CMB, oxygenation	CMB, venous trauma	SN Swallow Tail Neuromelanin	FLAIR/SWI Mismatch	Calcium, bleeding	Vascularization, bleeding


MS LESION APPEARANCE

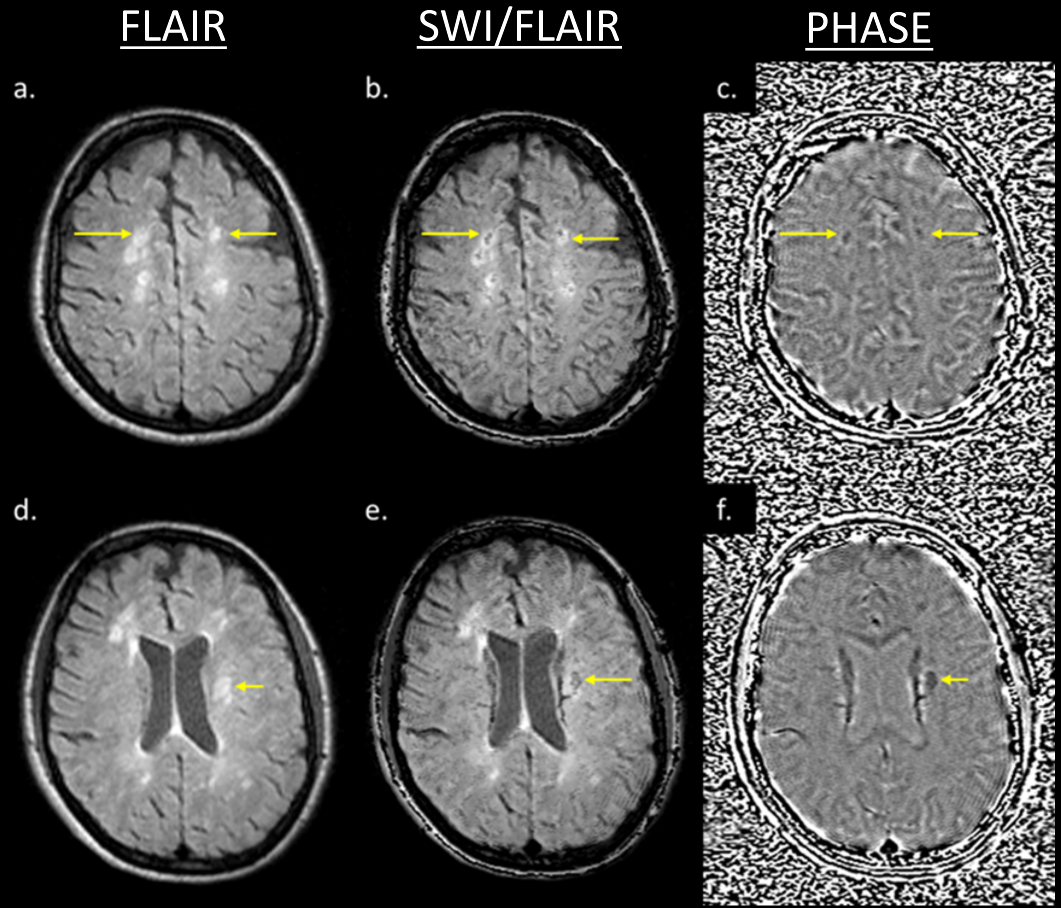
- SWIM provides superior lesion contrast, in agreement with MWF
- SWIM provides enhanced resolution in a fraction of the acquisition and processing time

T2 SWIM MWF



MS LESION APPEARANCE

SWI-FLAIR Contrast provides differentiation of inflammatory vs. demyelinating lesion

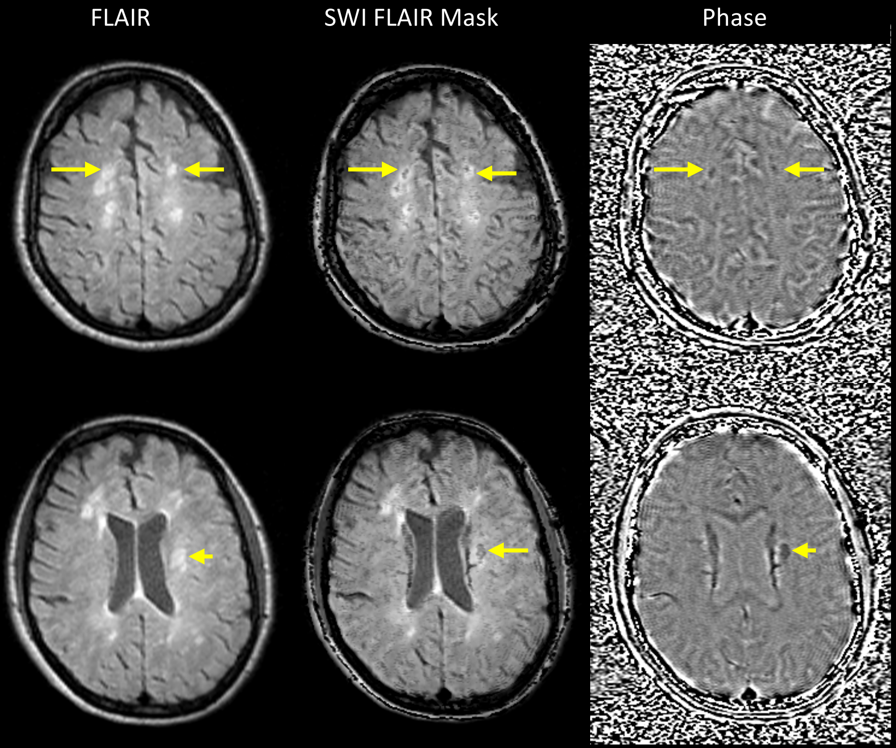


DIFFERENTIATING MS LESIONS WITH FLAIR-SWI

Note that the FLAIR-SWI image has dark regions where there is putative demyelination.

Where there are no black holes in the lesions, this may be early stage inflammation only without demyelination.

That is our hypothesis.



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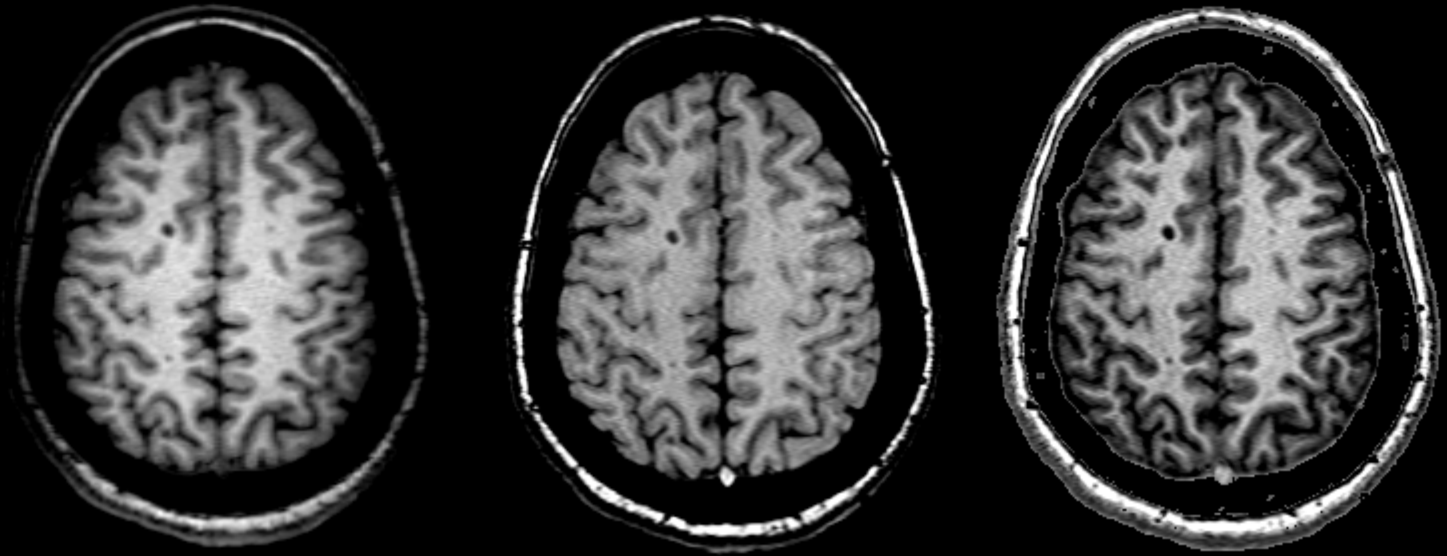
MS LESIONS T1W v. STAGE T1W T1We



