

**FUNCTIONAL OUTCOME AFTER SURGERY FOR INTRACRANIAL MENINGIOMA AT THE
KENYATTA NATIONAL HOSPITAL**

Dr Kagasi Travor

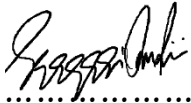
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A dissertation submitted in partial fulfilment for the award of degree of Master of
Medicine in Neurosurgery at the University of Nairobi

2023

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I **Dr Kagasi Travor** declare that this research proposal is my original work and has not been presented before for any awards or degree.

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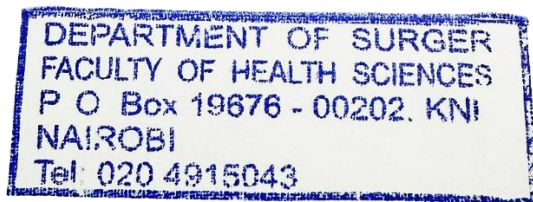
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Dedication

To my mother who taught to keep the focus, to strive to be better, to persevere through all. She who loves me endlessly, supports and encourages me in all my pursuits. I hope this achievement fulfils the dream and vision you had for me.

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LIST OF ABBREVIATIONS AND ACRONYMS

WHO	World Health Organization
FIM	Functional Independence Measure
ADL	Activities of Daily Living
CT	Computed Tomography
MRI	Magnetic Resonance Imaging
CNS	Central Nervous System
KPS	Karnofsky Performance Scale
IGS	Image Guidance Systems
AVM	Arteriovenous malformation
mRS	Modified Ranking Scale
GCS	Glasgow Coma Scale
MMSE	Mini-mental Status Examination

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ABSTRACT

Background

Intracranial meningiomas represent 34.4% to 41.4% of all brain tumors at the Kenyatta National Hospital. Meningiomas and their attendant treatment can cause various functional and neuropsychological impairments that affect the patient life. Traditionally surgical outcomes have been gauged on the Simpson grade achieved at surgery, the recurrence rates, rates of complication, overall and progression free survival amongst other surgical outcomes. The functional outcome that assess the performance of these patients in activities of daily life is a less studied outcome. Functional outcome is significant because it provides insight into the patient's quality of life following intracranial meningioma excision. The Functional Independence Measure is an outcome measure for activities of daily living that can objectively determine impairments in various domains.

Study Design

The was a retrospective observational cross-sectional study.

Broad objective

To determine the functional outcome after surgery for intracranial meningioma at the Kenyatta National Hospital

Study population

Adult patients with intracranial meningioma operated at the Kenyatta National Hospital

Materials and Method

Consecutive convenient sampling technique was used to recruit participants into the study. A structured data collection tool was be used to collect data relevant for this study. Exposure data was collected on age, sex, extent of resection (Simpson grade) of intracranial Meningioma, and WHO grade of meningioma. Outcome data was the Functional Independent Measure. Exposure and outcome data were measured at the same time though some exposure data was retrieved from patient records.

Results

In this study, 42 participants were enrolled, with an average age of 46.8 years and a male-to-female ratio of 1:4.25. Majority of the patients presented within 13.6 months with headaches 97.7% and seizures 41.9%. Neuroimaging revealed that the average size of meningioma was 138.4 cm³, and perilesional edema was observed in 90.6% of cases. Surgical resection achieved a Simpson grade II in 52.4% of cases and Simpson grade I in 38.1% of cases. Most meningiomas were classified as WHO grade 1 (95.2%), specifically the Meningothelial variant (61.9%). Following surgery, there was a noticeable improvement in functional status, as indicated by a mean total gain of 161.9% in the Functional Independent Measure (FIM), a motor sub score gains of 174%, and a cognitive sub score gain of 149.6%. However, there was no statistically relevant association between the functional outcome and extent of surgical resection.

Conclusion

There was statistically significant improvement in the functional outcome after surgery for intracranial meningioma at the Kenyatta National Hospital measured using the Functional Independence Measure. The Simpson grade achieved at surgery did not influence the functional outcome.

Key words: Meningioma, functional outcome, functional independent measure

Chapter 1

1.1 INTRODUCTION AND BACKGROUND

Meningiomas represent 34.4% to 41.4% of all primary brain tumors at the Kenyatta National Hospital (1). The incidence is increasing due to widespread use of neuroimaging (2). There is a higher preponderance in females than males with those commonly affected being older than 65 years (1,3).

The neurologic presentation of meningioma depends largely on their location within the cranial cavity. Focal neurological symptoms, such as cranial nerve impairments, generalized or partial seizures, and elevated intracranial pressure, which can result in headaches, can all appear singly or simultaneously (4).

Meningiomas are treated by surgical extirpation. Maximum safe resection with the intention of completely removing the tumor is the purpose of surgery. The surgical approach and radicality is predicated upon the locality of the tumor, the degree of brain invasion and vascular encasement (5).

According to the WHO the quality of life is multifactorial and considers the cultural and value system the in which the patient lives (6). The functional abilities allow patients to adapt to activities of daily living, to fit productively within his domicile and community and to live independently (7). Functional disabilities can arise directly from the effects of meningioma compressing the brain or as a complication of surgery after craniotomy and resection of meningioma. The neurologic manifestation of tumor or the neurologic impairments that occur after surgery have an impact on the functional and performance status of the patient (8).

Neurosurgeons typically use the Karnofsky Performance Scale to evaluate the functional status of patients with brain tumors, to predict prognosis and to decide treatment of these patients. Patients with poor scores are usually poorer candidates for aggressive therapies including radical surgery and chemotherapy. The KPS has had good utility over the years but is subjective and does not objectively quantify impairments in different domains of function (9).

The Functional Independence Measure (FIM), a scale containing 18 items, objectively assesses different functional domains in patients after therapy. It has durable reliability and is easy to administer. The FIM measures performance in the activities of daily living (ADL). The ADL are part of the functional assessments done to determine the functional outcome. The FIM has also been used for evaluation of rehabilitation outcomes in patients with meningioma with good functional improvements observed in patients with post-operative neurologic impairments after rehabilitation (8).

Outcome measures for meningioma surgery including the extent of surgical resection, rate of recurrence, complication rates, overall and progression free survival have been well studied in literature. The patients' functional outcome and quality of life after meningioma resection is less studied. Despite the high incidence and surgical treatment

of meningiomas amongst brain tumors in Kenya there is paucity of data as regards their functional outcomes after surgical resection. The situation is similar internationally but there is a growing interest in in this topic because the functional outcome affects the quality of life of patients operated for intracranial meningioma. The aim of this research therefore will be to assess the functional outcomes of patients who underwent surgery for meningioma and the factors affecting the current functional outcomes.

