

**CORRELATION OF SUSCEPTIBILITY WEIGHTED IMAGING
FINDINGS OF INTRACRANIAL GLIOMAS WITH
HISTOPATHOLOGICAL FINDINGS AT KENYATTA NATIONAL
HOSPITAL**

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AWARD OF MASTER OF MEDICINE IN DIAGNOSTIC IMAGING AND RADIATION
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DECLARATION

I, **Dr. Mohamed Muhidin Sharif**, do hereby declare that the work contained herein is my original idea and has not been presented at any other university or institution of higher learning to the best of my knowledge. Further, I have acknowledged all sources used and have cited these in the reference section.

Dr. Mohamed Muhidin Sharif

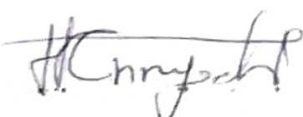
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LIST OF ABBREVIATIONS AND ACRONYMS

ADC-	Apparent Diffusion Co-efficient
BOLD-	Blood Oxygen Level-Dependent
CMB-	Cerebral Micro-bleed
CNS-	Central Nervous System
CP-	Cerebellopontine
CT-	Computed Tomography.
DSC-	Dynamic Susceptibility Contrast
DWI-	Diffusion Weighted Imaging
Dx-	Diagnosis
ERC-	Ethics and Research Committee
FLAIR-	Fluid Attenuation Inversion Recovery
GBM-	Glioblastoma Multiforme
GE-	Gradient Echo
GM-	Gray Matter
GRE-	Gradient-Recalled Echo
HR-SWI-	High Resolution Susceptibility Weighted Imaging.
ITSS-	Intratumoral Susceptibility Signal
KNH-	Kenyatta National Hospital
mIP-	Minimum Intensity Projections
MRI-	Magnetic Resonance Imaging
MRS-	Magnetic Resonance Spectroscopy
PCNSL-	Primary CNS Lymphoma.
PWI-	Perfusion Weighted Imaging.
QSM-	Quantitative Susceptibility Mapping
SOL-	Space Occupying Lesion
SWI	Susceptibility Weighted Imaging
SVS	Susceptibility Venous Sign
T-	Tesla

TBI-	Traumatic Brain Injury
T1-	Longitudinal Relaxation Time
T2-	Transverse Relaxation Time
TE-	Echo Time
TR-	Repetition Time
US-	United States
UON-	University of Nairobi
WHO-	World Health Organization
WM-	White Matter
1.5T-	1.5 Tesla
3T-	3 Tesla
3D-	Three Dimensional

ABSTRACT

Background: Gliomas are heterogeneous group of neoplasms and constitute the most common overall malignant brain tumor. Conventional Magnetic Resonance Imaging (MRI) provides excellent anatomic details and soft tissue contrast. Despite this, MRI may not accurately diagnose or grade intracranial tumors in all instances especially for glioma grading. Due to significant morbidity and mortality associated with brain biopsies including complexity of surgery, cost and economic burden on the patients, accurate preoperative diagnosis is important. Several advanced MRI methods and sequences such as Susceptibility Weighted Imaging, Diffusion Weighted Imaging, Perfusion Weighted Imaging and Spectroscopy have therefore been introduced for narrowing down differential diagnosis and grading of gliomas. Internationally, several studies have been done to demonstrate the utility of Susceptibility Weighted Imaging in assessment of gliomas. However, no local study has been done to assess the utility of Susceptibility Weighted Imaging (SWI) in assessment of gliomas.

Aim: To determine diagnostic accuracy of Susceptibility weighted imaging in evaluation of brain gliomas using histopathology as gold standard.

Methodology: This was a retrospective and prospective cross-sectional study and was conducted in Kenyatta National Hospital Radiology, Neurosurgical, Health Records departments and UON pathology department following approval from KNH-UON ERC. Administrative approval was sort for the retrospective arm to access the medical records of histologically proven brain gliomas which were correlated with SWI findings in patients who met the inclusion criteria. For the prospective part of the study, informed consent was obtained from participants who met the inclusion criteria and the findings were correlated with histopathological results. Study subjects were 47 patients who were diagnosed with a glial tumor based on histopathological examination and who had had MRI done with SWI sequence included and met the inclusion criteria.

Relevant data of eligible patients was collected. Data was recorded in data collection tool and cleaned. The collected data was entered and analysed in SPSS version 23.0. The variables analysed included demographics (i.e. age, sex), positive signs in conventional MR and SWI findings. Descriptive data was presented as means with standard deviation, median and mode. SWI findings were summarised and presented using percentages. 2x2 contingency tables were used to calculate diagnostic accuracy data which will be presented as sensitivity, specificity, positive and negative predictive values.

Conclusion: SWI has a role in preoperative grading of gliomas in combination with other advanced MRI techniques and conventional MRI studies. The study established, the addition of SWI sequence in reviewing MR images to have overall diagnostic accuracy of 74.5% sensitivity of 84.2%, specificity of 67.9%, positive predictive value of 64.0% negative predictive value of 86.4%. in grading of intracranial gliomas with histopathology being the gold standard. By identifying both haemorrhagic and calcific foci, SWI can help in characterization and grading of gliomas. SWI provides invaluable information about pathophysiology and internal tumour architecture of gliomas. This information is vital in preoperative grading of tumours.

1.0 CHAPTER ONE: INTRODUCTION

Brain tumors have high morbidity and mortality due to the role of regulating body functions the brain plays and, the functional consequences of pathological process on the brain. The demographics of brain tumors vary with age. The incidence peaks among young children especially those younger than 5 years and then again in the fifth to seventh decade of life. Prevalence of specific tumors varies with location. The most common location of all intracranial tumors is the meninges, followed by cerebral hemispheres, sellar region, cranial nerves, brainstem and cerebellum. (1)

In the US, the overall average annual age-adjusted incidence rate for primary brain and CNS tumors was 23.79 per 100,000 between the years 2013 to 2017. (2) The actual number of brain tumors in Kenya is not well known. According to the data from National Cancer Registry, primary brain tumors account for 2.3% of male tumors and 0.9% of female tumors.

An unpublished study done at Kenyatta National Hospital (KNH) on the pattern of brain tumors by Muriithi et al (2015), found that the most common tumors were meningiomas (41.4%) and gliomas (26.3%). Amongst the gliomas, glioblastoma accounted for 55% of all the gliomas and had the worst prognosis. In this study metastatic tumors accounted for 5.11%. (3)

Brain and CNS tumors are generally classified according to WHO classification of tumors which assigns brain tumors to various grades. (4)

Diagnostic challenges are faced by even experienced radiologist and giving a single diagnosis based on CT or MRI poses a challenge because of the poor sensitivity of the imaging modalities. These challenges can be due to various reasons including inadequate clinical history and similar appearances of intracranial lesions on imaging. Indirect imaging features such as calcification, pattern of enhancement, location, cyst formation and age of presentation can help even the most experienced radiologist make a 70- 90% accurate histological diagnosis. The residual 10-30% differentiation of intracranial tumors is difficult to accurately diagnose due to similar imaging appearance. Therefore, indirect imaging features and clinical data will give inconclusive results, if solely relied on. (5)

Gliomas are heterogeneous group of neoplasm and constitute the most common overall malignant brain tumor. Grades I-IV are used by the World Health Organization to classify gliomas, with grade I being the least malignant and grade IV being the most malignant. Glioma grading is crucial because it is the patient's most crucial prognostic factor. Surgery is used to treat benign tumors, while chemoradiotherapy is used to treat malignant tumors. Consequently, before any treatment is commenced, it is vital to make accurate diagnosis from pre-treatment imaging.

In patients with suspected gliomas, the initial investigation of choice in narrowing differential diagnosis is magnetic resonance imaging (MRI). (6,7) Locally because of wide availability of CT, most patients have CT as the initial investigation. CT is useful in identifying calcification in tumors, differentiation of intraaxial and extraaxial tumors and identification of mass effect. However, CT is nonspecific in differential diagnosis of intraxial lesions and rim enhancing lesions. MRI is superior to CT because of its excellent soft tissue contrast and multiple sequences which delineate brain lesions both anatomically and physiologically. (7) Currently confirmatory diagnosis and grading of gliomas is based on histopathological assessment which requires open biopsy of lesion or stereotactic biopsies.

Magnetic resonance imaging (MRI) is the standard imaging method for evaluating suspected brain tumors both before surgery and after treatment. MRI has excellent soft tissue contrast which makes it very useful in brain imaging. It has multiple sequences which delineate brain lesions both anatomically and physiologically. (8)

Susceptibility weighted imaging (SWI) is a useful recently developed method in magnetic resonance imaging (MRI) that is increasingly being used to narrow differential diagnosis of many neurologic disorders. It uses magnetic susceptibility difference between tissues and the signal loss created by disturbances of homogenous magnetic fields. These disturbances can be caused by paramagnetic, diamagnetic and ferromagnetic substances.(9,10) To enhance contrast, it was developed to take advantage of susceptibility difference between deoxygenated blood in veins and the surrounding brain. (11)

Information such as the precise anatomic location of the tumor and its relationship to other relevant anatomic structures seen in structural MR imaging scans of patients with gliomas has a role on therapeutic decision. Currently, diffusion weighted imaging (DWI), perfusion weighted

imaging (PWI) as well as MR spectroscopy (MRS) provide additional physiologic information which helps in narrowing differential diagnosis of space occupying lesions and guiding therapeutic interventions. Despite all this, definitive non-invasive glioma-grading remains a challenge for radiologists. However, with introduction of SWI in MRI sequences, researchers hope MR imaging will play a more important role towards definitive non-invasive glioma-grading.

There is correlation between the amount of neovascularity in a tumor and its malignant potential. Additionally, necrosis and haemorrhage within a tumor is associated with poor prognosis. Dynamic susceptibility contrast (DSC) perfusion MRI can be used to indirectly measure the amount of blood to a tumor. Relative tumor blood volume ratio increases with vascularity increase and this can be used in grading of tumors. (12)

SWI is fast becoming an important brain imaging sequence in evaluation of brain lesions. It is also under study because its full potential is yet to be realized. This study seeks to analyse the importance of this sequence in evaluation of gliomas and various brain lesions.

CHAPTER TWO: LITERATURE REVIEW

2.1 Clinical Application

2.1.1 Detection of Gliomas

MRI is the imaging investigation of choice in evaluation of gliomas and it shows high accuracy level in preoperative diagnosis, tumor characterization and grading of primary intraaxial brain gliomas.(7) Conventional MRI sequences including T1, contrast enhanced T1, T2, FLAIR can be used to show features such as perilesional edema, necrosis, mass effect, enhancement pattern and tumor heterogeneity.

Various studies have shown SWI is more sensitive when compared to conventional MRI sequences including T1, contrast-enhanced T1, T2, PWI, DWI and FLAIR in tumor vasculature, haemorrhage or internal architecture detection (Figure 1 and 2). Small vessels can be depicted using SWI in low grade gliomas such as astrocytoma and more complex vasculature can be found within high grade gliomas such as glioblastoma multiforme (GBM) (13,14). This information is helpful for neurosurgical therapeutic information.

In a study done by Jianxing XU, Hai Xu et al. on the contribution of Susceptibility Weighted Imaging and Diffusion Weighted Imaging for grading gliomas has shown that combining the two sequence provide important information for preoperative tumor grading. (15).