T1W

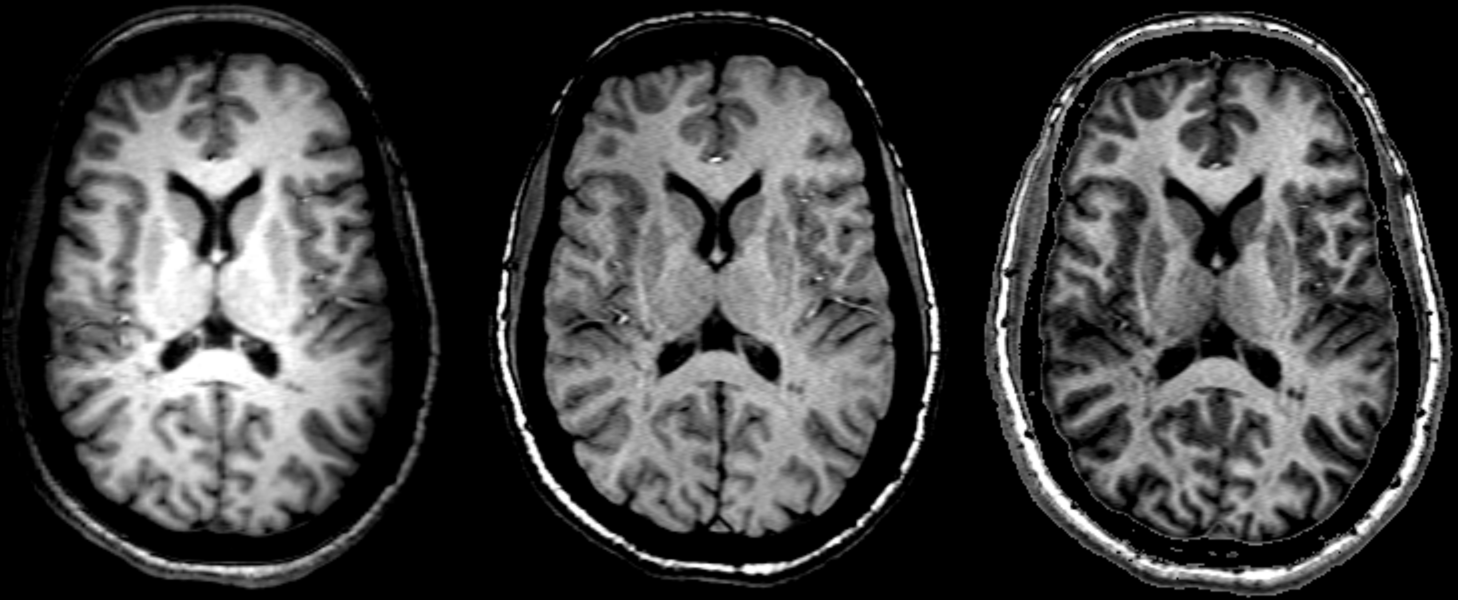
STAGE T1W

STAGE
T1We

Scaling the window level to match as closely as possible shows that STAGE T1W and T1We are equivalent in their ability to differentiate NAWM, GM, and lesion tissue. The STAGE T1We may offer additional contrast to identify the correct boundary between tissues and lesions.

Haacke et al. 2019 submitted manuscript.

MS LESIONS T1W v. STAGE T1W T1We



a) T1W

b) STAGE T1W

c) STAGE T1We

With the same window level settings as previous slide, the inhomogeneity of the conventional T1W can be seen. STAGE T1W and T1We are bias-field corrected, ensuring that the window level is kept consistent and the structures appear without the need for rescaling between slices. Further enhancement is also seen for WM/GM contrast and Lesion/NAWM contrast within the T1We.

Haacke et al. 2019 submitted manuscript.

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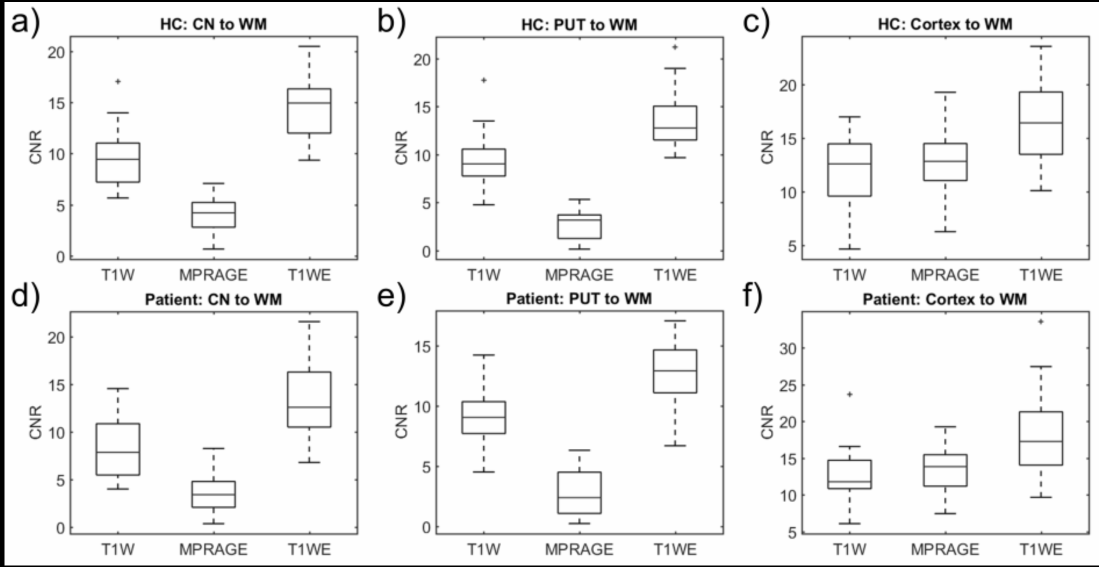
STAGE Imaging, Part III: Technical Advances and Clinical Applications of A Rapid Multi-Contrast Multi-Parametric Brain Imaging Method



CNR comparison among conventional T1W from a GRE scan, MPRAGE and STAGE T1WE at 3T measured over 67 HC and 67 PD patients. Compared to T1W and MPRAGE, STAGE T1WE had significantly improved CNR for CN, PUT and cortex