Chapter 2

2.0 LITERATURE REVIEW

2.1 Epidemiology of Intracranial Meningioma

Meningiomas are the commonest primary tumor of the brain seen at the Kenyatta National Hospital representing 34.4 to 41.4% of primary tumors of the brain (1,3). Meningiomas account for 37.1% of all primary brain tumors, according to data from the Central Brain Tumor Registry of the United States (CBTRUS) (2). Meningiomas arise from proliferation of meningothelial cells that are found in the arachnoid layer of the meninges of the brain (10). The incidence of intracranial meningioma increases with age and are dramatically commoner with patients 65yrs and older. These tumors remain rare in the pediatric population below the age of 14 years (10,11).

Meningiomas at all sites in the cranial cavity and the spine have an uncanny female preponderance. They are 3.2 times more prevalent in female patients at the Kenyatta National Hospital according to S. Wahome *et al* with a mean age of 43.97 years (3). The Central Brain Tumor Registry of the United States (CBTRUS) reports 2.16 times higher incidence in women (2).

2.2 Pathobiology of meningiomas

Meningioma arise from meningothelial cells / arachnoid cap cells found within the arachnoid mater. These arachnoid cap cells form part of the arachnoid villi or granulation and are in contact with the venous surface of the dural venous sinuses. The remainder of the arachnoid granulation is composed of a fibrous capsule that surrounds the arachnoid cap cells (12). These arachnoid villi are most abundant at the superior sagittal sinus. Other areas where the arachnoid villi are found include the paired cavernous sinuses, tuberculum sellae, lamina cribrosa of the ethmoid, the confluence of sinuses and the foramen magnum (12).

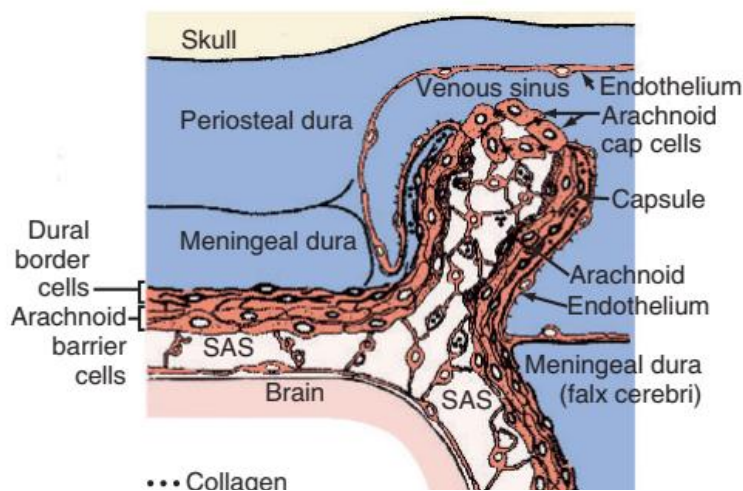


Figure 1 Diagrammatic representation of the arachnoid villus (Adopted from Youmans chapter 47: meningiomas, page 1108)

Meningiomas are characteristically dura based insidiously growing tumors. Their growth is usually well circumscribed, encapsulated and globular compressing the surrounding brain without invading the brain in most cases. Alternatively, their growth can be in a sheet like fashion and contours itself along the bony surface to form the enplaque meningioma. Enplaque meningiomas are commonest along the sphenoid ridge. Even though bone and dura invasion are frequent, meningiomas are typically easily removed from the pia mater during surgery. Invasion of the brain occurs in higher grade tumors of the malignant type (10).

Several factors have been implicated in the tumorigenesis of meningioma. These include genetic, hormonal and environmental factors.

2.3 The genetics of meningioma

Genetic alterations in meningioma have been studied extensively over the last decade. Different researchers have put forth various genetic aberrations in meningiomas. There seems to be consensus on a few as causative in the tumorigenesis of meningiomas (10). The Neurofibromatosis type 2 (NF2) gene is located in the Meningioma chromosomal area, which has been identified on the long arm of chromosome 22. The most frequent chromosomal abnormality in meningioma is monosomy 22/deletion of chromosome 22q with or without NF2 gene mutation. Monosomy 22 is present in 50% of all meningiomas, in most of the NF-2 associated meningiomas and in 40-70% of meningiomas that occur sporadically (13). Inactivating mutations in the NF-2 allele are present in 60% of these meningiomas, which is consistent with the two-hit theory of tumorigenesis (13,14). The range of mutations identified in the NF-2 gene runs the gamut from insertion, deletion to missense affecting the splicing regions of the gene (15).

The Merlin protein is made by the NF-2 gene. Merlin, also referred to as schwannomin, functions to control cellular development, proliferation, and motility by connecting essential proteins to the cytoskeleton. Mutated NF2 truncates the Merlin protein making it dysfunctional. This leads to disordered cellular growth and cellular adhesion through the macula adherens. A mutant NF2 is characterized by loss of contact-mediated inhibition during proliferation (14). In schwannoma the loss of merlin causes increased levels of ErbB receptors. ErbB receptors regulate downstream mitogenic signaling through Ras/Raf/MEK/ERK and PI3K/AKT pathways. These findings suggest that merlin in tumorigenesis in meningiomas (16). Re-expression of the wild type of Merlin inhibits both tumor growth and cell motility in mice with NF2 mutations, which are more likely to form metastatic cancers (17).

Frequency of mutations in the NF2 gene locus generally far exceeds the mutations that occur in NF2 in meningiomas suggesting that concomitant mutations are required for tumorigenesis. BAM22, a member of the -adaptin family of genes, was discovered to be inactivated in 9 out of 71 meningiomas (18). In meningiomas with loss of chromosome 22q heterozygosity, a recent study discovered decreased expression of the breakpoint

cluster region (BCR) gene, which suggests that there may be more potential genes besides NF2 involved in the tumorigenesis of meningiomas (19).

Meningiomas have also been reported to contain additional chromosomal abnormalities. Chromosomal losses have been linked to chromosome losses 1p, 10, 14/14q, and less frequently 6q, 9p, and 18q, or the sex chromosomes. Additionally, gains in chromosomes 20, 17, 15, 12, 9, and 1q have been found in a variety of meningioma populations, and they account for 30% of these tumors (13,20). Others genes have also been identified by next generation sequencing and these include AKT1 (E17K mutation), SMO (L412F and W535L mutations), KLF4 (K409Q mutation) and TRAF7 genes (18,20). Some of these mutations have been found to correlate with distinct clinico-pathological characteristics including location and histologic type. There have been added potential genes but their putative role remains to be elucidated.

These genetic markers are important in studying the cytogenetic progression of meningiomas. Ketter et al proposed different patterns of cytogenetic variations that escalated the tumor grade and aggressiveness. These cytogenetic and genomic profiles have a standing on the way the meningiomas behave biologically. They affect the recurrence after treatment and therefore the disease and event free survival and the functional outcome (20,21). The prognosis is better for tumors with monosomy 22 and diploid karyotypes. In contradistinction those meningiomas with complex karyotypes harbor a poorer recurrence free survival (15).