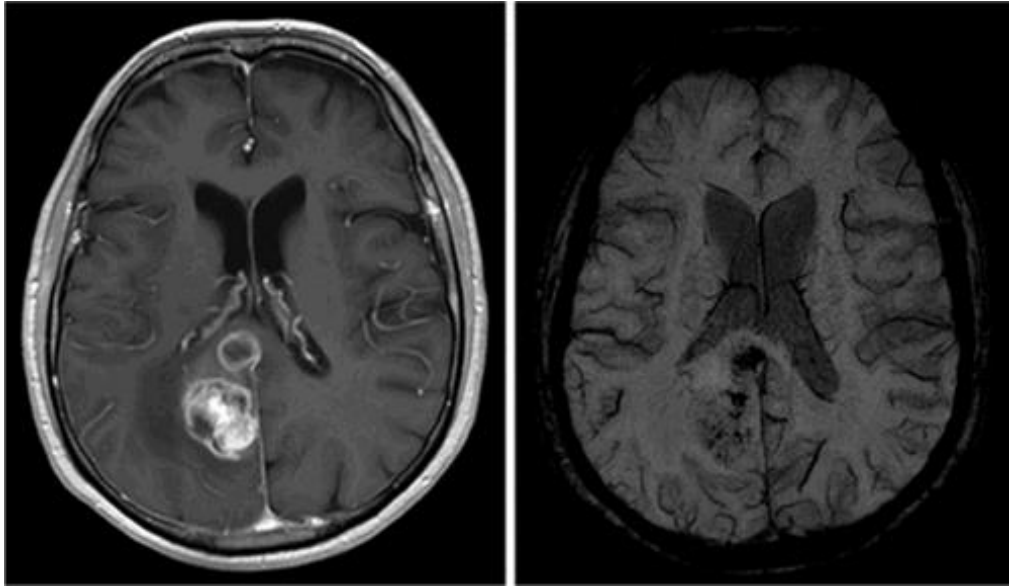


Figure 1: SWI with mIP reformatted demonstrating grade IV Glial Tumor. © *Journal of Neurosurgery, Volume 123(2015): Issue 6(DEC 2015): pages 1351-1614.*

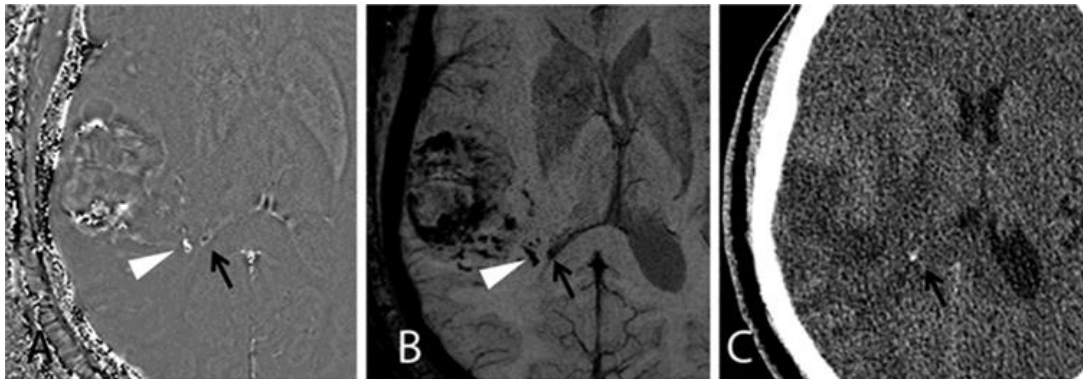


Figure 2: SWI image showing calcification and haemorrhage. © *Journal of Neurosurgery, Volume 123(2015): Issue 6(Dec 2015): pages 1351-1614.*

Presence of calcification is important in tumor diagnosis. Several studies done have correlated calcification in tumors with longer patient survival and better prognosis when compared to tumors without calcification. Computed tomography (CT) is used to reveal calcification but SWI can also effectively show intratumoral calcification (16,17).

In addition, quantitative susceptibility mapping provides a means of differentiating haemorrhage and calcification in tumor imaging (18).

2.1.2. Characterization of Gliomas

By identifying both haemorrhagic and calcific foci, SWI can help in characterization and grading of gliomas. SWI provides invaluable information about pathophysiology and internal tumor architecture of gliomas (19). The contribution of intratumoral susceptibility signal (ITSS) correlate to intratumoral haemorrhage, vascularity or calcification and this helps in narrowing differential diagnosis. In cases presenting similar imaging findings, it is imperative to differentiate gliomas from other tumors of medical conditions, SWI can help in differential diagnosis. This has an impact in the management of patients.

Calcification is an important factor during assessment of brain tumors and it helps in differential diagnosis. Oligodendrogliomas was shown to demonstrate the highest frequency of calcification among intraaxial primary brain tumors accounting for approximately 80%. In a study done by Zulfigar et al. on detection of intratumoral calcification oligodendrogliomas using Susceptibility Weighted Imaging and comparing it with conventional MRI, found that SWI is better able to detect calcification in oligodendrogliomas than conventional MRI (17).

A study by Park SM et al. (20), on the added value of high resolution susceptibility weighted imaging and apparent diffusion coefficient (ADC), concluded that HR-SWI and ADC could improve diagnostic accuracy of MR protocol for brain tumor imaging.

Peters S et al. (21) found that Susceptibility weighted imaging was able to accurately differentiate glioblastoma and lymphoma. Using SWI, the radiologists determined correct diagnosis in 82.2% of cases and without SWI, the diagnosis was correct in 75.5% of cases.

Haemorrhage and vascularity are two distinctive characteristic noted on SWI imaging and can help differentiate PCNSLs from high grade gliomas. This aids in clinical management of these malignant tumors (22).

2.1.3 Grading of Gliomas

Histopathology is the gold standard for grading of gliomas. Grading of tumors accurately has implications on patient management, because high grade lesions are treated differently from low grade lesions. Low grade gliomas are treated surgically with intent for curative care whereas patients with incompletely resected tumor adjuvant chemo radiotherapy is given (23).

Histopathological features assessed include nuclear atypia, microvascular proliferation, mitotic activity and necrosis. Irrespective of the amount of atypia, low grade tumors show lack of

marked mitosis, microvascular proliferation and necrosis. On the other hand, high grade gliomas such as glioblastoma show marked mitosis and high microvascular proliferation. Pseudopalisading necrosis is seen in glioblastoma and is characterised by irregular serpiginous areas with densely packed cells which are radially oriented surrounding them(24) .

The appearance of gliomas on conventional MRI can help radiologist in grading gliomas accurately. Radiological features which can help in characterization and grading of gliomas include oedema, tumor heterogeneity, location, haemorrhage, necrosis and mass effect (25). Several MRI sequences and other imaging modalities have helped radiologist in accurately grading gliomas and various studies have been made to determine the sensitivity and specificity of each modality when compared to the other. (26–30). Locally, Kibaru et al, did a study on accuracy of magnetic resonance spectroscopy in evaluation of brain tumors and grading of gliomas and this found significant role of MRS in grading of gliomas. Wajih et al. (31) also did a study locally titled, “Clinical Application Of Magnetic Resonance Spectroscopy In Diagnosis Of Intracranial Mass Lesion,” to show the role played by MRS in evaluation of intracranial masses.

For more than 10 years now, susceptibility effects have been used for glioma grading preoperatively to impact therapeutic options (32).

Hori et al. (32) looked the magnetic susceptibility artifacts in lesions for glioma grading and they found that the ratio of area of hypointensity in the tumor was a good predictor of glioma grading. Further assessment of correlation between small vessel proliferation, microhemorrhage and tumor grading was evaluated by Li et al. (13). Li et al found that there was increased vasculature and haemorrhages for high grade tumors as compared to low grade tumors. Microhemorrhage and small vasculature are measures of neoangiogenesis which is a key factor in tumor grading.

Pinker et al. (33), assessed the correlation between high resolution contrast enhanced SWI susceptibility effects and areas of increased blood flow on positron emission tomography (PET) and histological grading. They found that there was positive correlation between susceptibility effect as seen on high resolution contrast enhanced and increased blood flow and also good correlation with histological grading, whereby on histological examination, tumors with increased and decreased susceptibility on high resolution SWI were found to be high and low grade, respectively.

Li, X. et al. assessed the role of glioma ITSS grade in showing histopathological grade and molecular expressions and there was significant effect in pathological and molecular prediction (34).

Simona Guadino, Giammaria Marzialli et al. did a preliminary study to assess role of SWI and ITSS in grading and differentiation of paediatric brain tumors and found that ITSS has a potential role for tumor grading and differentiating tumor categories in paediatric population (35).

Kim et al. (36) did a preliminary study titled, “Added Value And Diagnostic Performance Of Intratumoral Susceptibility Signal In The Differential Diagnosis Of Solitary Enhancing Lesion,” and found that there is improvement in accuracy level for the differential diagnosis of solitary enhancing lesions when using ITSS on high resolution SWI when compared with conventional MRI.

Park et al. came with a semi quantitative method of grading cerebral neoplasms using ITSS. ITSS are hypointense linear or dot like structures within the tumour on SWI. The method of grading was to determine the number of ITSS seen within the tumour (37).

Hori et al. also came up with a scheme of grading cerebral neoplasms and noted that the ratio of hypointensity in the SW image relative to the tumour size can be used to grade tumors. Hypointensity ratios closely match with WHO grading of brain tumors and were more accurate as compared to other semi quantitative method of grading such as ITSS grading (32). However, semi quantitative method of grading is limited by subjective intra- and interobserver differences in score assignment.

Di leva et al. have shown a fractal based computational method of grading gliomas. The intratumoral SWI pattern from intratumoral bleed or vasculature and quantified by means of computational fractal-based analysis was shown to closely match WHO grading of gliomas (38). The radiological features of gliomas enable radiologists to grade gliomas. This include crossing midline, surrounding edema, heterogeneity, haemorrhage, cystic changes or necrosis and mass effect and, enhancement pattern. In a study done by Dean et al which correlated the MRI features of gliomas with histopathological results found that low grade gliomas demonstrated well defined boarder, little mass effect, vasogenic edema and heterogeneity. High grade tumors demonstrated poorly defined boarders, exhibited moderate to significant mass effect, vasogenic

edema and tumor heterogeneity. In this study, haemorrhage was reported in all glioma grades but was greater with high grade gliomas. (25).

Similar imaging features of space occupying lesions such as brain metastasis, infectious lesions such as abscess, tuberculoma and glioma are difficult to differentiate and pose diagnostic challenges to radiologists despite advances in MRI imaging methods.

2.2 Fundamentals of Susceptibility Weighted Imaging

2.2.1. Introduction

Susceptibility weighted imaging (SWI) is a new imaging method that is increasingly being used to narrow differential diagnosis of many neurologic disorders. Initially it was developed for MR venography by utilizing blood oxygen level-dependent (BOLD) and using phase image for contrast enhancement in MR imaging (11).

SWI is a 3D gradient-recalled echo (GRE) sequence that uses magnitude and filtered-phase information.(9,10) SWI combines magnitude and filtered-phase data which goes through further post processing to develop minimum intensity projections(mIP) images to show smaller haemorrhages not seen with T2* imaging (39,40). Phase image is used to differentiate calcification from haemorrhage (41) and mIP images are useful in vascular lesions.