Haacke et al. 2019 MRI, Accepted in Production

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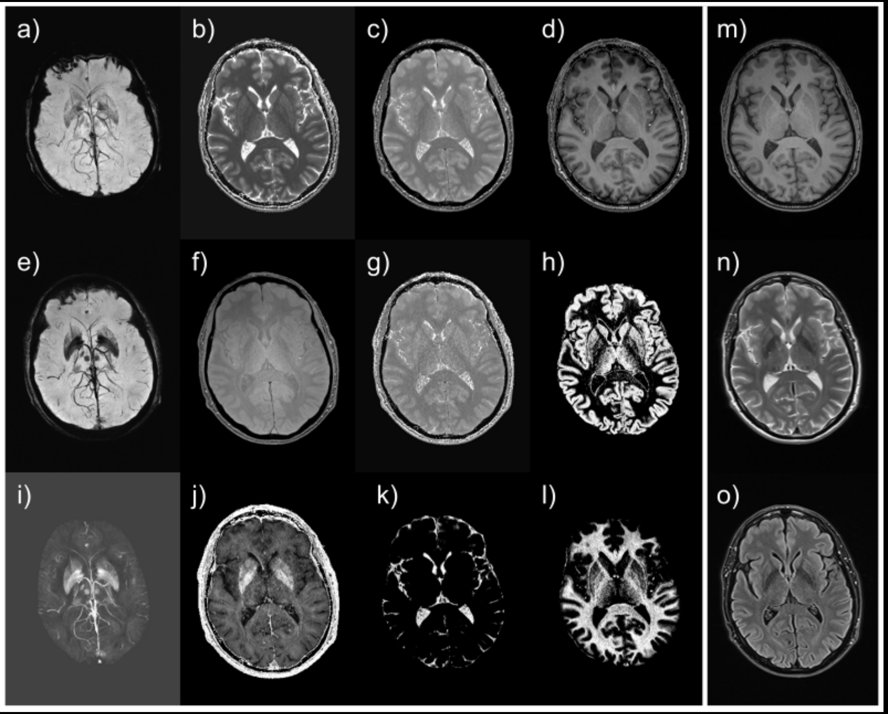
STAGE Imaging, Part III: Technical Advances and Clinical Applications of A Rapid Multi-Contrast Multi-Parametric Brain Imaging Method



Comparison between STAGE and conventional MRI on a 67-year old male healthy control subject scanned with the double-echo version of STAGE on a 3T scanner. Images in the left panel (al) were from STAGE taking 5 minutes with a spatial resolution of 0.67 x 1.34 x 2.0 mm^3 and 64 slices covering the whole brain. Images in the right panel (m-o) were from conventional MRI providing only T1, T2 and FLAIR in 5.5 min with the same resolution and coverage. a) SWI; b) T1 map; c) PSD map; d) T1WE; e) tSWI; f) PDW; g) tPSD map; h) sDIR-GM; i) QSM; j) R2* map; k) sDIR-CSF; l) sDIRWM; m) T1-MPRAGE; n) T2 TSE; o) T2 FLAIR. The images for SWI, tSWI and QSM were minimum/maximum intensity projections with an effective slice thickness of 16 mm.

Haacke et al. 2019 MRI, Accepted in Production

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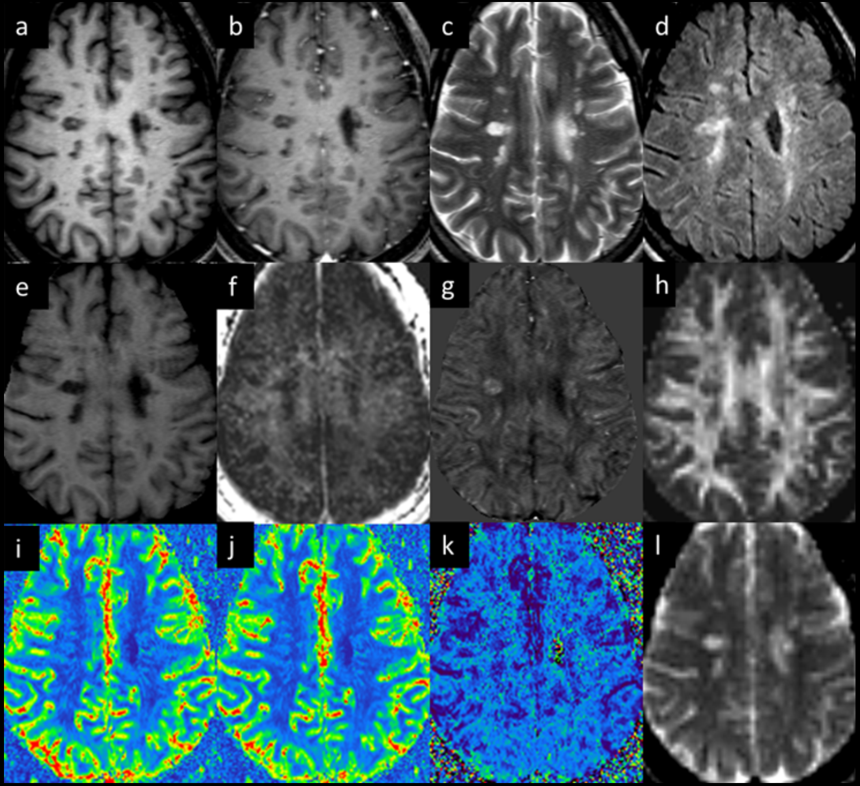
A Comparison Of MRI Methods to Assess MS Lesions: Implications for Patient Characterization and Clinical Trial Design



- Lesion appearance in different modalities: (a) pre-contrast T1W, (b) post-contrast T1W, (c) T2W, (d) T2 FLAIR, (e) MTR, (f) MWF, (g) QSM, (h) FA, (i) CBV, (j) CBF, (k) MTT, and (l) ADC.
- STAGE collected in combination with advanced white matter quantification sequences in order to better understand imaging biomarkers for MS.

Haacke et al. 2019, Submitted Manuscript

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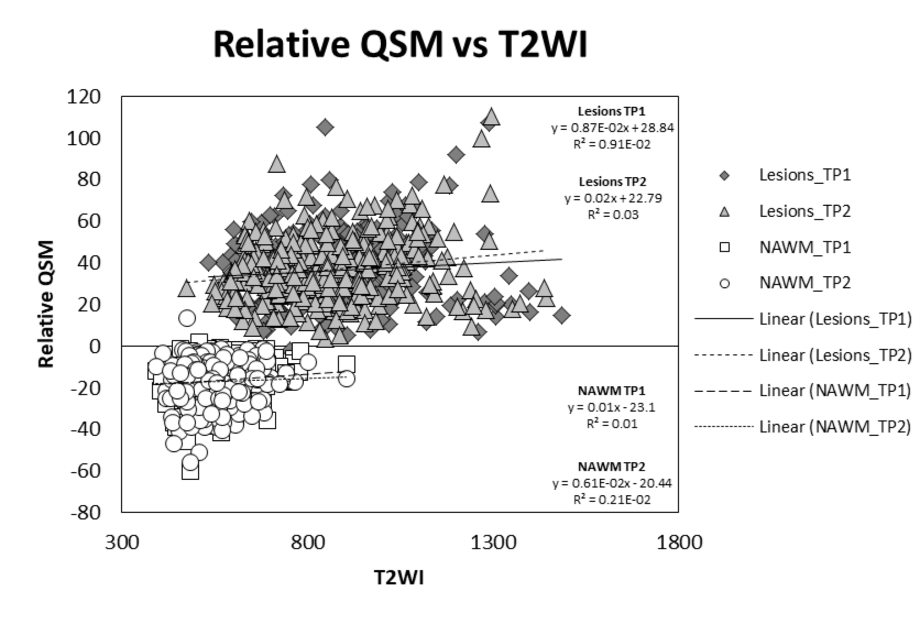
A Comparison Of MRI Methods to Assess MS Lesions: Implications for Patient Characterization and Clinical Trial Design



- Relative QSM versus T2WI. There appears to be a mild linear dependence suggesting increased water content corresponds to increasing susceptibility (but perhaps also related to increased demyelination).