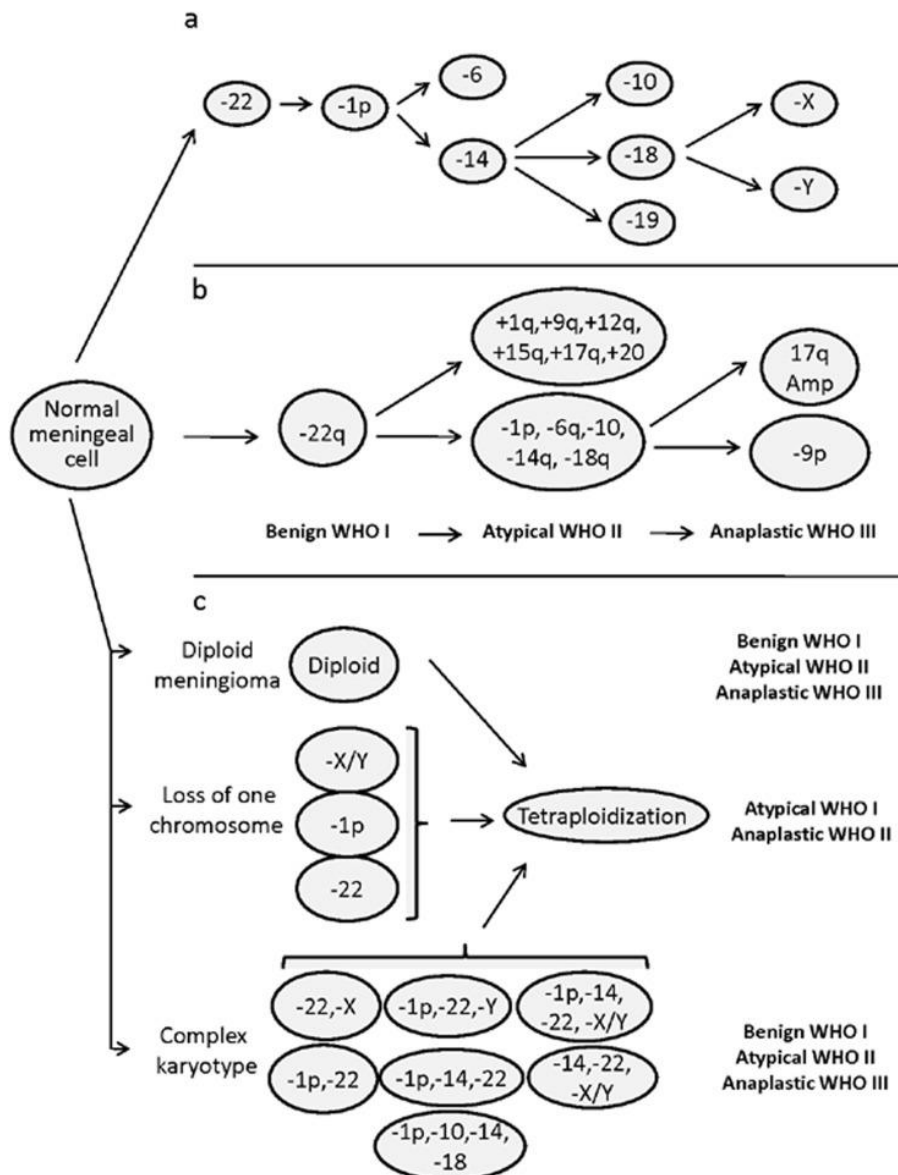


Figure 2: Patterns of cytogenetic changes that may reflect the development of

These genetic changes affect many cellular signaling pathways, which has an effect on meningioma formation. This is exemplified in the figure 3 below

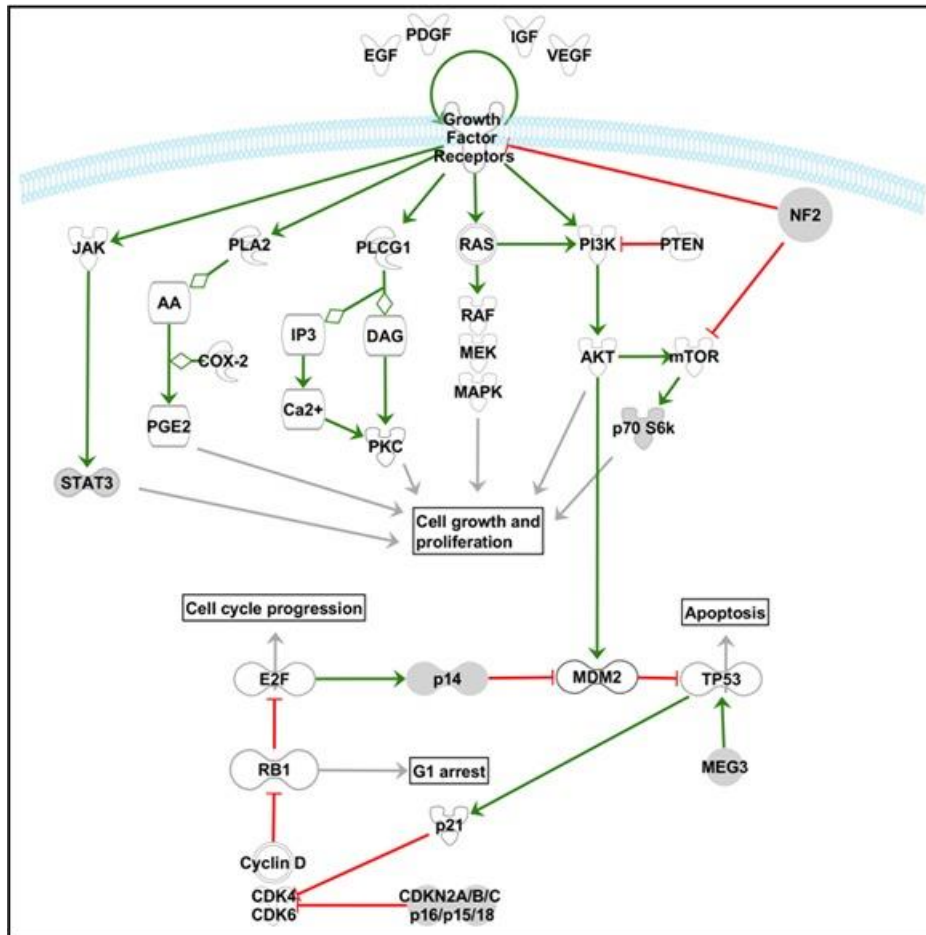


Figure 3: Schematic diagram illustrating the key elements of some of the most relevant signaling pathways involved in the pathogenesis of meningiomas [9]

World Health Organization/ CNS 5 classification of brain tumors in 2021 identified crucial diagnostic Genes, Molecules, Pathways, and/or Combinations that are involved in meningiomas. NF2, AKT1, TRAF7, SMO, PIK3CA, KLF4, SMARCE1, BAP1, H3K27me3, TERT promoter, and CDKN2A/B in CNS WHO grade 3 meningiomas are a few of them. These molecular markers dictate the tumor biological behavior and can confer aggressive phenotypes in different tumors in the same WHO grade. Work is ongoing to identify therapies for these molecular targets and this could be forthcoming in the future (22).