Acquisition of SWI images takes long depending on the magnetic strength of the MRI machine. At 1.5T it has a long acquisition time of over 8min, this is greatly reduced at 3T machines where the acquisition time is less than 5 minutes. Other advantages of 3T over 1.5T are better image resolution and better signal to noise ratio. At lower magnetic strength, the images are prone to artifacts and are noisy. (23)

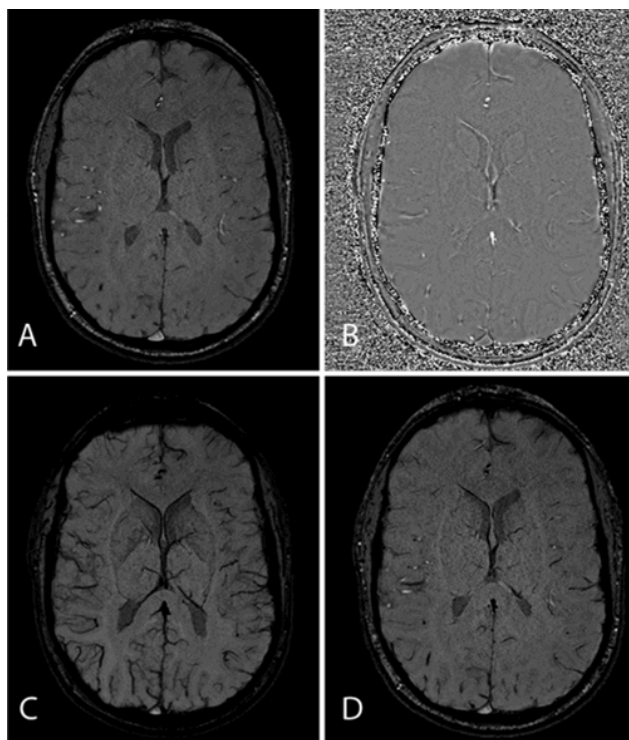


Figure 3: Sets of images provided on SWI studies. © *Journal of Neurosurgery, volume 123(2015): Issue 6(DEC 2015): Pages 1351-1614.*

2.2.2 Technical Aspect

All examination performed using 3T MRI machine digital system (PHILIPS), according to the following parameters.

T1W: TR: 324msec, TE: 2.3msec, 268X169X30slices, acquisition matrix, field of view of 240X190X149 mm, and a gap of 1 mm, a scanning time of 1min 45s.

T2W: TR: 3000msec, TE:80msec, 472X304X33slices acquisition matrix, field of view of 260X204X164 mm, and a gap of 1mm, and scanning time of 2min 00s.

FLAIR: TR: 11000msec, TE:125msec, field of view of 260X210X164mm, and a gap of 1mm.

SWI: TR: 3.1sec, TE: 7.2 sec, a 384X316X136 slices acquisition matrix, field of view 230mmX189mmX136mm, scanning time 2min 45sec.

2.2.3 Limitation of Susceptibility Weighted Imaging

One of the major limitation of SWI is it is prone to artifacts such as air-tissue artifacts in phase data and susceptibility artifacts of bony structures which can distort images (42–46).

Another limitation associated with SWI is the long scanning time required to obtain an SWI image and this brought the disadvantage of motion artifacts because of patient discomfort. Several studies have shown the long scanning time required for SWI (47–50).(51–54)(47-50)

2.3 Study Justification

MRI machines are currently available in many parts of Kenya both in private and public facilities. This has helped in evaluation and diagnosis of many intracranial tumors. Despite the advances in conventional MRI imaging, about 10-30% of intracranial tumors diagnosis remain unclear. This is largely because they appear similar on conventional imaging.

The gold standard for definitive diagnosis of gliomas is through histopathological assessment which is invasive and costly. Several advanced MRI methods and sequences including Susceptibility Weighted Imaging, Diffusion Weighted Imaging, Perfusion Weighted Imaging, and Spectroscopy have therefore been introduced for narrowing down differential diagnosis and preoperative grading of gliomas.

Susceptibility weighted imaging (SWI) is a useful recently developed method in MR imaging that is increasingly being used to narrow differential diagnosis of many neurologic disorders. SWI can be used in characterization and grading of gliomas preoperatively.

No local study or data is available on the role of SWI in evaluation of gliomas and most of studies done internationally have shown the significance of SWI sequence in imaging of gliomas and the future prospective SWI has in evaluation of intracranial tumors.

This study will help to assess the importance of this sequence in evaluation of gliomas.

2.4 Research Question

What is the accuracy of susceptibility weighted imaging in assessment of intratumoral architecture and grading of gliomas?

2.5 Hypothesis

SWI is accurate in assessment of intratumoral architecture and grading of gliomas.

2.6 Study Objectives

2.6.1 Broad Objectives

To co-relate SWI findings of intracranial gliomas with histopathological findings.

2.6.2 Specific Objectives

- a)** Determine the role of SWI in differentiating intratumoral calcification and haemorrhage.
- b)** Evaluate the role of SWI in differentiation of low- and high-grade gliomas.
- c)** Compare SWI diagnostic findings with histopathology.

CHAPTER THREE: METHODOLOGY

3.1 Study Design

This was a retrospective and prospective cross-sectional study

3.2 Study Duration

Over a period of 25 months 1st December 2019 to 31st December 2021.

3.3 Study Area Description

KNH Radiology Department and Neurosurgical Department and UON Pathology Department.

3.4 Study Population

Population characteristics: The study included all patients with brain MRI+SWI features of glioma and had confirmed histopathological diagnosis according to WHO classification system or were awaiting histological diagnosis after undergoing open surgery at KNH. The patients were recruited from KNH Neurosurgical department, their MRI images were reviewed at radiology department and histological diagnosis were confirmed at the UON pathology department. Patients without histology results, had MRI brain without SWI sequence included and those with poor brain MRI and SWI image quality due to artifacts were excluded from the study.

3.5 Sampling

All patients with MRI brain who met the inclusion criteria were recruited into the study.

3.5.1 Inclusion Criteria

- a) All patients with brain MRI+SWI feature of glioma and have confirmed histopathological diagnosis of glioma after undergoing open surgery.
- b) All patients with brain MRI+SWI feature of glioma who underwent brain surgery and were awaiting histology results.
- c) Patients with MRI brain data of good imaging quality for diagnostic purpose.

3.5.2 Exclusion Criteria

- a) Patients without histology results.
- b) Patients with MRI brain but no SWI sequence included.
- c) Patients with poor brain MRI and SWI image quality either due to artefacts such as motion. These were subjectively analysed.

In this study, there was no discrimination based on gender, ethnicity, religion, race, political affiliation or socioeconomic status.

3.6 Sample Size Determination

Sample size calculation was based on the reported sensitivity from a study done by Park, M.J et al where the reported sensitivity of SWI was **85.2% (95% CI, 79% - 98%)**. Using the formula:

$$n = \frac{Z_{1-\beta}\sqrt{\pi(1-\pi)} + Z_{1-\alpha}\sqrt{(\pi-\delta)(1-\pi+\delta)}}{\delta^2}$$

Where:

n = required sample size

π = % sensitivity of SWI, taken from a study by Park, M.J, i.e. 85%

δ = degree of precision (difference in the lower and upper of the CI of the sensitivity value from the study by Park, M.J.) =16%

$Z_{1-\beta}$ = Standard normal for 80% power = 0.84

$Z_{1-\alpha}$ = Standard normal for 95% confidence interval = 1.96

Substituting the values, the required sample size is 47.

3.7 Recruitment and Consenting Procedures

Patients who met the inclusion criteria had the MRI images reviewed at Kenyatta National Hospital Radiology department and follow up histology done.

Convenience sampling method was employed. Adults were provided with a consent form and for children less than 18 years, parent/guardian consents were required. In a language understandable by the participants, they were informed about the purpose of the study, that participation is on voluntary basis and the study did not in any way affect or influence their treatment plan. Thereafter the participant or guardian was allowed to sign the form and provide contact information for any further clarification if need be, if they so wish.

3.8 Variables

- Demographics: age, sex
- Conventional MRI characteristics of the tumours on T1, T2, FLAIR and T1 post contrast.

- SWI findings
 - Intratumoral haemorrhages.
 - Intratumoral calcifications.
 - Intratumoral susceptibility signal.

SWI diagnosis.

Histopathology diagnosis.

3.9 Data Collection Procedures

Collection of data was via a structured questionnaire. Source of demographic information was patient's medical records. The primary investigator assisted by colleagues in the MRI department KNH independently reviewed SWI findings on static films and from the console. This was followed by comparing with the radiologist report and it was verified by the supervisor consultant radiologist. For the retrospective arm, administrative approval was sought to access reports of histologically proven gliomas which were correlated with the SWI findings. For the prospective arm, informed consent was obtained from the participants and included all patients with MRI+SWI features of gliomas who underwent brain surgery and were awaiting histology results. Thereafter, the histopathology reports were accessed from the pathology medical records. Participants with no histology results were excluded from the study. Histopathological results will be collected once all imaging data has been reviewed.

3.10 Quality Assurance Procedures

- a) All studies were done by a 3T Magnetic resonance scanner (PHILIPS) using a dedicated head coil.
- b) Studies were devoid of artefacts secondary to motion.

3.11 Ethical Considerations

Approval to conduct the study was obtained from KNH-UoN ethics and Research Committee. Ethical guidelines were employed in line with the World Medical Association Declaration of Helsinki(55).

- The name, religion and ethnicity of the patients were not documented. Patients were identified by MRI number only to safeguard confidentiality.
- No additional cost was incurred by the patients participating in the study

- Identity of the patient and any other additional information was kept anonymous by the investigator.
- The information in the questionnaire was known only to the investigator, supervisor radiologist, radiographer and bio-statistician.

3.12 Data Management

Relevant data of eligible patients was collected. Data was recorded in data collection tool and cleaned. The collected data was entered and analysed in SPSS version 23.0. The variables analysed included demographics (i.e. age, sex), positive signs in conventional MR and SWI findings. Descriptive data was presented as means with standard deviation, median and mode. SWI findings were summarised and presented using percentages. 2x2 contingency tables were used to calculate diagnostic accuracy data which was presented as sensitivity, specificity, positive and negative predictive values.

3.13. Study Results Dissemination Plan

The findings of the study will be shared with relevant stakeholders such as KNH Radiology department, KNH Neurosurgical department. The findings will also be presented in local and international forums and will be published in relevant journals.

3.14 Study Limitations

SWI is a new imaging modality and not routinely incorporated into MRI brain in evaluation of brain tumors and not so many patients have SWI in their MRI brain images. A larger sample size with a longer study duration was required to help in solving this. The prospective arm of the study posed a challenge as the availability of patients to present themselves for brain biopsy following the radiological findings were dependent on multiple socio-economic factors that were not in the investigator's control. Availability of histopathological results also relied on documentation available in the patients' hard copy files as there was no established Hospital Information Database. Also, validation and standardisation of histology reports was not possible due to the retrospective nature of the research.

During the COVID-19 period, the following safety measures were put in place for participants and researchers as per KNH infection prevention and control measures.

- Infection prevention and control measures were initiated at the point of entry of the MRI department by ensuring all walk-in patients observe hand hygiene through either cleaning hands with an alcohol-based hand rub or with soap and water.
- All patients wore surgical masks during imaging procedure.
- Personnel wore personal protective equipment when handling COVID-19 patients.
- Personnel were at all times wearing surgical masks or N95 masks when handling all patients.
- Disinfectants were available to both participants and researchers.
- Image viewing stations, keyboards, mice were disinfected.
- Researchers ensured social distancing and avoided crowding in the examination room and reporting room.

4.0 CHAPTER FOUR: RESULTS

4.1 Participants Characteristics

The present study had 47 participants, 23 males and 24 females (Table 1). The mean age was 23.8 (SD 22.1) years, where the minimum age was 3.0 years, and the maximum was 72.0 years. The median age was 11.0 (IQR 5.0 – 45.0) years. Almost half (48.9%) of the patients were 10.0 years and below.

Table 1:Demographic characteristics

	Frequency, <i>n=47</i>	Percent
Age in years		
≤10	23	48.9
11 – 30	6	12.8
31 – 50	10	21.3
>50	8	17.0
Sex		
Male	23	48.9
Female	24	51.1

The present study looked at SWI MR characteristics of tumors and results of Table 2 indicate that intratumoral haemorrhage (46.8%) had the highest number in terms of the characteristics of the tumor. 14 cases demonstrated both hemorrhage and calcification. Among the 47 participants, 10 cases had no ITSS (Grade 0), 12 cases had ITSS 1-5 (Grade 1), 3 cases had ITSS 6-10 (Grade 2), 22 cases had 11 or more (Grade 3). All Grade 4 histopathological tumors had ITSS present. 88.9% (16 cases) had ITSS grade 3 and 11.1 % (2 cases) had ITSS grade 1. 1 participant only had grade 3 tumors and ITSS grade 3. (Table 9).