Haacke et al. 2019, Submitted Manuscript

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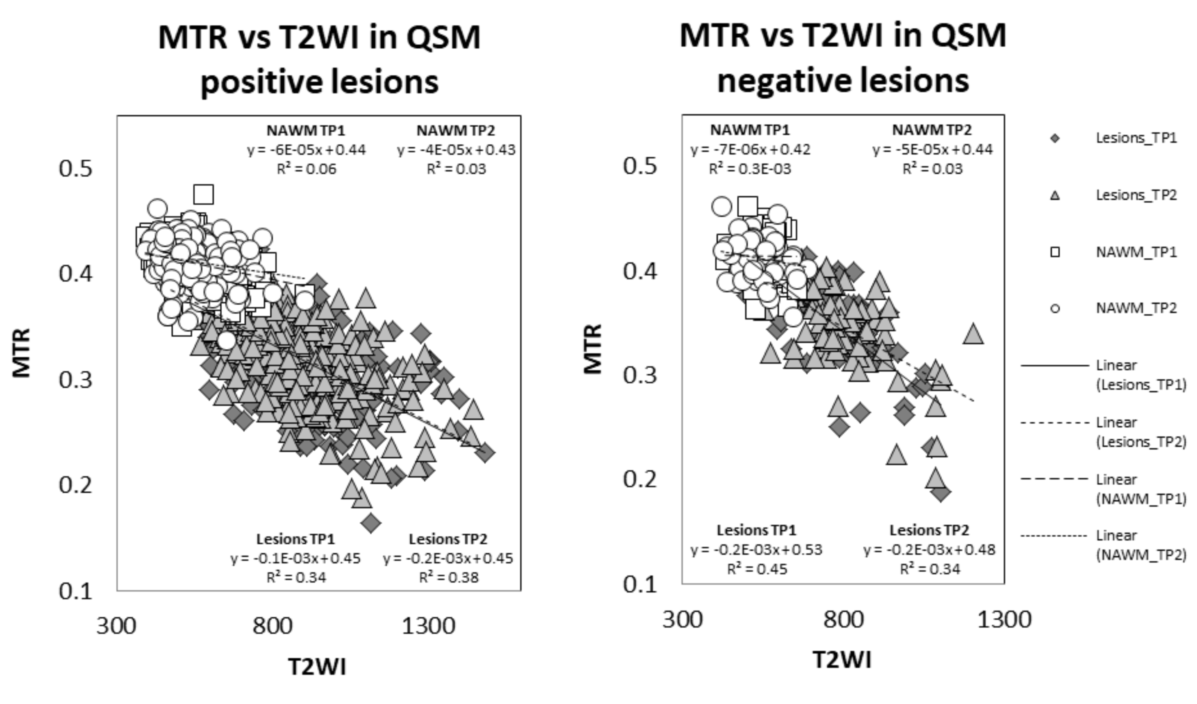
A Comparison Of MRI Methods to Assess MS Lesions: Implications for Patient Characterization and Clinical Trial Design



- MTR appears to correlate strongly with T2 suggesting that water content is the key driver to these changes. However, many of the QSM negative lesions still have high MTR suggesting less demyelination compared to the range of values seen with QSM positive lesions.

Haacke et al. 2019, Submitted Manuscript

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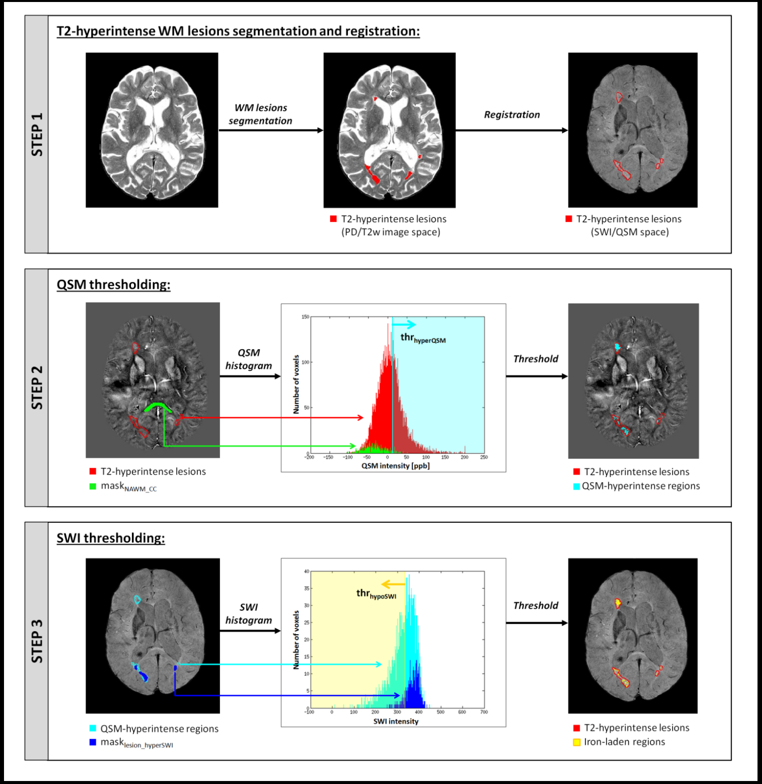
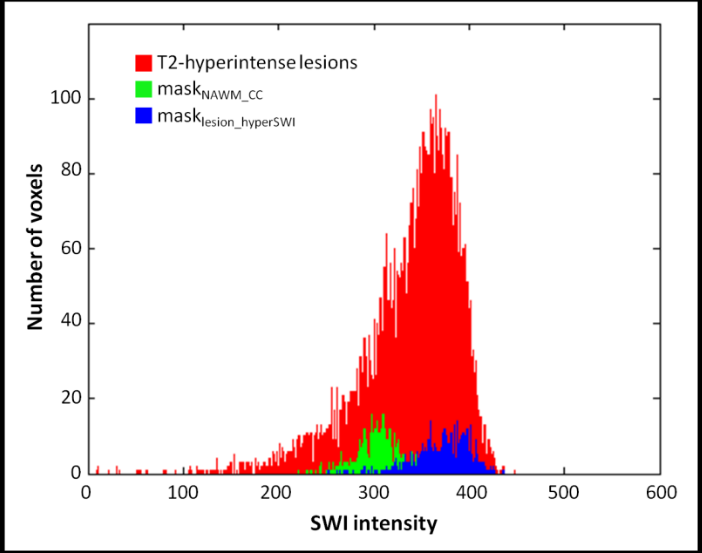
Semi-automatic detection of putative iron laden regions in MS white matter lesions on SWI and QSM data at 1.5T



Pipeline for the semi-automatic detection of putative iron-laden regions. T2-hyperintense lesions were segmented on PD/T2-weighted images and registered to SWI/QSM space (panel STEP 1, in red). Then, QSM thresholding was performed within the T2-hyperintense lesion mask (panel STEP 2, in red), to obtain the mask of QSM- hyperintense regions (panel STEP 2, in cyan). The lower threshold for QSM thresholding - thr_{hyper_QSM} (panel STEP 2, vertical cyan line) - was defined as the 95^{th} percentile of the QSM intensity distribution within $mask_{NAWM\_CC}$ (panel STEP 2, in green). Finally, SWI images were thresholded within the QSM- hyperintense regions, to detect the putative iron-laden regions (panel STEP 3, in yellow). The upper threshold for SWI thresholding - $thr_{hypoSWI}$ (panel STEP 3, vertical yellow line) - was defined as the 25^{th} percentile of the SWI intensity distribution within $mask_{lesion\_hyperSWI}$ (panel STEP 3, in blue).

Pelizzari et al. 2019 submitted manuscript.