DNA methylation groups in meningioma could help in identifying novel medical therapies for meningioma. In Choudhury et al study unsupervised DNA methylation clustering yielded 3 methylation groups. Merlin-intact meningiomas formed 34% of the tumors and had the best outcomes. Meningiomas that were immune-enriched (38%) had varying findings and exhibited lymphatic vessels, HLA expression, and immune cell infiltration. The poorest outcomes were seen in hypermitotic meningiomas (28%), which contained convergent mutations that disrupted the cell cycle, including FOXM1 overexpression, USF1 gain, and CDKN2A/B loss. In vitro, in vivo and studies on xenografts and organoids with immune-enriched and hypermitotic meningioma were reported to be inhibited by cell cycle inhibitors (23).

A correlation between the risk of meningioma and endogenous hormones has been suggested. That meningiomas are commoner in women points to this assertion. Harvey Cushing was the first to note the role of hormones and meningioma growth. He has noted deterioration of vision in patients with suprasellar meningiomas during pregnancy postulating that these tumors increased in size significantly during pregnancy to cause visual symptoms (24). Since Cushing's times there have been studies done on the matter and there is epidemiologic connection between meningioma and pregnancy (25). Multiple studies done have found no correlation between the use of combined oral contraceptives while other has found a correlation between hormonal replacement therapy and increased risk for meningioma. The 1.3 million-woman Million Women Study did not discover a link between oral contraceptive use in the five years prior and an elevated incidence of meningioma. Current data therefore is equivocal as regards oral contraception as a risk factor for meningioma.

Head trauma has been touted as a risk factor ever since Harvey Cushing, but studies show no connection. After an average follow-up of 8 years, a cohort analysis of 228 055 Danish patients hospitalized for head injuries between 1977 and 1992 found no link (26). Attempts to find links between meningioma and specific occupation and industrial chemical exposures have proved futile. There is no positive data on diet and meningioma nor is there any link with allergic conditions as there is for glial tumors (27,28).

First-degree relatives of meningioma patients have been shown in several studies to have an elevated chance of developing the disease. First-degree kin of a patient with a meningioma diagnosis were shown to have a two-fold increased risk of developing the meningioma, while their spouses did not (29).

Hemminki et al with data from the Swedish and Norwegian Registry Databases found similar results in persons having a first-degree relative or two with meningioma (30).

2.4 Classification and Grading of Meningiomas

Intracranial meningiomas either convexity or skull base are classified according to their location within the cranium as shown in table 1.

Table 1: meningiomas by site

Cerebral convexity	Tuberculum sellae	Clival
Falcine	Lateral and Middle Sphenoid wing	Petro clival
Parasagittal	Clinoidal	Temporal bone
Tentorial	Cavernous sinus	Foramen magnum
Peritorcular	Spheno-orbital	Intraventricular

Falcotentorial	Cerebellar convexity	Pineal and 3rd ventricular
Olfactory groove	CP angle	Middle fossa floor

The World Health Organization (WHO) in 2016 classified meningiomas as Grade I (benign), Grade II (atypical) and Grade III (Malignant). This classification is based on the histologic and cyto-morphogenic features of the meningioma. This classification engenders 15 different meningioma variants stratified according to the histologic and cyto-morphogenic patterns into the 3 grades of meningioma (22). The criteria for categorization are as shown below in fig 4.

The different WHO grades have traditionally been attributed to the degree of risk for tumor progression and recurrence with grade I tumors having the lowest risk and grade 3 tumors highest. Work has been ongoing to profile meningiomas genetically and epigenetically through DNA and methylation sequencing. It has been noted that several chromosomal, genetic and epigenetic alterations confer different biologic behavior meningiomas even in the same WHO grade (31).

In CNS 5/ The 2021 WHO Classification of Tumors of the CNS molecular characteristics are integrated into the classification system after recognition of the effect of molecular profiles on the biologic behavior of meningioma. As an addition to the 2016 classification SMARCE 1 loss in meningioma places it as a grade II and is seen in clear cell variant. CDKN2A/B homozygous deletion or TERT promoter mutation places the meningioma as a grade III in the new WHO 2021 classification (22).

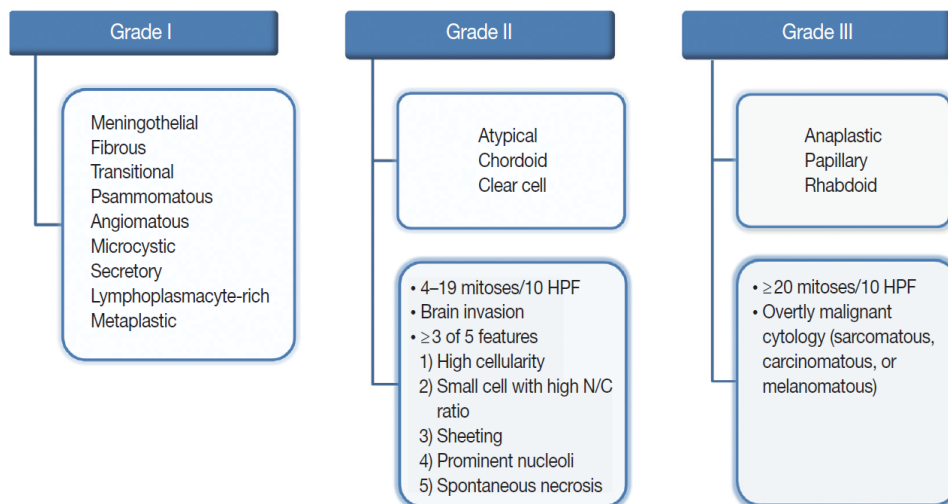


Figure 4: 2016 classification of meningiomas (Adopted from *Journal of Pathology and Translational Medicine J Pathol Transl Med* 2383-7837 2383-7845) [31]

Joseph Driver *et al* noted that clinical behavior of meningiomas often fails to conform to the WHO grade. Additional prognostic information is therefore required so as to optimize the outcome of meningioma treatment. He proposed a 3-tier integrated categorization based on the histology, extent of tumor resection and molecular profile (31). In his series

this classification predicts well the risk of recurrence and outcome. Example of such 3-tier grade is shown in fig 5