Grade 2 histopathological tumors, 20% (1 case) had ITSS grade 1, 20% (1 case) had ITSS grade 2 and 60% (3 cases) had ITSS grade 3. 23 participants had histopathological grade 1, 10 cases (43.5%) had no ITSS (Grade 0), 8 cases (34.8%) had ITSS grade 1, 2 cases (8.7%) had ITSS Grade 2 and 3 cases (13%) had ITSS grade 3 (Table 10). All participants with high grade tumors had ITSS present and 18 participants with low grade tumors had ITSS present (Table 4).

Table 2: SWI MR Characteristics of the tumor

	Frequency, <i>n=47</i>	Percent
None	10	21.3
Intratumoral hemorrhage	22	46.8
Intratumoral calcification	1	2.1
Both	14	29.8

Table 3: SWI Intratumoral susceptibility signal grade

	Frequency, <i>n=47</i>	Percent
Grade 0 (No ITSS)	10	21.3
Grade 1 (ITSS 1-5)	12	25.5
Grade 2 (ITSS 6-10)	3	6.4
Grade 3 (11 or more)	22	46.8

Table 4: Distribution of tumor grade according to ITSS

	ITSS Present	ITSS Absent
HGG	19	0
LGG	18	10

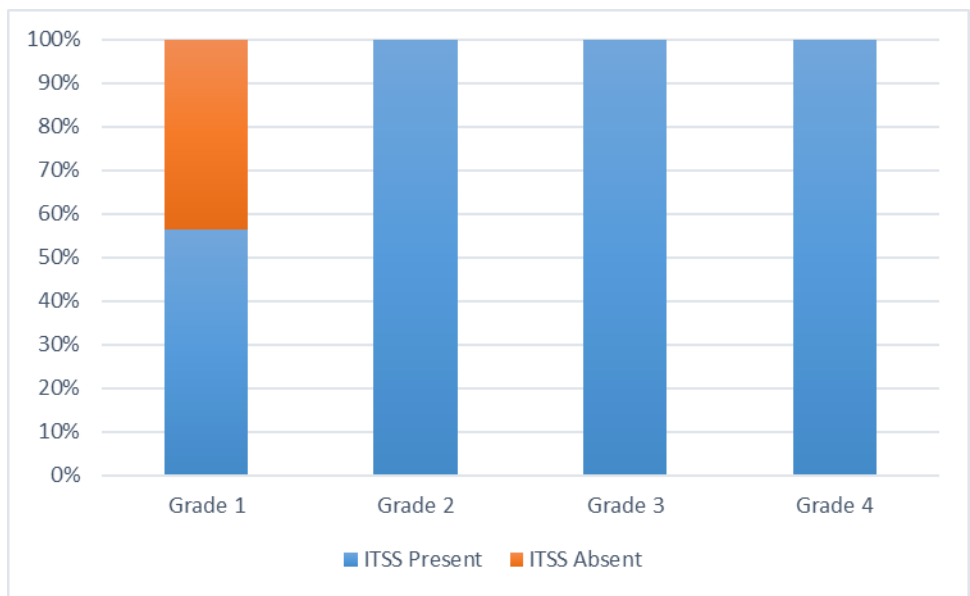


Figure 4: Tumor grade according to ITSS

Table 5: Histopathological diagnosis

	Frequency, <i>n=47</i>	Percent
Anaplastic astrocytoma	1	2.1
Classic ependymoma	1	2.1
Diffuse astrocytoma	3	6.4
Ependymoma	1	2.1
Gemistocytic astrocytoma	1	2.1
Glial neoplasm	1	2.1
Glioblastoma multiforme	18	38.3
Microcytic Cerebellar astrocytoma	1	2.1
Pilocytic astrocytoma	18	38.3
Pilocytic astrocytoma/Pleomorphic Xanthoastrocytoma	1	2.1
Subependymal giant cell astrocytoma	1	2.1

Table 6: Histopathological grade

Grade	Frequency, <i>n=47</i>	Percent
1	23	48.9
2	5	10.6
3	1	2.1
4	18	38.3

There was a statistically significant difference in the mean age for those with low grade tumors was lower as compared to those with high grade. The distribution of sex amongst the low grade and high-grade tumor patients was not statistically significant.

Table 7:

	Low grade	High grade	p-value
Age (years), <i>Mean±SD</i>	9.9±10.2	44.3±18.5	<0.001
Sex, <i>n (%)</i>			
Male	12 (42.9)	11 (57.9)	0.312
Female	16 (57.1)	8 (42.1)	

4.2 Compare SWI Diagnostic Findings with Histopathology

Table 8: Association between ITSS and tumor grade

	ITSS Present	ITSS Absent
Grade 1	13	10
Grade 2	5	0
Grade 3	1	0
Grade 4	18	0

Table 9: Distribution of histopathological and ITSS grade

	ITSS 0	ITSS 1	ITSS 2	ITSS 3
Grade 1	10	8	2	3
Grade 2	0	1	1	3
Grade 3	0	0	0	1
Grade 4	0	2	0	16

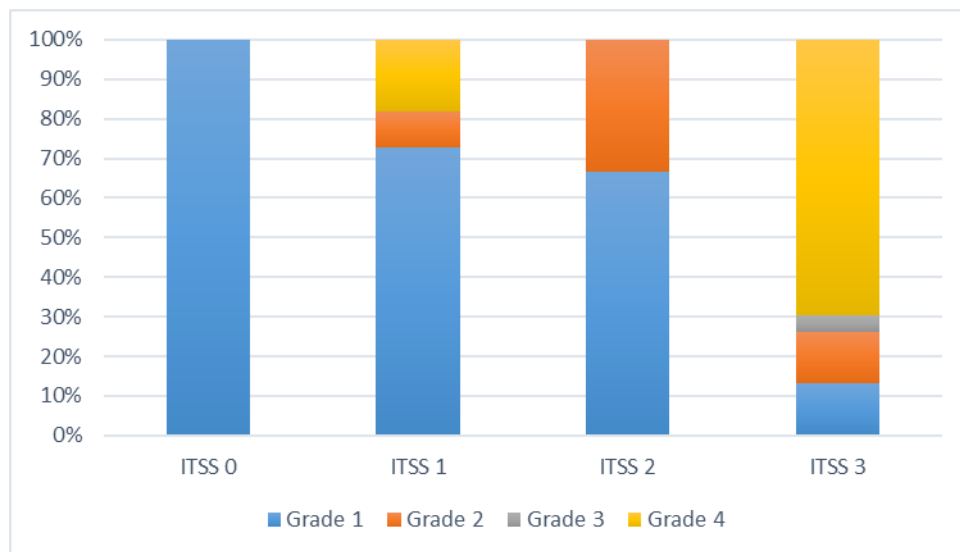


Figure 5: SWI sensitivity

The SWI was found to have sensitivity of 84.2% (95% CI, 60.4% - 96.6%), specificity of 67.9% (95% CI, 47.7% - 84.1%), and overall diagnostic accuracy of 74.5% (95% CI, 59.7% - 86.1%).

The positive predictive value (PPV) was 64.0% (95% CI, 50.1% - 75.9%), and the negative predictive value was 86.4% (95% CI, 68.5% - 94.9%)

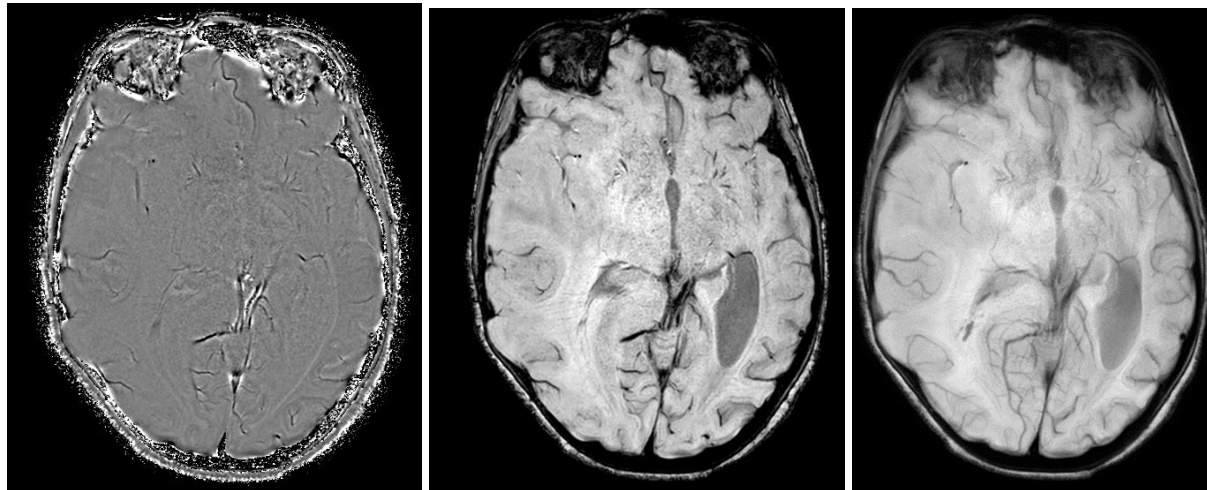
Table 10 :Diagnostic accuracy of SWI

		Histopathology				
		Positive	Negative	PPV	NPV	
SWI	Positive	16	9	64.0%		
	Negative	3	19		86.4%	
	Sensitivity	84.2%				
	Specificity		67.9%			
	Diagnostic accuracy					74.5%

4.3 Imaging Description of Sample Cases

4.3.1 Internal Quality Control

Different machines have different ways of identification for haemorrhage. In this study we used PHILIPS 3T for identification.



Phase mask image

SWI image

Magnitude image

Figure 6:Case 1 : A 54year old female with GBM diagnosed on histopathology. MRI scan done shows a left temporoparietal mass that demonstrates heterogeneous signal intensity on T2W, peripheral enhancement post gadolinium. On SWI, phase mask image shows both calcification and hemorrhage, on magnitude phase ITSS was more than 11. HPE-High grade, SWI- High grade.

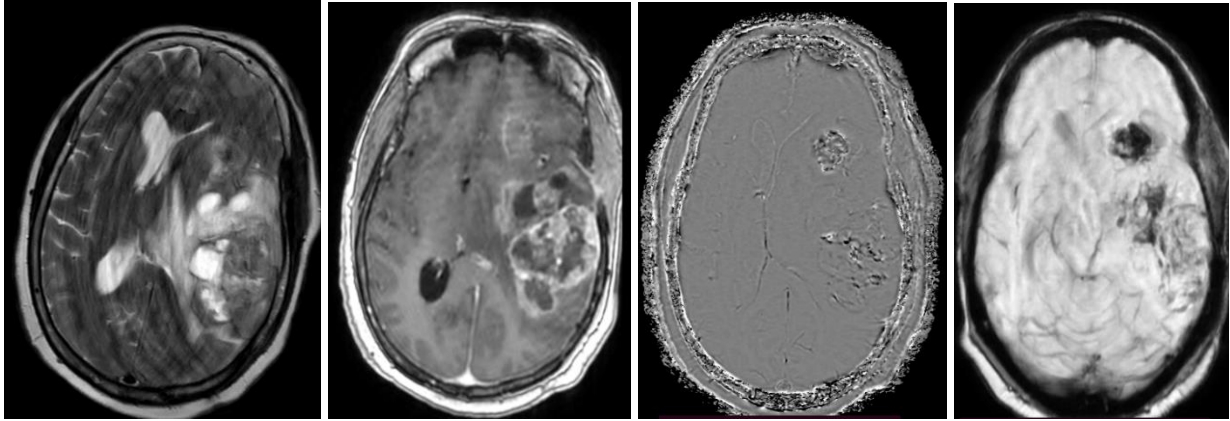


Figure 7:Case 2: A 3-year-old boy with pilocytic astrocytoma. There is a well-defined cerebellar mass which is hypointense on T1W with isointense nodule, hyperintense on T2W with isointense nodule on T2W and has an enhancing nodule post gadolinium. On SWI, no blooming seen. HPE-Low grade, SWI-low grade.