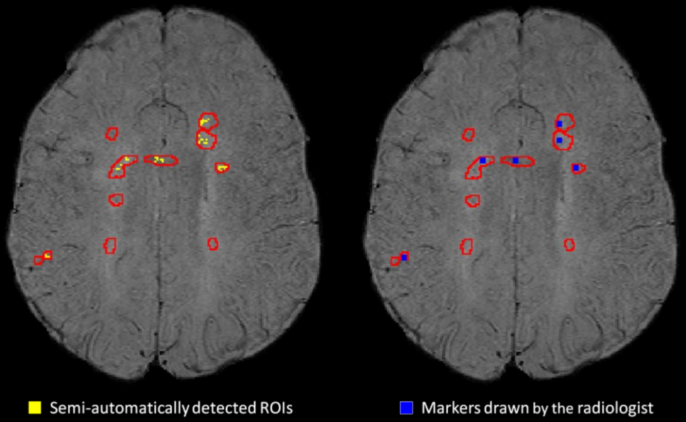
Semi-automatic detection of putative iron laden regions in MS white matter lesions on SWI and QSM data at 1.5T



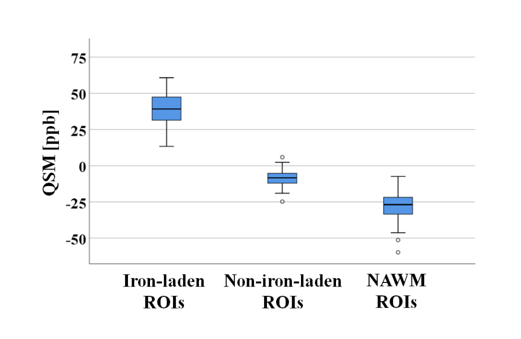
SWI histogram within T2-hyperintense WM lesions, mask$_{NAWM_CC}$ and mask$_{lesion_hyperSWI}$. The majority of the voxels within the T2-hyperintense WM lesions (in red) has higher intensities with respect to NAWM (in green) due to demyelination. To reduce the probability of false negatives in detecting putative iron-laden regions, thr$_{hypoSWI}$ was set according to the intensity distribution within mask$_{lesion_hyperSWI}$ (in blue).

Pelizzari et al. 2019 submitted manuscript.

Semi-automatic detection of putative iron laden regions in MS white matter lesions on SWI and QSM data at 1.5T



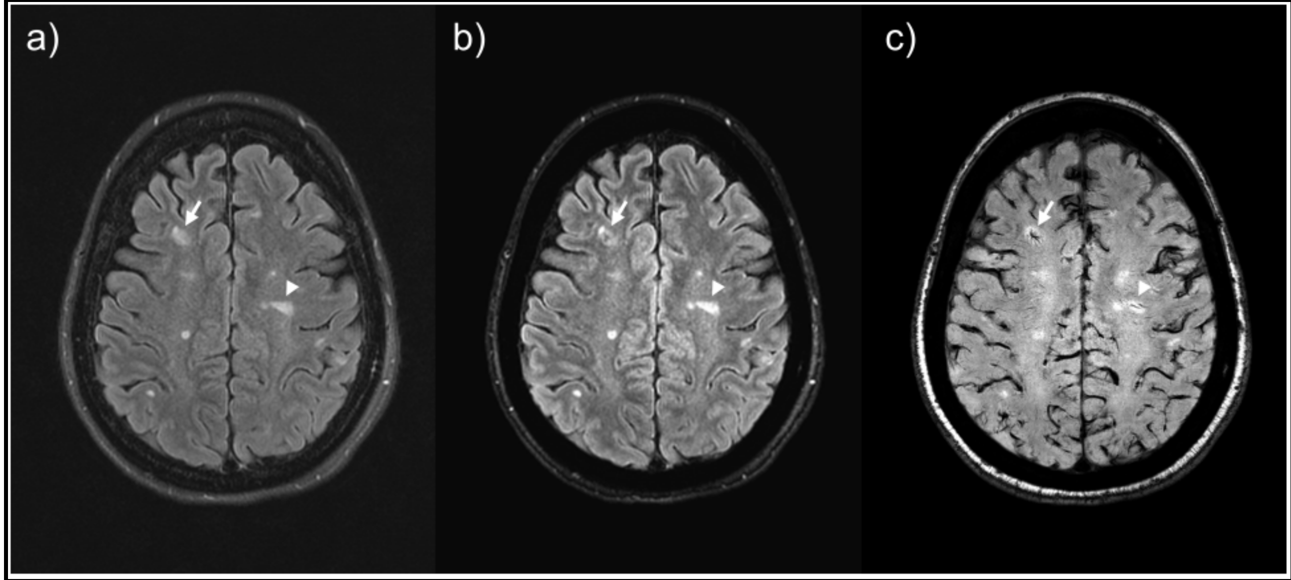
Method validation. Putative iron-laden regions detected with the semi-automatic method (in yellow, on the left) and markers of WM lesions presenting with iron deposits set by the radiologist (in blue, on the right).



Group QSM values within putative iron-laden ROIs, non-iron-laden ROIs and within the NAWM ROI. Putative iron-laden ROIs are characterized by higher QSM values compared to non-iron-laden ROIs and NAWM.

Pelizzari et al. 2019 submitted manuscript.

STAGE Imaging, Part III: Technical Advances and Clinical Applications of A Rapid Multi-Contrast Multi-Parametric Brain Imaging Method



Representative tSWI-FLAIR in patient with MS. Multiple WMH lesions are shown on the T2 weighted FLAIR (a) data. By combining the tSWI derived from STAGE, the tSWI-FLAIR (b) had suppressed signal at the center of one WMH lesion (arrows). With the presence of an iron-based contrast agent (Ferumoxytol), the contrast enhanced tSWI-FLAIR (c) presented not only the central vein sign (arrow-head) but also a small venous angioma that clearly delineates the region of inflammation (arrow). The use of Ferumoxytol enhanced tSWIFLAIR could help the study of WMH origins.

Haacke et al. 2019 MRI, Accepted in Production

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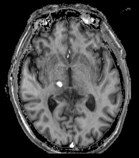
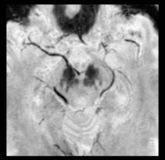
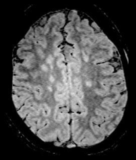
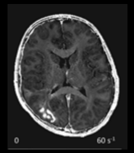
DISEASES AND CONDITIONS