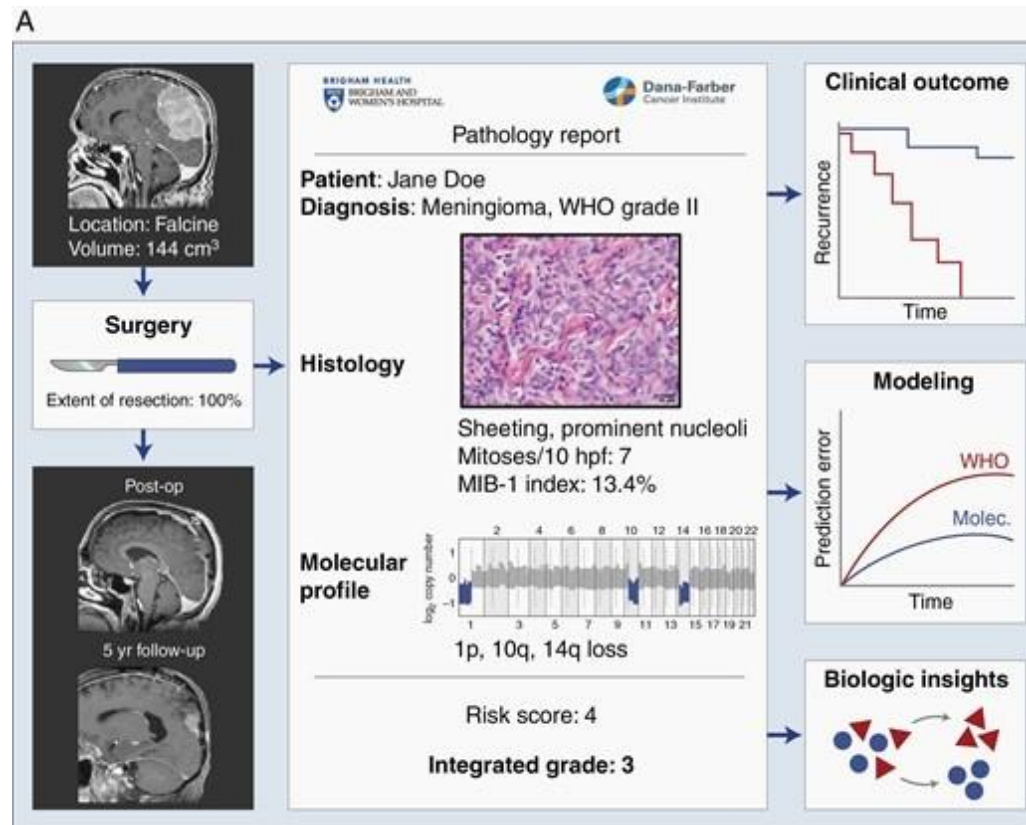


Figure 5: 3 tier grading of meningioma (Adopted from; A molecularly integrated grade for meningioma, *Neuro-Oncology*, Volume 24, Issue 5, May 2022[32])

2.5 Brain invasion in meningioma

Brain invasion is a stand-alone criterion for the diagnosis of WHO grade II meningioma. Brain invasion is defined as tumor tissue within the adjacent brain without a separating connective tissue layer (32). This entails tumor growth beyond the pia mater of the brain. Intraoperatively there may be a cleavable plane at the brain-tumor interface even when there is brain invasion (32). The extent of surgical resection is considered regardless of brain invasion. A gross total removal is considered if all tumor is removed despite there being invasive growth. In terms of outcome brain invasion is not prognostic of progression free survival although some studies have suggested that brain invasion is prognostic for a subtotal resection and not for gross total resection for progression free survival (33,34). Studies are limited as regards correlation between brain invasion and the functional outcome.

2.6 Clinical features

Meningiomas are frequently an incidental finding and asymptomatic. There are no pathognomonic clinical features, and their locale intracranially usually affects the symptomatology. These tumors seldom invade surrounding tissue and often grow

slowly. Focal neurological symptoms, such as cranial nerve impairments, generalized or partial seizures, and elevated intracranial pressure, which can result in headaches, can all appear singly or simultaneously (4).

2.7 Radiology for meningioma

2.7.1 CT Scan

Meningiomas usually appear as homogeneous tumor that enhances and has broad dural base. Psammomatous calcifications are often present. Cerebral edema may be minimal or it may be exuberant extending throughout white matter of a hemisphere. 50% of intraventricular meningioma produce extra ventricular edema and on angiography these may appear deceitfully malignant. Prostate carcinoma may mimic where it has metastasized to the skull and caused hyperostosis (4).

2.7.2 MRI

MRI is the cornerstone of diagnosis. Benign meningiomas usually appear as well circumscribed masses that enhance homogeneously on administration of gadolinium. These usually have a thickened contrast enhancing dural tail although this finding may also be present in lymphoma, metastasis and hemangiopericytoma and may confound the diagnosis of meningioma. Peritumoral edema seen on T2 and FLAIR images may be present and is common in secretory meningiomas. Central core necrosis can be seen as T1 hypointense and non-enhancement both in benign and malignant meningiomas (12). In irradiation meningiomas, 68-gallium-labeled somatostatin receptor analog (68Ga-DOTATATE) may play a diagnostic role in identifying recurrence (5).

2.8 Treatment of meningioma

2.8.1 Surgery for Meningioma

Asymptomatic incidental meningiomas can be followed up with radiologic surveillance until a time when demonstrable growth is seen in serial imaging, symptoms arise or the tumor is large (35,36). Surgery is the treatment of choice for meningioma that are symptomatic and increasing in size. The aim of surgery is a maximal safe resection with the aim for a radical resection. The surgical approach and radicality is predicated upon the locality of the tumor, the degree of brain invasion and vascular encasement (5). To keep recurrence at bay it is important to remove all diseased bone, dura together with the tumor whenever technically feasible (37). The extent of surgical resection is graded according to the Simpson grade as follows

Simpson Grading

Grade 0: Complete tumor excision, plus removal of an additional 2 cm of bone and dura from tumor site

Grade I: Complete tumor excision, including any dural attachments or abnormal bone

Grade II: Complete tumor excision with coagulation of dural attachment

Grade III: Complete tumor excision without resection or coagulation of its dural

attachment

Grade IV: Partial tumor resection

Grade V: Biopsy only (38).