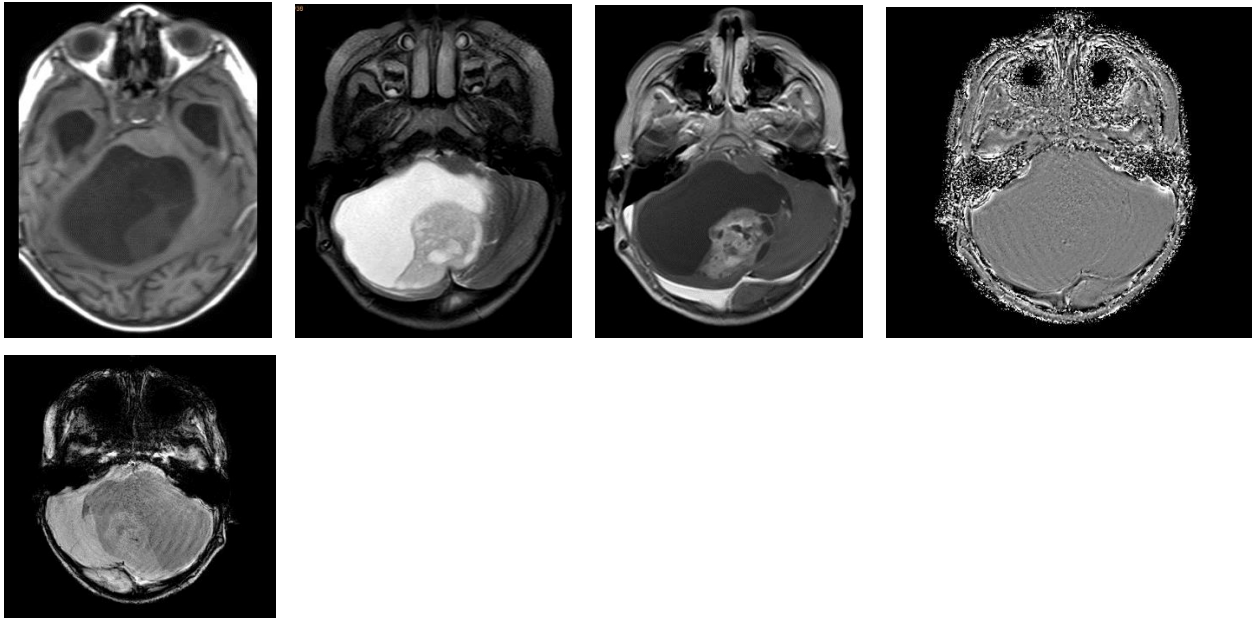


Figure 8:Case 3; A 40-year-old male, right frontotemporal mass that is hypointense on T1W, hyperintense on T2W, minimal enhancement post gadolinium administration, SWI no blooming noted. HPE-GBM, high grade, SWI ITSS 0-Low grade.

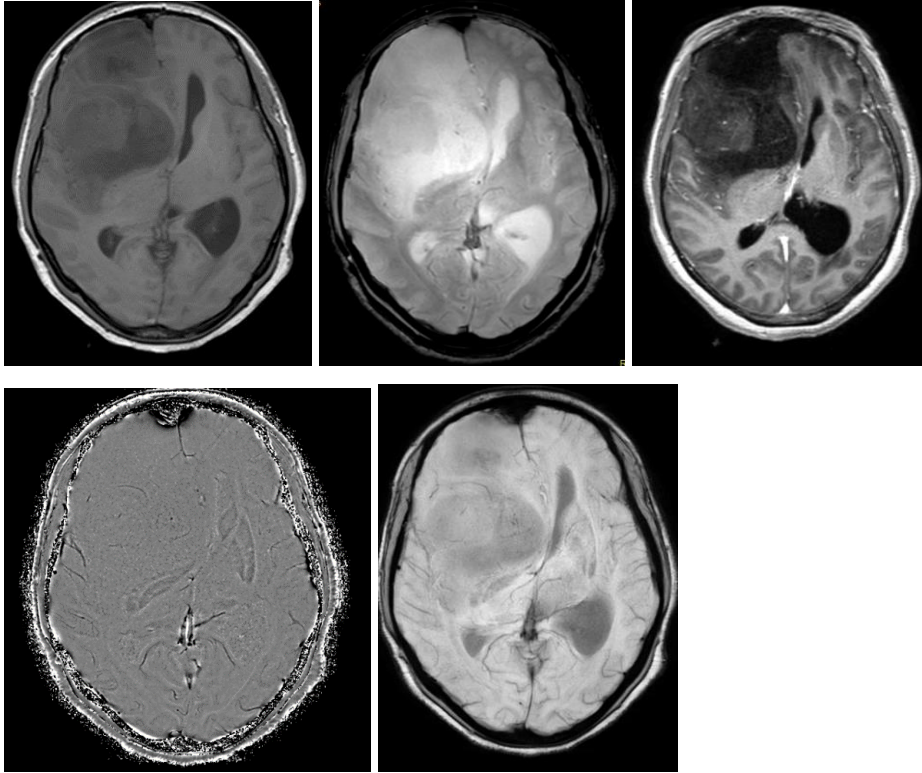


Figure 9:Case 4; A 53-year-old female, histopathology showed high grade (GRADE IV)-GBM. Left temporal well defined mass that is hypointense on T1W, hyperintense on T2W, peripheral rim enhancement post contrast. SWI, both calcification and hemorrhage, ITSS grade 1. HPE-High grade, SWI-Low grade.

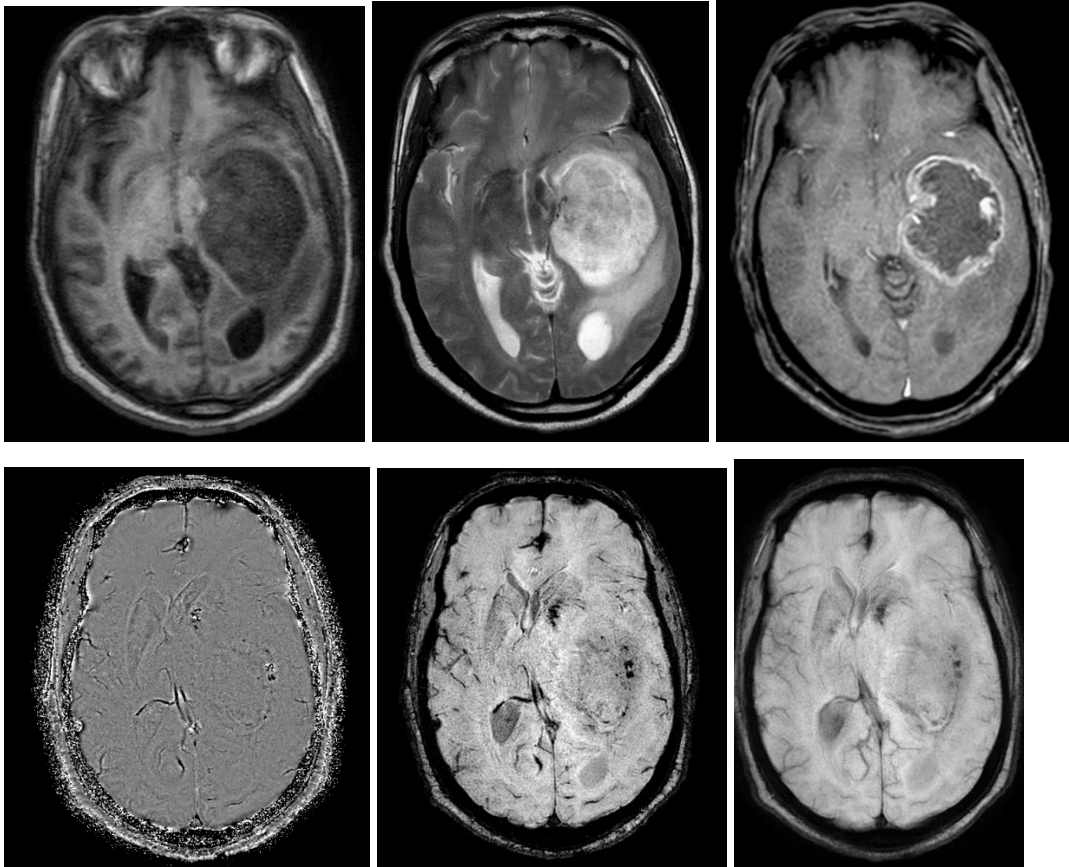


Figure 10:Case 5: An 11-year-old girl, right parietal ill-defined mass. SWI, Phase mask image shows both hemorrhage and calcification. ITSS grade 3(>11), HPE-GBM.

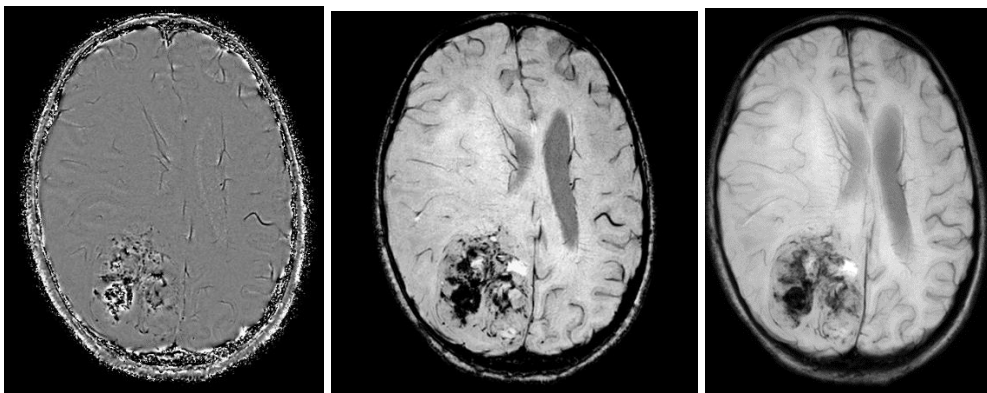
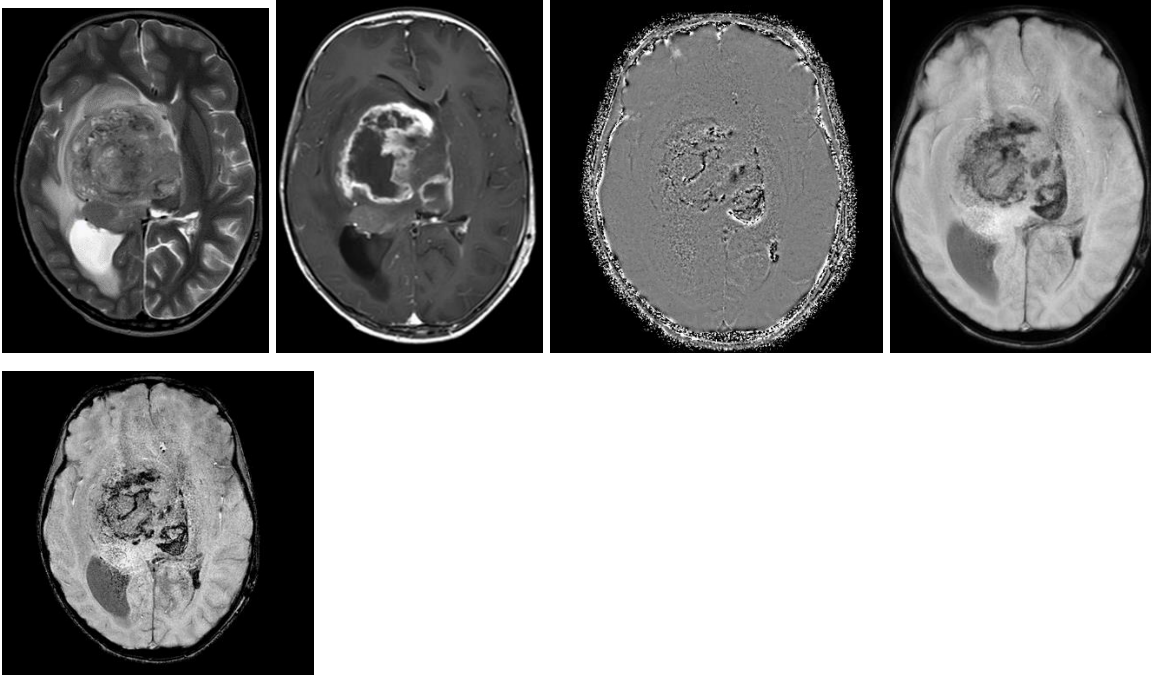


Figure 11:Case 6 : A 5-year-old boy, right thalamic mass, well defined, heterogeneous on T2W, peripheral rim enhancement post gadolinium administration. SWI, phase mask shows both

calcification and hemorrhage, ITSS grade 3 (>11), histopathological examination Grade IV-GBM.