DISEASE	Dementia	Stroke	TBI	Parkinson's	Multiple Sclerosis	Sturge-Weber	Tumor
BIOMARKER	Microbleeds, Volumetrics	CMB, oxygenation	CMB, venous trauma	SN Swallow Tail Neuromelanin	FLAIR/SWI Mismatch	Calcium, bleeding	Vascularization, bleeding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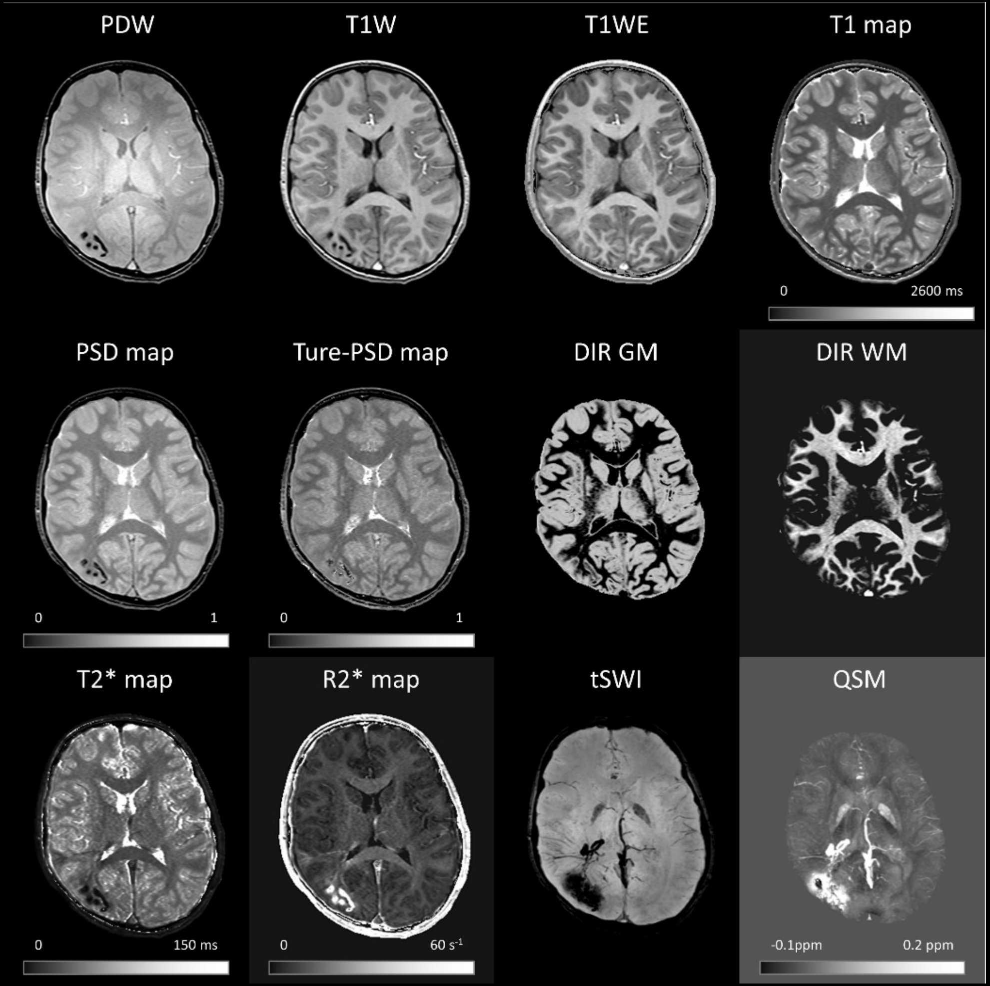

[1] Chen, et al., ISMRM 2019, p3021, May 14, 2019, Montreal, CA

STAGE at 3T for a child with Sturge Weber Syndrome

Eliminates need for contrast agent.

No CT required for differentiating bleeds from calcifications.

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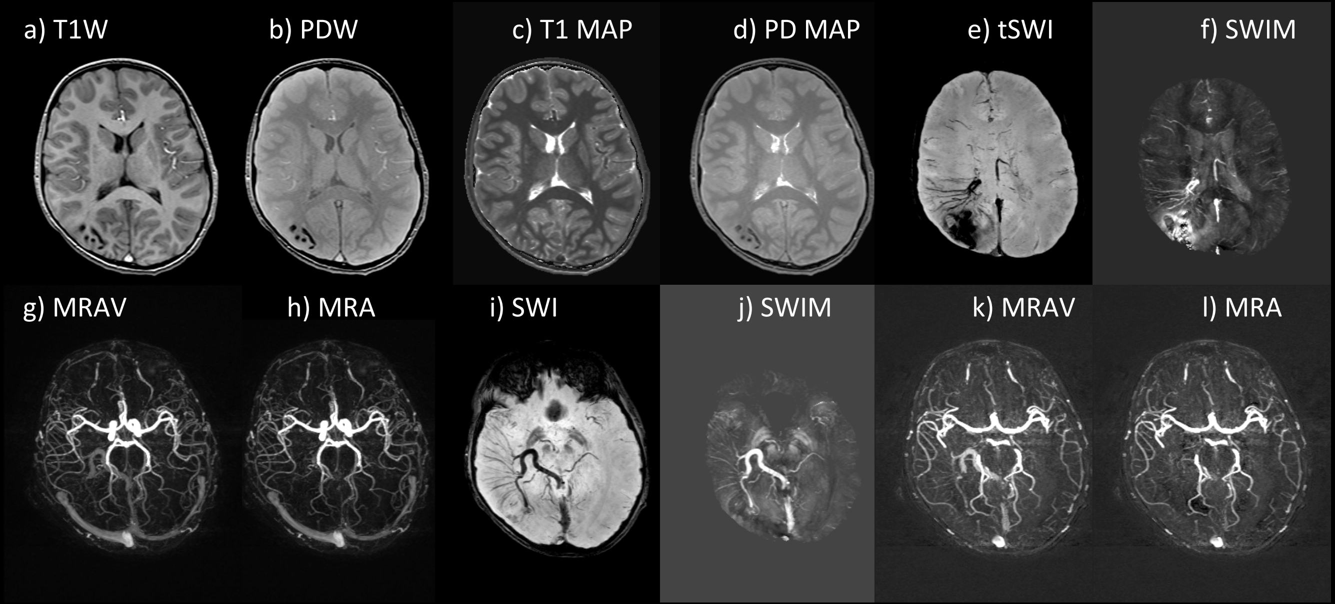
STAGE APPLICATION: STURGE-WEBER



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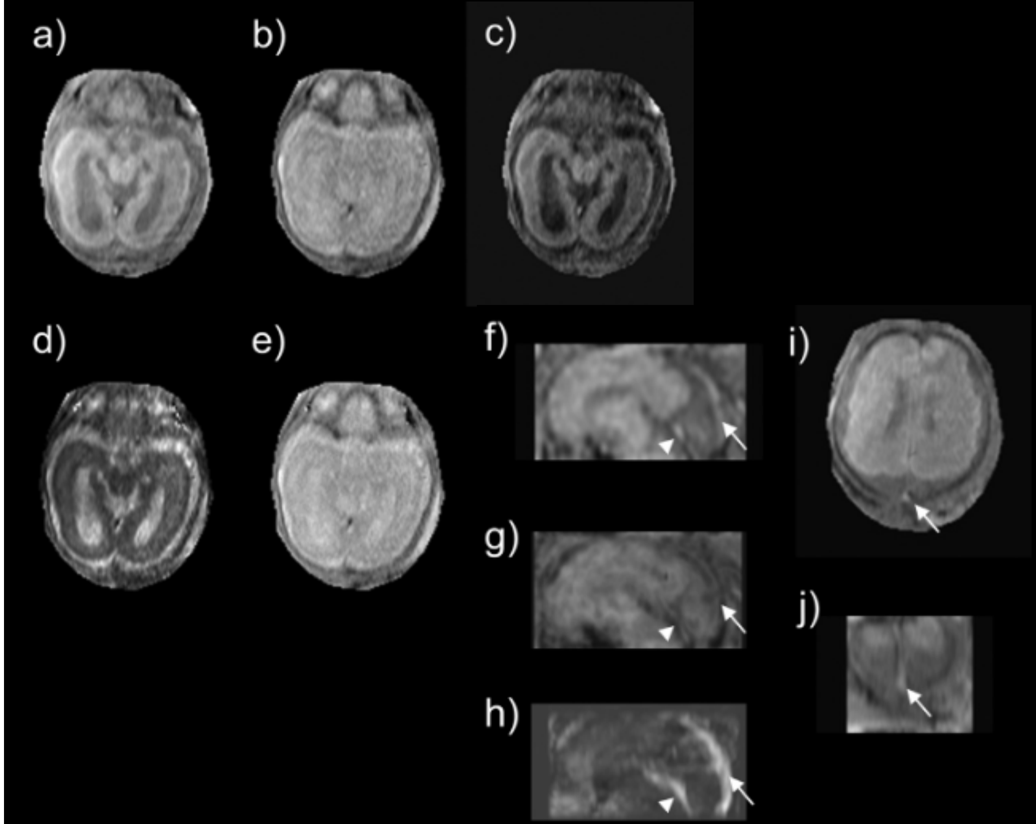
Fetal Brain Imaging



- STAGE for fetal brain imaging (28-week gestational age, ventriculomegaly) using 2D acquisitions. a) T1W (FA = 75o); b) PDW (FA = 15o); c) T1WE; d) T1map; e) PSD map; f), i) and j) are T1W images in sagittal view, axial view and coronal view; g) and h) were the minimum/maximum intensity projection of SWI (g)and QSM (h) with effective slice thickness of 15 mm showing the superior sagittal sinus (arrow) and straight sinus (arrow head). Images in this figure were cropped from the original images of the mother.