The Simpson grade is used to predict the risk of meningioma recurrence. The 10-year risk of recurrence is 9, 19, 29, 40 and 100% for grade I – V respectively (38). In a study involving 458 meningioma patients, Nanda et al. reported that the Simpson grade affected the rate of meningioma recurrence for both the skull base ($p=0.047$) and convexity ($p=0.012$) for grade 1 meningiomas. In this series, they also found that female sex and the Karnofsky Performance Scale (KPS) were independent predictors of recurrence free survival (39). Additionally, MIB-1 index, tumor size (<6cm versus > 6 cm), WHO grade, tumor multiplicity, and tumor location were indicators of recurrence and progression-free survival (38).

Patients who undergo incomplete resection are more likely to experience recurrences, have worse resection success rates during subsequent operations, and even worse (40) have lower overall survival rates (41).

Operative adjuncts can accurately localize the tumor, identify the desired trajectory, identify and map out critical neurovascular structures. Various image guidance systems have been developed and are extensively used in intra-axial tumors of the brain. Their use has also gained traction in meningioma surgery. However, no prospective, randomized studies employing IGS for meningioma excision have demonstrated superior outcomes. In their study, Paleologos et al. included 270 patients who underwent meningioma surgery (100 with IGS, 170 without IGS). They found that using IGS resulted in faster operation times, a reduction in significant morbidity, shorter hospital stays, and lower treatment costs when 100 patients with comparable baseline characteristics were matched (50 in each group) (42).

Type of Image Guidance Surgery	Description	Products
Articulated arms	Consist of movable arm with multiple position sensors that provide correlation of pointer location with imaging Require movement into and out of operative field for use	ISG Wand (ISG Technologies, Inc., Mississauga, Ontario, Canada/Elekta, Atlanta, GA) Radionics Operating Arm (Radionics, Burlington, MA)
Light-emitting diode systems	Pointing probe and array attached to skull or head holder have light-emitting diodes that emit pulses of infrared light Cameras receive the infrared light and determine the location of the pointer relative to the head array Allow stereotactic microscope integration	iNtelleCt Cranial Navigation System (Stryker, Kalamazoo, MI) EasyGuide Neuro (Phillips, Shelton, CT) SMN-Zeiss (Carl Zeiss, Inc., Thornwood, NY)
Passive infrared systems	Consist of cameras that emit pulses of infrared light that are returned by reflective spheres attached to the pointer probe, head array, and surgical instruments Allow stereotactic microscope integration	Brainlab VectorVision (Brainlab USA, Redwood City, CA) StealthStation TREON (Medtronic Navigation, Louisville, CO)
Electromagnetic systems	Create a small magnetic field that tracks a magnetically active pointer	Cygnus Stereotactic System (Compass International, Inc., Rochester, MN) StealthStation AxiEM (Medtronic Navigation, Louisville, CO)

Figure 6: types of image guidance systems (Adopted from Almefty meningioma Chapter 35: Image guidance techniques for meningioma)

2.8.2 Radiation - Stereotactic Radiosurgery (SRS)

Radiosurgery may be utilized as the main course of treatment modality for small tumors that are asymptomatic, symptomatic tumors on locations that carry a high surgical morbidity, recurrent smaller volume tumors, patients with concomitant major medical morbidity, elderly patients and younger individuals who opted for radiosurgery over other procedures. Relative contraindications to radiosurgery include tumors larger than 3.5cm, tumors with symptomatic compression of the optic apparatus, optic nerve sheath meningiomas with visual preservation and tumors with atypical radiologic or previous atypical histologic features (43). The response to radiosurgery is durable with a 91% control rate at 4 years with the tumors regressing or unchanged in size (43). Radiation surgery provides a more durable control after Simpson grade II, III and IV than surgery alone. Pollock et al found remarkably similar recurrence rates after radiosurgery alone to Simpson results after resection alone (44). The risks of open surgery, brain retraction, anesthesia, and extended hospital stays are eliminated by radiosurgery. In a survey by Almefty et of patients who had undergone radiosurgery 5-10 years prior, of the patients who were employed at the time of radiosurgery 74% remained employed, 14% had resumed employment. 65% of the patients described that their overall activity had remained the same, 8% had improved and 275 had reduced activity (44). Radiosurgery therefore is a well-tolerated, powerful biologic treatment that has excellent long-term outcomes (45).

2.9 Functional outcome after surgery for Intracranial meningioma treatment

Surgical or oncologic outcomes evaluates extent of surgical resection, overall or progression free survival, recurrence rates and surgical complication rates among other

direct surgical outcomes measures. The functional outcome of cranial surgery on the other hand is the alteration of how the patient performs in their day to day living and/or how the feels after treatment. Depending on who evaluates the functional integrity there are multiple perspectives that can arise. These perspectives will differ if it is the neurosurgeon, the patient themselves, the patient's proxy or any other investigator evaluates (8). These functional outcomes can be subjective dealing with how the patient feels about their condition e.g. patient reported fatigue levels or objective dealing with how the patients performs specific tasks or set of outlined activities e.g. neurocognitive assessment or muscle strength assessment (8).

Functional outcomes can be examined from various perspectives, such as neurologic evaluation, neurocognitive performance, daily living activities, seizure outcomes, and health-related quality of life (HRQoL). Seizure activity, neurological assessment and examination and neurocognitive performance directly assess brain function. Activities of Daily Living (ADL) and HRQoL are both subjective and objective evaluations of how well the brain is functioning. Reported by the patient or his kin, health-related quality of life comprises several components, including physical, psychological, and social capacities. The health-related quality of life after brain tumor treatment can be assessed using a variety of techniques (46).

The EORTC QLQ-BN20, which is the brain tumor-specific version of the EORTC Quality of Life Questionnaire-C30 (QLQ-C30), comprises 11 scores, with 7 single questions measuring the patient's general health, symptoms of headache, seizures, fatigue, hair loss, pruritus, and bladder control, and 4 multiple item scales measuring future uncertainty, visual compromise, motor deficit, and communication or language dysfunction (7,47).

The 36-Item Short Form Health Survey (SF-36) is a frequently used instrument for evaluating health-related quality of life (48). Overall health, energy, physical functioning, role physical, bodily pain, social functioning, role emotional, and mental health are the eight scales that the SF-36 evaluates. (49).

Benz et al in their study; Quality of life after intracranial meningioma surgery, found statistically lower scores using the SF-36 in cases compared to controls. Significant differences were found in General Health and Vitality, and Physical Role of the SF-36 (50). Others studies have found differences in the improvement of the quality of life after meningioma surgery however, the variations lacked statistical significance (50). Neurosurgeons have traditionally used the Karnofsky Performance Scale (KPS) to gauge the functional status of the patient before and after surgery. KPS has been used as a functional outcome measure to compare different therapies and assess the overall prognosis (50).

Roel et al (2021) used the KPS to evaluate the functional outcome after surgery for giant intracranial meningiomas in geriatric patients and found that 36% of non-giant and 14% of giant meningioma geriatric patients were discharged home. At 1 year the independence

rates were 69% and 57% respectively for non-giant and giant meningioma patients using the KPS (51).