5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

Brain tumors have high morbidity and mortality due to the role of regulating body functions the brain plays and, the functional consequences of pathological process on the brain. Diagnostic challenges are faced by even experienced radiologist and giving a single diagnosis based on CT or MRI poses a challenge because of the poor sensitivity of the imaging modalities. These challenges can be due to various reasons including inadequate clinical history and similar appearances of intracranial lesions on imaging. Indirect imaging features such as calcification, pattern of enhancement, location, cyst formation and age of presentation can help even the most experienced radiologist make a 70- 90% accurate histological diagnosis. The residual 10-30% differentiation of intracranial tumors is difficult to accurately diagnose due to similar imaging appearance. Therefore, indirect imaging features and clinical data will give inconclusive results, if solely relied on. (5)

The main objective in this prospective cross-sectional study was to determine the diagnostic accuracy of Susceptibility weighted imaging in evaluation of brain gliomas using histopathology as gold standard. Using ITSS SWI grading system, we were able to grade radiologically intracranial gliomas depending on the amount of ITSS Using ITSS, by consensus between the primary investigator and the radiologist, a cut-off of 6 was made for low and high grade The present result indicates that the degree of ITSS in the tumor was higher in high grade tumors than in low grade tumors. The present study also found ITSS in all histopathologically diagnosed high grade gliomas.

Similar findings were reported in a study done by Park SM et al (16) which reported glioblastoma multiforme having the highest ITSS grade, showing ITSS usefulness in predicting high grade gliomas. Pinker et al (17), also reported ITSS is also correlated with tumor grade as determined by histopathology and PET. In this study we also looked at SWI characteristics of gliomas. Compared to conventional MRI imaging, SWI was superior in detection of calcification within tumors. Similar findings were demonstrated in a study by Zulfigar et al. on detection of intratumoral calcification oligodendrogliomas using Susceptibility Weighted Imaging and

comparing it with conventional MRI which found that SWI is better able to detect calcification in oligodendrogliomas than conventional MRI. [\(18\)](#)

In this study, we compared the SWI MRI diagnostic findings with histopathological findings.

The study established, the addition of SWI sequence in reviewing MR images to have overall diagnostic accuracy of 74.5% in grading of intracranial gliomas with histopathology being the gold standard. SWI was found to have a sensitivity of 84.2%, specificity of 67.9%, overall diagnostic accuracy of 74.5%. The positive predictive value was 64.0% and negative predictive value was 86.4%. The findings were comparable to studies done on the usefulness of SWI in tumor grading. Xu J et al assessed on combination SWI and DWI MRI imaging for grading gliomas and using ITSS to preoperatively grade tumors obtained a sensitivity, specificity, PPV and NPV of 82.8%, 75.0%, 82.8% and 75.0% respectively. [\(19\)](#) The present study had lower specificity and PPV and this inconsistency may be as a result of lack of objective method of assessing the degree of ITSS as there is interpersonal variation. Also, the susceptibility effect on SWI may be changed by variations in imaging parameters and post processing methods amongst different institutions.

The present study showed ITSS presence in glioma is indicative of high-grade tumor and absence of ITSS indicate low grade tumor. Similar findings were reported in previous studies done on the same. Hence, it can be postulated that SWI can be used in preoperative grading of gliomas in combination with other advanced MRI techniques and conventional MRI studies.

By identifying both hemorrhagic and calcific foci, SWI can help in characterization and grading of gliomas. SWI provides invaluable information about pathophysiology and internal tumor architecture of gliomas. [\(20\)](#)

5.2 Conclusion

SWI has a role in preoperative grading of gliomas in combination with other advanced MRI techniques and conventional MRI studies. The study established, the addition of SWI sequence in reviewing MR images to have overall diagnostic accuracy of 74.5% in grading of intracranial gliomas with histopathology being the gold standard. SWI was found to have a sensitivity of 84.2%, specificity of 67.9%, overall diagnostic accuracy of 74.5%. The positive predictive value was 64.0% and negative predictive value was 86.4%.

The findings were comparable to studies done on the usefulness of SWI in tumour grading. By identifying both haemorrhagic and calcific foci, SWI can help in characterization and grading of gliomas. SWI provides invaluable information about pathophysiology and internal tumour architecture of gliomas. This information is vital in preoperative grading of tumours.

5.3 Study Limitations

Lack of health record information for patients' medical records, especially histopathological diagnosis led to lots of data missing, thus limiting the number of patients to be recruited. The study had a retrospective arm in cases selection and possibility of bias during selection may have prevailed. There is lack of objective method of assessing the degree of ITSS as there is interpersonal variation. The study used WHO classification of CNS tumours 2016. The latest classification system is 5th edition 2021 and puts emphasis on molecular markers both in terms of classification and grading. Due to socioeconomic status, our patients could not afford molecular studies.

5.3 Recommendations

A large study over a long duration of time should be done to assess the significance of SWI in addition to conventional MRI imaging in tumor assessment and other utility of SWI sequence in brain pathologies. SWI imaging protocol should be included in evaluation of all brain tumors. We recommend to file all histology reports of patients for record keeping purpose. We recommend a study on various other clinical application of SWI.

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APPENDICES

Appendix A - Data Collection Form

Title: GLIOMAS: A Retrospective and Prospective Study on Correlation of Susceptibility Weighted Imaging Findings of Intracranial Gliomas with Histopathological Findings at The Kenyatta National Hospital.

Investigator: Dr. Mohamed Muhidin Sharif, Resident Department of Diagnostic Imaging and Radiation Medicine, University of Nairobi

PATIENT NUMBER	MRI NUMBER	AGE	SEX

SWI MR CHARACTERISTICS OF THE TUMOR

INTRATUMORAL HEMORRHAGE	
INTRATUMORAL CALCIFICATION	

SWI INTRATUMORAL SUSCEPTIBILITY SIGNAL GRADE

GRADE 0 (NO ITSS)	
GRADE 1 (ITSS 1-5)	
GRADE 2 (ITSS 6-10)	
GRADE 3 (11 or more)	

HISTOPATHOLOGICAL DIAGNOSIS.

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HISTOPATHOLOGICAL GRADE

GRADE I	
GRADE II	
GRADE III	
GRADE IV	

Comments/remarks

Appendix B - Consent Information Document-ADULT

Participant Information and Consent Form Sample-Adult Consent for Enrolment in The Study

(To be administered in English or any other appropriate language e.g. Kiswahili translation)

Title of Study: Correlation of SWI Imaging Findings of Intracranial Gliomas with Histopathological Findings at The Kenyatta National Hospital.

Principal Investigator and Institutional Affiliation: Dr. Mohamed Muhidin Sharif, Resident at University of Nairobi, Department of Diagnostic Imaging and Radiation Medicine

Introduction:

I am Dr Mohamed Muhidin Sharif. I am currently pursuing my postgraduate studies at the University of Nairobi. As part of my studies, I am required to undertake research. I am doing research to document use of susceptibility weighted imaging in evaluation of gliomas.

The purpose of this consent form is to provide you with adequate information in order to help you decide whether or not to be a participant in the study. You are free to ask any questions about the research, its purpose, implications of participating in the study, risks and benefits, volunteer rights, and any added information not included in this form that needs clarification. After your questions are satisfactorily answered, you can decide to take part in the study or not. This process is known as 'informed consent'. After you agree to take part in this study, I will request you to sign your name on this form.

You should understand the general principles which apply to all participants in a medical research:

- i) Participation in the study is on voluntary basis.
- ii) You have a right of withdrawal from the study at any time without necessarily giving a reason for your withdrawal.
- iii) If you refuse to take part in the study, this does not in any way affect services provided to you in the facility or any other health facility.

A copy of this form will be provided to you for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Protocol No. _____

What Is This Study About?

The above researchers are interviewing individuals who are undergoing brain MRI for a brain tumour. The reason for the interview is to find out your age, sex and duration of symptoms. All those who take part in this research study will also have their brain MRI images reviewed. There are no further investigations or tests required. There will be approximately _____ participants in this study who are randomly chosen. We request for your consent to consider taking part in this study.

What Will Happen If You Decide To Be In This Research Study?

If you agree to take part in this research, the following will happen:

You will be interviewed in an area where your privacy guaranteed and you are comfortable to answer questions. The interview will take few minutes. After the interview has finished, I will request to go through your MRI brain images. If necessary, we will ask your phone number to contact you. Any contact information you provide will be used only by people conducting this study and will never be shared with others.

Are There Any Risks, Harms Discomforts Associated with This Study?

MRI is a safe imaging modality with no radiations involved. One of the scares patients have is the risk of MRI as an imaging modality and before any procedure you sign consent to undergo the examination. Generally, medical research has the potential to introduce psychological, social, emotional and physical risks. One of the risks of being in the study is loss of privacy. Any information you give us is confidential and we will keep it private. We will identify you with a code-number in a password-protected computer database and all our paper records will be kept in a secure cabinet. You have the right to decline the interview or any questions asked in the process. Also, all our staff conducting this study are professionals with training in these examinations/interviews.

Are There Any Benefits Being In This Study?

The study will help us understand better the use of MRI in evaluating specific brain tumors known as gliomas. This will further broaden our understanding of the above tumors and have an impact on the management of patient will similar tumors.

Will Being In This Study Cost You Anything?

No additional costs will be incurred.

Can I Withdraw From The Study Anytime?

Participation in the study is on voluntary basis and you have a right of withdrawal from the study and that at any time you can decide to withdraw from the study without necessarily giving a reason for your withdrawal. This does not in any way affect services provided to you in the facility or in any other health facility.

For more information about your rights as a research participant you may contact the following persons:

Principal investigator:

Dr. Mohamed Muhidin Sharif,

Telephone no.: +254724553252

Department of Diagnostic Imaging and Radiation Medicine

University of Nairobi,

Lead Supervisor:

Dr. Callen Onyambu,

M.B.Ch.B. (UON), M.Med. Diagnostic Imaging (UON)

Senior Lecturer and Consultant Radiologist

Department of Diagnostic Imaging and Radiation Medicine,

University of Nairobi.

Tel no.: +254721539987.

Or

The Secretary,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Telephone No. 2726300 Ext. 44102

Email: uonknh_erc@uonbi.ac.ke.

Appendix C - Consent Information Document (Participants under 18 Years of Age.)

Participants Under 18 YEARS of Age Assent Information and Consent Form Sample-Parent/Guardian Consent for Enrolment in the Study

(To be administered in English or any other appropriate language e.g. Kiswahili translation)

TITLE OF STUDY: Correlation of SWI Imaging Findings of Intracranial Gliomas with Histopathological Findings at The Kenyatta National Hospital.