Haacke, EM, et al. *Mag. Res. Imaging,* 2020. Jan; 65:15-26

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Fetal Brain Imaging

Fetal Images: Playing Checkers or GO

Hmmm: “What’s my next move?”

29 weeks: Image courtesy of Drs. Mody and Hernandez and the WSU perinatal MRI team

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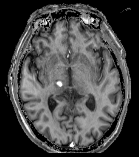
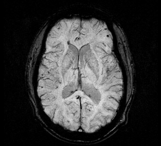
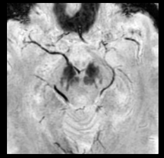
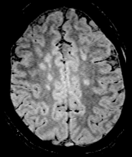
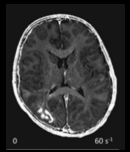
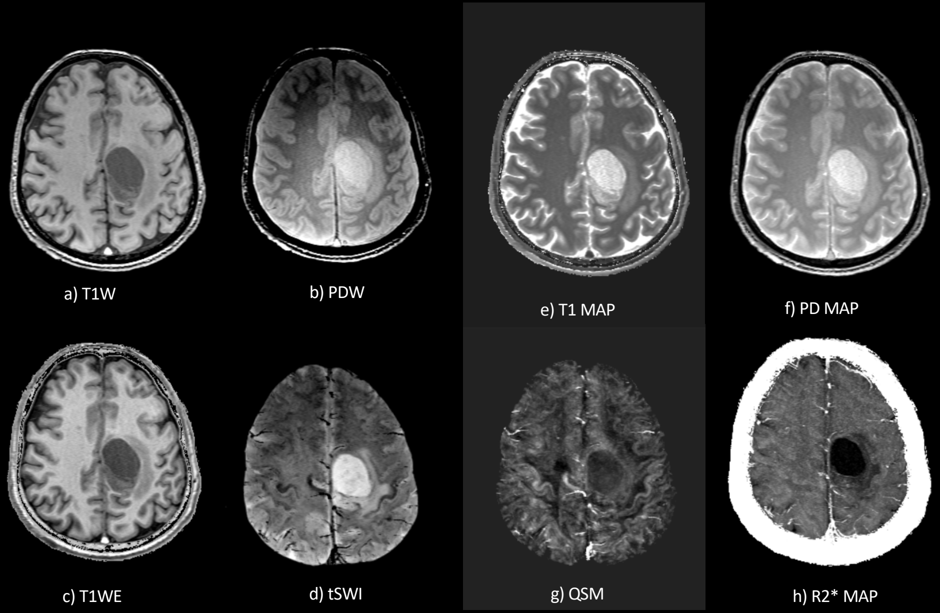







STAGE APPLICATIONS: BRAIN TUMOR CASE

Qualitative Images | Quantitative Data



Tumor case findings:

T1W images show the tumor and a darkening of the tissue around it.

This darkening appears to be a region of increased water content.

There is also a subtle but evident change in signal representative of edema in the tissue surrounding the tumor.

Images from Henan provincial people hospital courtesy of
Meiyun Wang, MD, PhD.

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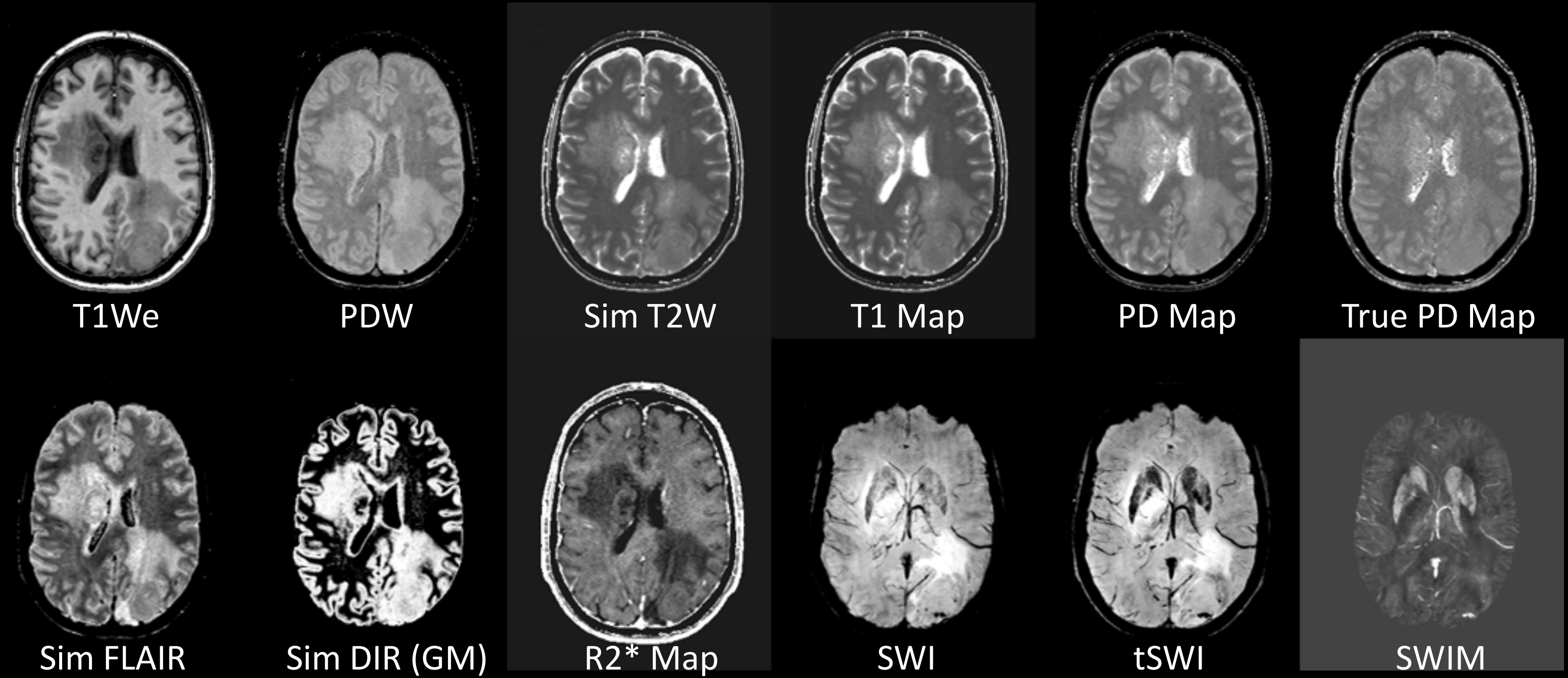
TUMOR METASTASIS



- Bleeding, vascularization, compartmentalize signals using PD and T1 Map, volumetrics
- Track disease progression