Ahmeti et al (2021) in a series of 768 meningioma patients found improvements after surgery in the KPS ($p < 0.001$) except in the very elderly above years (52). They found the greatest risk of postoperative complications and risk of dependence and therefore a poorer functional outcome in these elderly patients. The KPS however is used most extensively preoperatively for treatment modality decisions and overall as a prognostic indicator (9).

The modified ranking scale (mRS) was originally intended for evaluation of disability after stroke and is the most widely used scale in stroke clinical trials. mRS has been used in evaluation of long-term outcomes of AVM surgery and in spinal meningioma (53).

The Functional Independent Measure (FIM) is a scoring system for activities of daily living that objectively determines impairment in different functional domains that have been caused by a brain tumor or its treatment. The KPS and NPS unlike the FIM are subjective and fall short in determining accurately the degree of impairment and in assessing the degree of improvement after treatment. The FIM and its congener the Barthel index provide a more objective measure of impairment and degree of improvement after treatment (54). Most of other scoring systems for activities of daily living as a functional outcome measure do not capture cognitive data (55) whilst detailed neuropsychological assessment is laborious and requires dedicated trained staff (56). The FIM contains cognitive domains that are easy to administer and are useful in evaluating functional outcome after treatment (57). The 18 item FIM score is shown below in Fig 7.

The FIM has shown solid structure and reliability as a functional outcome measure [62] With intraclass correlation coefficients between 0.86 and 0.88, the inter-rater reliability of FIM has been determined to be at an acceptable psychometric performance (58).

Anoush Dehnadi et al found who studied the validity, reliability and reproducibility of the FIM head injured patients found the inter-rater reliability acceptable on admission and at discharge. The FIM showed correlation with the at admission and at discharge and also correlated well with the physical health components of SF-36 (PCS). FIM cognitive score correlated well with the MMSE scores (59,60).

The functional independence measure is popular amongst rehabilitation specialist working with neurologic patients as an objective way of performance-based assessment of improvements during rehabilitation(61) [64]

Natsume et al compared the FIM in patients with different brain tumors after surgery before the patients had been enrolled in adjuvant therapy programs and rehabilitation. The baseline scores were better for benign tumors like meningioma, craniopharyngioma, pituitary tumors that for malignant one like glioblastoma. In their study older patients had lower cognitive and self-care domain scores. Patients with left parietal lobe lesions had the highest rates of morbidity; those with frontal, occipital, and right temporal tumors fared better (62).

FIM™ instrument

Functional Independence Measure

L E V E L S	7 Complete Independence (Timely, Safely) 6 Modified Independence (Device)	NO HELPER		
	Modified Dependence 5 Supervision (Subject = 100%+) 4 Minimal Assist (Subject = 75%+) 3 Moderate Assist (Subject = 50%+) Complete Dependence 2 Maximal Assist (Subject = 25%+) 1 Total Assist (Subject = less than 25%)	HELPER		

	ADMISSION	DISCHARGE	FOLLOW-UP
Self-Care			
A. Eating	<input type="text"/>	<input type="text"/>	<input type="text"/>
B. Grooming	<input type="text"/>	<input type="text"/>	<input type="text"/>
C. Bathing	<input type="text"/>	<input type="text"/>	<input type="text"/>
D. Dressing - Upper Body	<input type="text"/>	<input type="text"/>	<input type="text"/>
E. Dressing - Lower Body	<input type="text"/>	<input type="text"/>	<input type="text"/>
F. Toileting	<input type="text"/>	<input type="text"/>	<input type="text"/>
Sphincter Control			
G. Bladder Management	<input type="text"/>	<input type="text"/>	<input type="text"/>
H. Bowel Management	<input type="text"/>	<input type="text"/>	<input type="text"/>
Transfers			
I. Bed, Chair, Wheelchair	<input type="text"/>	<input type="text"/>	<input type="text"/>
J. Toilet	<input type="text"/>	<input type="text"/>	<input type="text"/>
K. Tub, Shower	<input type="text"/>	<input type="text"/>	<input type="text"/>
Locomotion			
L. Walk/Wheelchair	<input type="text"/> <input type="text"/> <small>W Walk C Wheelchair B Both</small>	<input type="text"/> <input type="text"/> <small>W Walk C Wheelchair B Both</small>	<input type="text"/> <input type="text"/> <small>W Walk C Wheelchair B Both</small>
M. Stairs	<input type="text"/>	<input type="text"/>	<input type="text"/>
Motor Subtotal Score	<input type="text"/>	<input type="text"/>	<input type="text"/>
Communication			
N. Comprehension	<input type="text"/> <input type="text"/> <small>A Auditory V Visual B Both</small>	<input type="text"/> <input type="text"/> <small>A Auditory V Visual B Both</small>	<input type="text"/> <input type="text"/> <small>A Auditory V Visual B Both</small>
O. Expression	<input type="text"/> <input type="text"/> <small>V Vocal N Nonvocal B Both</small>	<input type="text"/> <input type="text"/> <small>V Vocal N Nonvocal B Both</small>	<input type="text"/> <input type="text"/> <small>V Vocal N Nonvocal B Both</small>
Social Cognition			
P. Social Interaction	<input type="text"/>	<input type="text"/>	<input type="text"/>
Q. Problem Solving	<input type="text"/>	<input type="text"/>	<input type="text"/>
R. Memory	<input type="text"/>	<input type="text"/>	<input type="text"/>
Cognitive Subtotal Score	<input type="text"/>	<input type="text"/>	<input type="text"/>
TOTAL FIM Score	<input type="text"/>	<input type="text"/>	<input type="text"/>

NOTE: Leave no blanks; enter 1 if patient not testable due to risk
 Copyright © 1993 Uniform Data System for Medical Rehabilitation, a division of U B Foundation Activities, Inc

Functional Independence Measure. Copyright © 1996. Uniform Data System for Medical Rehabilitation.
 All rights reserved. Reprinted with permission of UDSMR, University at Buffalo, 232 Parker Hall, 3435 Main Street, Buffalo, NY 14214.