Principal Investigator and Institutional Affiliation: Dr. Mohamed Muhidin Sharif, Resident at University of Nairobi, Department of Diagnostic Imaging and Radiation Medicine

Introduction:

I am Dr Mohamed Muhidin Sharif. I am currently pursuing my postgraduate studies at the University of Nairobi. As part of my studies, I am required to undertake a research. I am doing research to document use of susceptibility weighted imaging in evaluation of gliomas.

The purpose of this consent form is to provide you with adequate information in order to help you decide whether or not to be a participant in the study. You are free to ask any questions about the research, its purpose, implications of participating in the study, risks and benefits involved, volunteer rights, and any added information not included in this form and that needs clarification. After your questions are satisfactorily answered, you can decide to take part in the study or not. This process is known as 'informed consent'. After you agree to take part in this study, I will request you to sign your name on this form.

You should understand the general principles which apply to all participants in a medical research:

- i) Participation in the study is on voluntary basis.
- ii) Anytime you can decide to withdraw from the study.
- iii) If you refuse to take part in the study, this does not in any way affect services provided to you in the facility or any other health facility.

A copy of this form will be provided to you for your records.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Protocol No. _____

What Is This Study About?

The above researchers are interviewing individuals who are undergoing brain MRI for a brain tumour. The reason for the interview is to find out your age, sex and duration of symptoms. All those who take part in this research study will also have their brain MRI images reviewed. There are no further investigations or tests required. There will be approximately _____ participants in this study who are randomly chosen. We request for your consent to consider taking part in this study.

What Will Happen If You Decide To Include your Child in This Research Study?

If you agree your child to take part in this research, the following will happen:

You will be interviewed in an area where your privacy guaranteed and you are comfortable to answer questions. The interview will take few minutes. After the interview has finished, I will request to go through your child's MRI brain images. If necessary, we will ask your phone number to contact you. Any contact information you provide will be used only by people conducting this study and will never be shared with others.

Are There Any Risks, Harms Discomforts Associated With This Study?

MRI is a safe imaging modality with no radiations involved. One of the scares patients have is the risk of MRI as an imaging modality and before any procedure you sign a consent to undergo the examination.

Generally, medical research has the potential to introduce psychological, social, emotional and physical risks. One of the risk of being in the study is loss of privacy. Any information you give us is confidential and we will keep it private.

We will identify you with a code-number in a password-protected computer database and all our paper records will be kept in a secure cabinet. You have the right to decline the interview or any questions asked in the process. Also, all our staff conducting this study are professionals with training in these examinations/interviews.

Are There Any Benefits Being In This Study?

The study will help us understand better the use of MRI in evaluating specific brain tumors known as gliomas. This will further broaden our understanding of the above tumors and have an impact on the management of patient will similar tumors.

Will Being In This Study Cost You Anything?

No additional costs will be incurred.

Can I Withdraw My Child From The Study Anytime?

Participation in the study is on voluntary basis and you have a right of withdrawing your child from the study and that anytime you can decide to withdraw your child from the study without necessarily giving a reason for your withdrawal. This does not in any way affect services provided to your child in the facility or in any other health facility.

Additional Information For Parents/Guardians Of Participants Who Are Minors.

- On behalf of the participant you will be required to complete MRI safety questionnaire on behalf of the participant, and provide consent accordingly.
- The participant will only be included in the study if you consent. You can refuse to allow your child to be included in the study if you want.

For more information about your rights as a research participant you may contact the following persons:

Principal investigator:

Dr. Mohamed Muhidin Sharif,

Telephone no.: +254724553252.

Department of Diagnostic Imaging and Radiation Medicine

University of Nairobi,

Lead Supervisor:

Dr. Callen Onyambu,

M.B.Ch.B. (UON), M.Med. Diagnostic Imaging (UON)

Senior Lecturer and Consultant Radiologist

Department of Diagnostic Imaging and Radiation Medicine,

University of Nairobi.

Tel no.: +254721539987.

Or

The Secretary,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Telephone No. 2726300 Ext. 44102

Email: uonknh_erc@uonbi.ac.ke.

Appendix D - Consent Form (Statement of Consent)-ADULTS

Participant's statement

1. I have read this consent form or had the content read to me and I understood.
2. I have been given the chance to ask questions about this research study.
3. I have had my questions answered adequately in a language I understand.
4. The potential risks and benefits have been explained to me in a clear and precise manner.
5. I understand that I take part in this study voluntarily and that I can withdraw anytime.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes/ No

I agree to provide contact information for follow-up: Yes /No

Participant printed name: _____

Contact (mobile number): _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher 's Name: **Dr. Mohamed Muhidin Sharif**

Date: _____ Signature _____

Role in the study: Principal investigator.

For more information, contact:

Principal investigator:

Dr. Mohamed Muhidin Sharif,

Telephone no.: +254724553252.

Department of Diagnostic Imaging and Radiation Medicine
University of Nairobi,

Lead Supervisor:

Dr. Callen Onyambu,

M.B.Ch.B. (UON), M.Med. Diagnostic Imaging (UON)

Senior Lecturer and Consultant Radiologist

Department of Diagnostic Imaging and Radiation Medicine,
University of Nairobi.

Tel no.: +254721539987.

Or

The Secretary,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Telephone No. 2726300 Ext. 44102

Email: uonknh_erc@uonbi.ac.ke.

Appendix E - Consent Form (Statement of Consent) (Participants Under 18 Years of Age)

Parent/Guardian statement

1. I have read this consent form or had the content read to me and I understood.
2. I have been given the chance to ask questions about this research study.
3. I have had my questions answered adequately in a language I understand.
4. The potential risks and benefits have been explained to me in a clear and precise manner.
5. I understand that I take part in this study voluntarily and that I can withdraw anytime.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes/ No

I agree to provide contact information for follow-up: Yes /No

Participant printed name: _____

Contact (mobile number): _____

Name of Parent/Guardian providing consent for a minor: _____

Contact (mobile number): _____

Parent/Guardian Signature/Thumb stamp: _____ Date: _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher 's Name: **Dr. Mohamed Muhidin Sharif**

Date: _____ Signature _____

Role in the study: Principal investigator.

For more information, contact:

Principal investigator:

Dr. Mohamed Muhidin Sharif,

Telephone no.: +254724553252.

Department of Diagnostic Imaging and Radiation Medicine

University of Nairobi,

Lead Supervisor:

Dr. Callen Onyambu,

M.B.Ch.B. (UON), M.Med. Diagnostic Imaging (UON)

Senior Lecturer and Consultant Radiologist

Department of Diagnostic Imaging and Radiation Medicine,

University of Nairobi.

Tel no.: +254721539987.

Or

The Secretary,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Telephone No. 2726300 Ext. 44102

Email: uonknh_erc@uonbi.ac.ke.

Appendix F - Fomu ya Idhini Ili Kushiriki Katika Utafiti- (Watu Wazima)

Kichwa Cha Utafiti: “UTUMIZI WA SWI (SUSCEPTIBILITY WEIGHTED IMAGING) KATIKA UTAMBUZI WA VIDONDA VYA UBONGO”

Mpelelezi Mkuu Na Ushirika Wa Kitaasisi: Dr. Mohamed Muhidin, Mwanafunzi wa Shahada ya Uzamili Katika Radiology. Chuo Kikuu Cha Nairobi, Idara ya Radiology

Mimi ni Daktari Mohamed Muhidin Sharif; Hivi sasa ninaendelea na masomo yangu ya uzamili katika Chuo Kikuu cha Nairobi. Katika masomo yangu, ninahitajika kufanya utafiti. Ninafanya utafiti kuchunguza matumizi ya upigaji picha wenye uzito katika tathmini ya gliomas.

Ningependa kukuambia juu ya utafiti unaofanywa na mtafiti aliyeorodheshwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa habari za kutosha ili kukusaidia kuamua iwapo utakuwa mshiriki wa utafiti au la. Uko huru kuuliza maswali yoyote juu ya utafiti, madhumuni yake, ni nini maana ya wewe kushiriki katika utafiti, ikiwa kuna hatari yoyote inayohusika na faida yoyote, haki za kujitolea, na habari yoyote iliyoongezwa isiyojumuishwa katika fomu hii na inahitaji ufafanuzi. Baada ya kujibu kwa kuridhisha maswali yako yote, unaweza kuamua kushiriki katika utafiti au la. Utaratibu huu unajulikana kama 'idhini ya habari'. Baada ya kukubali kushiriki katika utafiti huu, nitakuomba utie sahihi jina lako kwenye fomu hii.

Unapaswa kuelewa kanuni za jumla ambazo zinatumiwa kwa washiriki wote katika utafiti wa matibabu:

- i. Kushiriki katika utafiti ni kwa hiari.
- ii. Wakati wowote unaweza kuamua kujiondoa kwenye utafiti.
- iii. Ukikataa kushiriki katika utafiti, hii haiathiri huduma unayopewa katika kituo hicho au kituo kingine chochote cha afya.

Tutakupa nakala ya fomu hii kwa rekodi zako.

Naweza kuendelea? NDIO AU LA

Utafiti huu umeidhinishwa na Itifaki ya Kamati ya Maadili na Utafiti ya Hospitali ya Kitaifa ya Kenyatta-Chuo Kikuu cha Nairobi Nambari_____

Utafiti Huu Unahusu Nini?

Watafiti hapo juu wanawahoji watu ambao wanapitia MRI ya ubongo kwa uvimbe wa ubongo. Sababu ya mahojiano ni kujua umri wako, jinsia na muda wa dalili. Picha za MRI za ubongo za wote watakaoshiriki katika utafiti huu zitakaguliwa na watafiti. Hakuna uchunguzi zaidi au

vipimo vinahitajika. Kutakuwa na takriban washiriki _____ katika utafiti huu ambao wamechaguliwa bila mpangilio. Tunaomba idhini yako kufikiria kushiriki katika utafiti huu.

Je, Nini Kitatokea Ukiamua Kuwa Kwenye Utafiti Huu?

Ikiwa unakubali kushiriki katika utafiti huu, yafuatayo yataokea:

Utahojiwa katika eneo ambalo faragha yako imehakikishiwa na unahisi vizuri kujibu maswali. Mahojiano yatachukua dakika chache. Baada ya mahojiano kumalizika, nitaomba kupitia picha zako za ubongo za MRI. Ikibidi, tutaauliza nambari yako ya simu kuwasiliana nawe. Maelezo yoyote ya mawasiliano utakayotoa yatatumika tu na watu wanaofanya utafiti huu na hawatashirikiwa na wengine kamwe.

Je, Kuna Athari Zozote, Madhara, Usumbufu Zinazohusiana Na Utafiti Huu?

MRI ni njia salama ya kuchukua picha bila mionzi. Hofu moja ambayo wagonjwa wanayo ni hatari ya MRI kama njia ya kuchukua picha na kabla ya utaratibu wowote utasaini idhini ya kufanyiwa uchunguzi.

Kwa ujumla, utafiti wa matibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihemko na kiafya. Moja ya hatari ya kuwa katika utafiti huu ni kupoteza faragha. Habari yoyote unayotupatia ni ya siri na itachukuliwa kama siri.

Tutatumia nambari ya kukutambulisha kwenye hifadhidata ya kompyuta inayolindwa na nywila na rekodi zetu zote za karatasi zitahifadhiwa kwenye baraza la mawaziri iliyofungwa. Una haki ya kukataa mahojiano au maswali yoyote yanayoulizwa katika mahojiano. Pia, wafanyikazi wetu wote wanaofanya utafiti huu ni wataalamu wenye mafunzo katika mitihani / mahojiano haya.

Je, Kuna Faida Zozote Ziko Katika Utafiti Huu?

Utafiti huo utatusaidia kuelewa vizuri matumizi ya MRI katika kutathmini uvimbe maalum za ubongo zinazojulikana kama gliomas. Hii itapanua zaidi ufahamu wetu wa hizi uvimbe na itaathiri jinsi wagonjwa wenye uvimbe wa ubongo husimamiwa.