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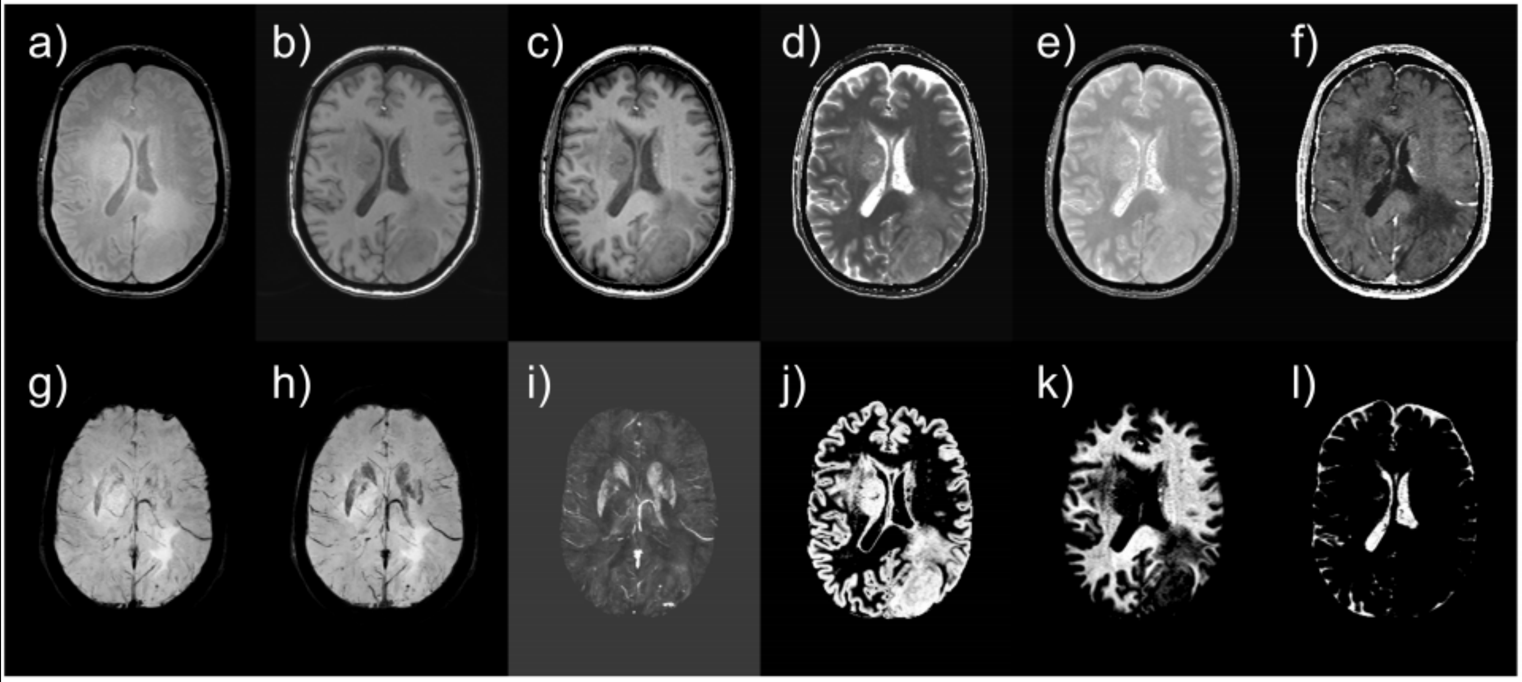
STAGE Imaging: Part III



A metastasis case (62Y, female) scanned with double-echo STAGE on a 3T scanner. a) PDW; b) T1W; c) T1WE; d) T1 map; e) PSD map; f) R2* map; g) SWI; h) tSWI; i) QSM; j) sDIR-GM; k) sDIR-WM; l) sDIR-CSF. Images g) to i) were maximum/minimum intensity projections giving an effective slice thickness of 16 mm. Note that edema can be seen in the PSD, T1, R2* maps and SWI.

Haacke et al. 2019 MRI, Accepted in Production

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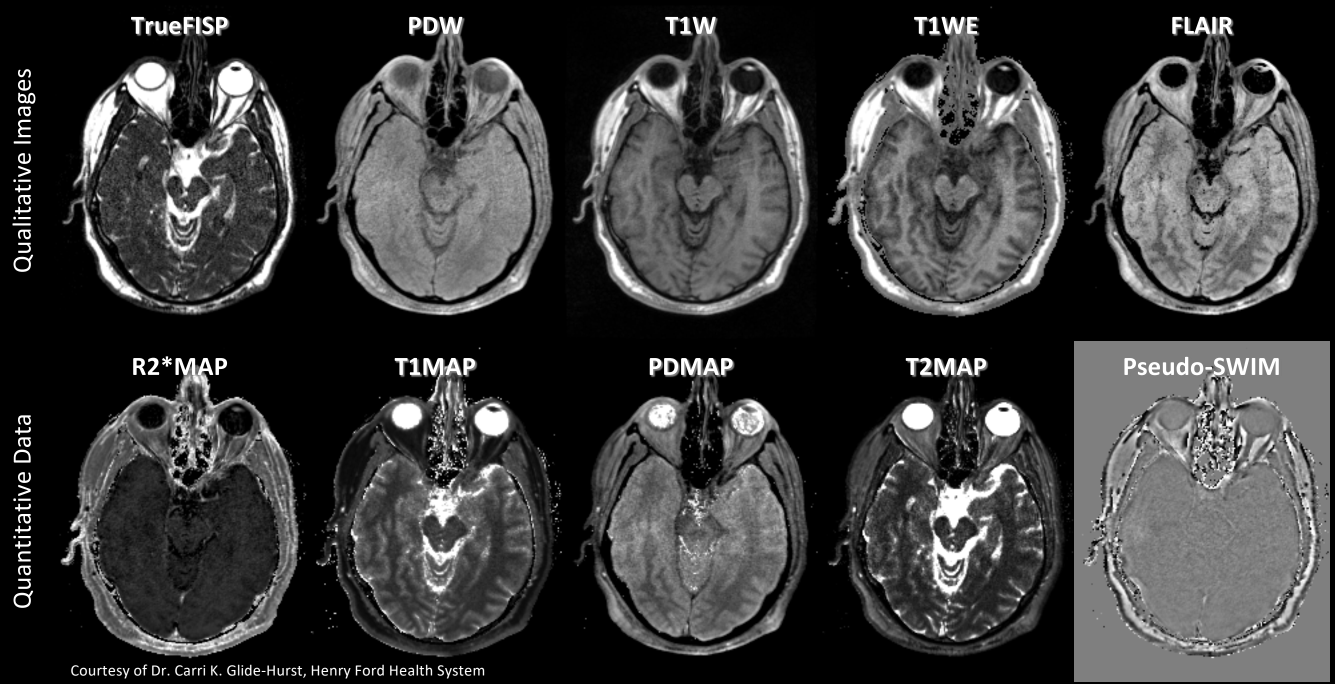
STAGE FOR MONITORING RADIATION THERAPY AT 0.35T



Courtesy of Dr. Carri K. Glide-Hurst, Henry Ford Health System

The goal is to enhance the visibility, contrast and structure of tumors for planning radiation therapy. The 10 min scans at 0.35T provided 5 qualitative images and 5 quantitative data with a resolution of 1x1x3 mm^3 covering the whole brain. TrueFISP, PDW and T1W were original acquired images, while all other images/data were processed results. T1WE has better GM/WM contrast and better SNR than original T1W.

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PILOT PARTNER OPPORTUNITY

Contribute to new research and gain early access to innovative technologies.

Become SpinTech Pilot Partner and share your experiences with us to create awareness and education about the STAGE platform.

Potential Metrics

- Diagnosis rate
- Impact on treatment
- Patient throughput and clinical staff time
- Revenue impact and cost of care
- Patient length of hospital stay
- Patient readmissions to hospital
- STAGE technical and workflow integration

Output Materials

- Clinical white papers
- Clinical case studies: comparative images and impact on patient care
- Clinical image gallery
- Customer testimonials: case studies, videos, interviews and quotes
- Publications