Je, Kuna Gharama Kuwa Katika Utafiti Huu?

Hakuna gharama za ziada zitakazopatikana.

Je, Ninaweza Kuondoka Kwenye Utafiti Wakati Wowote?

Kushiriki katika utafiti ni kwa hiari na una haki ya kujiondoa kutoka kwa utafiti na kwamba wakati wowote unaweza kuamua kujiondoa kwenye utafiti bila lazima kutoa sababu ya kujitoka kwako. Hii haiathiri kwa vyovyote huduma unazopewa katika kituo hicho au katika kituo kingine chochote cha afya.

Kwa habari zaidi juu ya haki zako kama mshiriki wa utafiti unaweza kuwasiliana na watu wafuatao:

Mchunguzi Mkuu:

Dr. Mohamed Muhidin Sharif,

Nambari ya Simu.: +254724553252.

Department of Diagnostic Imaging and Radiation Medicine
University of Nairobi,

Msimamizi Mkuu:

Dr. Callen Onyambu,

M.B.Ch.B. (UON), M.Med. Diagnostic Imaging (UON)

Senior Lecturer and Consultant Radiologist

Department of Diagnostic Imaging and Radiation Medicine,
University of Nairobi.

Nambari ya Simu: +254721539987.

Ama,

Katibu,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee

Nambari ya simu :. 2726300 Ext. 44102

Email:uonknh_erc@uonbi.ac.ke.

Appendix G - Fomu ya Idhini Ili Kushiriki Katika Utafiti-(Washiriki Walio Chini Ya Miaka 18).

Kichwa Cha Utafiti: “UTUMIZI WA SWI (SUSCEPTIBILITY WEIGHTED IMAGING) KATIKA UTAMBUZI WA VIDONDA VYA UBONGO”

Mpelelezi Mkuu Na Ushirika Wa Kitaasisi: Dr. Mohamed Muhidin, Mwanafunzi wa Shahada ya Uzamili Katika Radiology. Chuo Kikuu Cha Nairobi, Idara ya Radiology

Mimi ni Daktari Mohamed Muhidin Sharif; Hivi sasa ninaendelea na masomo yangu ya uzamili katika Chuo Kikuu cha Nairobi. Katika masomo yangu, ninahitajika kufanya utafiti. Ninafanya utafiti kuchunguza matumizi ya upigaji picha wenye uzito katika tathmini ya gliomas.

Ningependa kukuambia juu ya utafiti unaofanywa na mtafiti aliyeorodheshwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa habari za kutosha ili kukusaidia kuamua iwapo utakuwa mshiriki wa utafiti au la. Uko huru kuuliza maswali yoyote juu ya utafiti, madhumuni yake, ni nini maana ya wewe kushiriki katika utafiti, ikiwa kuna hatari yoyote inayohusika na faida yoyote, haki za kujitolea, na habari yoyote iliyoongezwa isiyojumuishwa katika fomu hii na inahitaji ufafanuzi. Baada ya kujibu kwa kuridhisha maswali yako yote, unaweza kuamua kushiriki katika utafiti au la. Utaratibu huu unajulikana kama 'idhini ya habari'. Baada ya kukubali kushiriki katika utafiti huu, nitakuomba utie sahihi jina lako kwenye fomu hii.

Unapaswa kuelewa kanuni za jumla ambazo zinatumiwa kwa washiriki wote katika utafiti wa matibabu:

- i. Kushiriki katika utafiti ni kwa hiari.
- ii. Wakati wowote unaweza kuamua kujiondoa kwenye utafiti.
- iii. Ukikataa kushiriki katika utafiti, hii haiathiri huduma unayopewa katika kituo hicho au kituo kingine chochote cha afya.

Tutakupa nakala ya fomu hii kwa rekodi zako.

Naweza kuendelea? NDIO AU LA

Utafiti huu umeidhinishwa na Itifaki ya Kamati ya Maadili na Utafiti ya Hospitali ya Kitaifa ya Kenyatta-Chuo Kikuu cha Nairobi Nambari_____

Utafiti Huu Unahusu Nini?

Watafiti hapo juu wanawahoji watu ambao wanapitia MRI ya ubongo kwa uvimbe wa ubongo. Sababu ya mahojiano ni kujua umri wako, jinsia na muda wa dalili. Picha za MRI za ubongo za

wote watakaoshiriki katika utafiti huu zitakaguliwa na watafiti. Hakuna uchunguzi zaidi au vipimo vinahitajika. Kutakuwa na takriban washiriki _____ katika utafiti huu ambao wamechaguliwa bila mpangilio. Tunaomba idhini yako kufikiria kushiriki katika utafiti huu.

Je, Nini Kitatokea Ukiamua Kumjumuisha Mtoto wako katika Utafiti Huu?

Ikiwa unakubali kumjumuisha mtoto wako katika utafiti huu, yafuatayo yatatokea:

Utahojiwa katika eneo ambalo faragha yako imehakikishiwa na unahisi vizuri kujibu maswali. Mahojiano yatachukua dakika chache. Baada ya mahojiano kumalizika, nitaomba kupitia picha zako za ubongo za MRI. Ikibidi, tutauliza nambari yako ya simu kuwasiliana nawe. Maelezo yoyote ya mawasiliano utakayotoa yatatumika tu na watu wanaofanya utafiti huu na hawatashirikiwa na wengine kamwe.

Je, Kuna Athari Zozote, Madhara, Usumbufu Zinazohusiana Na Utafiti Huu?

MRI ni njia salama ya kuchukua picha bila mionzi. Hofu moja ambayo wagonjwa wanayo ni hatari ya MRI kama njia ya kuchukua picha na kabla ya utaratibu wowote utasaini idhini ya kufanyiwa uchunguzi.

Kwa ujumla, utafiti wa matibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihemko na kiafya. Moja ya hatari ya kuwa katika utafiti huu ni kupoteza faragha. Habari yoyote unayotupatia ni ya siri na itachukuliwa kama siri.

Tutatumia nambari ya kukutambulisha kwenye hifadhidata ya kompyuta inayolindwa na nywila na rekodi zetu zote za karatasi zitahifadhiwa kwenye baraza la mawaziri iliyofungwa. Una haki ya kukataa mahojiano au maswali yoyote yanayoulizwa katika mahojiano. Pia, wafanyikazi wetu wote wanaofanya utafiti huu ni wataalamu wenye mafunzo katika mitihani / mahojiano haya.

Je, Kuna Faida Zozote Ziko Katika Utafiti Huu?

Utafiti huo utatusaidia kuelewa vizuri matumizi ya MRI katika kutathmini uvimbe maalum za ubongo zinazojulikana kama gliomas. Hii itapanua zaidi ufahamu wetu wa hizi uvimbe na itaathiri jinsi wagonjwa wenye uvimbe wa ubongo husimamiwa.

Je, Kuna Gharama Kuwa Katika Utafiti Huu?

Hakuna gharama za ziada zitakazopatikana.

Je, Ninaweza Kumuondoa Mtoto Wangu Kwenye Utafiti Wakati Wowote?

Kushiriki katika utafiti ni kwa hiari na una haki ya kumuondoa mtoto wako kutoka kwa utafiti na kwamba wakati wowote unaweza kuamua kumuondoa mtoto wako kutoka kwa utafiti bila

lazima kutoa sababu ya kumuondoa. Hii haiathiri kwa vyovyote huduma anazopewa katika kituo hicho au katika kituo kingine chochote cha afya.

Maelezo ya Ziada kwa wazazi au walezi wa washiriki wa umri chini ya 18.

- Kwa niaba ya mshiriki utahitajika kujaza dodoso la usalama wa MRI kwa niaba ya mshiriki, na utoe idhini ipasavyo.
- Mshiriki atajumuishwa tu kwenye utafiti ikiwa utakubali. Unaweza kukataa kuruhusu mtoto wako ajumuishwe kwenye utafiti ikiwa unataka.

Kwa habari zaidi juu ya haki zako kama mshiriki wa utafiti unaweza kuwasiliana na watu wafuatao:

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Appendix H – Fomu Ya Idhini (Watu Wazima).

Kichwa Cha utafiti: “UTUMIZI WA SWI(SUSCEPTIBILITY WEIGHTED IMAGING) KATIKA UTAMBUZI WA VIDONDA VYA UBONGO”

Jina la Mtafitu: Dr. MOHAMED MUHIDIN SHARIF, mwanafunzi wa Shahada ya Uzamili Katika Radiology Chuo Kikuu cha Nairobi, Idara ya Radiology.

1. Nimesoma fomu hii ya idhini au nimesomewa yaliyomo na nilielewa.
2. Nimepewa nafasi ya kuuliza maswali juu ya utafiti huu.
3. Nimejibiwa maswali yangu vya kutosha katika lugha ninayoelewa.
4. Hatari na faida zinazowezekana nimeelezwa kwa njia wazi.
5. Ninaelewa kuwa mimi hushiriki katika utafiti huu kwa hiari na kwamba ninaweza kujiondoa wakati wowote.

Kwa kusaini fomu hii ya idhini, sijatoa haki yoyote ya kisheria ambayo ninayo kama mshiriki wa utafiti.

Ninakubali kushiriki katika utafiti huu: Ndio / Hapana

Ninakubali kutoa habari ya mawasiliano kwa ufuatiliaji: Ndio / Hapana

Jina la mshiriki aliyechapishwa: _____

Mawasiliano (nambari ya rununu): _____

Saini ya mshiriki / Stempu ya kidole gumba _____ Tarehe _____

Kauli ya mtafiti

Mimi, aliyesainiwa chini, nimeelezea kabisa maelezo yanayofaa ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kwamba mshiriki amelewa na kwa hiari ametoa idhini yake.

Jina la mtafiti: DR. MOHAMED MUHIDIN SHARIF: _____

Saini _____

Wajibu katika utafiti: Mchunguzi mkuu.

Kwa habari zaidi, wasiliana na:

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Appendix H – Fomu Ya Idhini-Washiriki Walio Chini Ya Miaka 18 Ya Umri.

Kichwa Cha utafiti: “UTUMIZI WA SWI (SUSCEPTIBILITY WEIGHTED IMAGING) KATIKA UTAMBUZI WA VIDONDA VYA UBONGO”

Jina la Mtafitu: Dr. MOHAMED MUHIDIN SHARIF, mwanafunzi wa Shahada ya Uzamili Katika Radiology Chuo Kikuu cha Nairobi, Idara ya Radiology.

1. Nimesoma fomu hii ya idhini au nimesomewa yaliyomo na nilielewa.
2. Nimepewa nafasi ya kuuliza maswali juu ya utafiti huu.
3. Nimejibiwa maswali yangu vya kutosha katika lugha ninayoelewa.
4. Hatari na faida zinazowezekana nimeelezewa kwa njia wazi.
5. Ninaelewa kuwa mimi hushiriki katika utafiti huu kwa hiari na kwamba ninaweza kujiondoa wakati wowote.

Kwa kusaini fomu hii ya idhini, sijatoa haki yoyote ya kisheria ambayo ninayo kama mshiriki wa utafiti.

Ninakubali kushiriki katika utafiti huu: Ndio / Hapana

Ninakubali kutoa habari ya mawasiliano kwa ufuatiliaji: Ndio / Hapana

Jina la mshiriki aliyechapishwa: _____

Mawasiliano (nambari ya rununu): _____

Jina la Mzazi / Mlezi kutoa idhini kwa mtoto: _____

Saini: _____ Tarehe: _____

Kauli ya mtafiti

Mimi, aliyesainiwa chini, nimeelezea kabisa maelezo yanayofaa ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kwamba mshiriki ameelewa na kwa hiari ametoa idhini yake.

Jina la mtafiti: DR. MOHAMED MUHIDIN SHARIF: _____

Saini _____

Wajibu katika utafiti: Mchunguzi mkuu.

Kwa habari zaidi, wasiliana na:

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