Figure 7: FIM instrument: Adopted from <https://doi.org/10.1002/j.2048-7940.1999.tb02151.x>

DEGENERATIVE SPINE		
North American Spine Society Questionnaire	Separate Cervical and Lumbar instruments. Combines both disease-specific questions and SF-36 questions. Normative data published.	74
Oswestry Disability Index (ODI)	10 Domains, including intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel; 6-item scale per domain.	75
Japanese Orthopedic Association Scale	Reported for cervical myelopathy: scores 0-2 to 0-4 for motor function in arm and leg; sensory function in arm, leg, and trunk; and sphincter dysfunction. Higher scores signify greater function.	76
HYDROCEPHALUS		
Hydrocephalus Outcome Questionnaire (HOQ)	51-Question disease-specific multidimensional outcome measure developed and validated for pediatric hydrocephalus. Responses scored to yield overall score from 0 to 1. Can be converted to health utility index score.	77, 78
CRANIOFACIAL		
Whitaker Scale	I: No need for additional surgery II: Minor surgery advisable for soft tissue revision or bone contouring III: Major osteotomy or bone grafting required, although this would be less extensive than the original procedure IV: Major surgery required, equaling or exceeding the extent of the original procedure	79
ONCOLOGY		
Karnofsky Performance Status Scale	100-Point scale (scored by 10s) from 100 (normal) to 0 (dead), measuring degree of dependence; <70 is no longer independent.	80
European Organization for Research and Treatment of Cancer (EORTC) Core Quality of Life Questionnaire (QLQ-C30)	30-Item, self-reported questionnaire containing multidimensional quality-of-life measures; used in glioma outcomes	81, 82
University of Toronto scale	16 Items from Sickness Impact Profile, 13 items specific to brain tumor patients with an overall assessment question; question answered by visual analog-type scale between descriptive extremes	81
FUNCTIONAL		
Functional Independence Measure (FIM)	7-Point scale ranging from independence to total assistance applied to six ADL areas: self-care (eating, grooming, bathing, dressing, and toileting), sphincter control, mobility, locomotion (walking and stairs), communication, and social cognition	83
WeeFIM	Modification of FIM for pediatric patients	84, 85
Barthel Index	Contains 10 items (or 15 items if Granger modification version is used) addressing ADLs (feeding, transfers, toiletry, etc.). Each item is scored for dependent/incontinent versus independent/continent, with several items including intermediate grades. Total score 0-100 (0-20 for modification).	86, 87
PAIN		
McGill Pain Questionnaire	Very commonly in use. Adjectival description of pain to assess three domains: sensory-discriminative, motivational-affective, and cognitive-evaluative. Adjective selected by patient carries intensity weighting. Several scoring systems exist.	88
Visual Analog Scale	Ruler scale of 0-10 for pain.	89

Figure 8: Common scales used in Neurosurgery: Adopted from Youman and Winn Neurologic surgery chapter 57: Neurosurgical Epidemiology and Outcomes Assessment

2.10 STUDY JUSTIFICATION

Meningioma is the commonest primary brain tumor seen in KNH representing 34.4% to 44.1%. Meningiomas present from the outset with neurologic impairment. The primary treatment of intracranial meningioma is surgery. The surgical outcomes of extent of resection/Simpson grade, recurrence rates, complications, overall and progression free survival have been well studied in literature. The functional outcome after surgery that encompasses the performance of the patient in activities of daily living and their independence within society has been less studied. There is paucity of such information in literature and no such study has been done in Kenya.

Using an objective tool that is the Functional Independence Measure to evaluate the functional outcome of these patients this study would provide valuable information on the outcomes of surgery for meningioma.

2.11 STUDY QUESTION / HYPOTHESIS

What is the functional outcome after surgery of patients operated for intracranial meningioma at the Kenyatta National Hospital?

2.12 OBJECTIVES

2.12.1 Broad objective

To determine the functional outcome after surgery for intracranial meningioma in patients operated at the Kenyatta National Hospital

2.12.2 Specific Objectives

1. To determine the Functional Independent Measure (FIM) after surgery for intracranial meningioma
2. To assess the extent of resection (Simpson Grade) of intracranial meningioma.
3. To evaluate the relationship between Functional Independent Measure (FIM) and extent of resection (Simpson Grade)

CHAPTER 3 RESEARCH METHODOLOGY

3.1 STUDY DESIGN

This was a retrospective observational cross-sectional study. Exposure and outcome data were measured at the same time, though some exposure data were retrieved from patient records or their recall

3.2 Study area description

The neurosurgery unit at KNH including Neurosurgery ward 4C and Adult Neurosurgical Clinics.

3.3 Study population

Adult patients with intracranial meningioma that have undergone surgery at the Kenyatta National Hospital.

3.4 Criteria for inclusion

Adult patients (>18yrs) with a radiologic diagnosis of intracranial meningioma who were subsequently operated for the same at the Kenyatta National Hospital.

Patients on follow up at the adult neurosurgical clinics after surgery for intracranial meningioma during the study period.

3.5 Criteria for exclusion

Patients with intracranial meningioma who are less than 18 years of age.

Patients who opted out of the study.

3.6 Sample size determination

Sample size was calculated using the Fisher's formula;

$$n = \frac{Z^2 \times P(1 - P)}{d^2}$$

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level ($Z=1.96$ for 95% confidence interval)

P = expected true proportion (estimated incidence of intracranial meningiomas from Mwangombe et al (1) study at KNH at was 34.4%)

d = desired precision (0.05)

Substituting the formula

$$N = \frac{1.96^2 \times 0.344(1-0.344)}{0.05^2}$$

Adjusting for infinite population

Sample size was **346.7**

In the year 2021, 52 patients had surgery for intracranial meningioma in KNH from data collected from RedCap database at UoN/KNH brain tumour registry.

To adjust for small population size, we used the formula $N^* n / N+n$

N=sample size obtained from Fisher's formula

n=size of the small population

$$\frac{346.7*52}{346.7+52}$$

Sample size was calculated at **45 patients**

3.7 Sampling procedure

Patients who met the inclusion criteria were selected for the study.

Consecutive convenient sampling was employed to enroll all patients who consented to participate in this study once ethical approval from the KNH/UoN Ethical Review Committee had been sought.

3.8 Recruitment and consenting procedures

An explanation of the study was made to the patient/relatives and thereafter an informed consent was sought.

Documentation of informed consent was done by signing of consent form by the patient, next of kin or other appointed relative.

The patient was assigned a unique identifier for record while the study.

Demographic particulars were recorded using the data collection tool.

3.9 Data collection procedures

Data collection was done only by the principal investigator and his trained assistant(s) after taking an informed consent.

Data was gathered from the patients' files and by interview of the patient and/or next of kin using a standardized questionnaire that incorporates the Functional Independent Measure (FIM) instrument.

Data collection was done at admission and at 2 months after surgery.

3.9.1 Study variables

Objective	Independent variable	Dependent variable
1.To determine the Functional Independent Measure (FIM) after surgery for intracranial meningioma		Proportion of patients with sub-optimal functional independent measure.
2.To assess the extent of resection (Simpson Grade) of intracranial meningioma	Extent of resection (Simpson grade) of intracranial meningioma	
3.To evaluate the relationship between Functional Independent Measure (FIM) and extent of resection (Simpson Grade)	Extent of resection (Simpson grade) of intracranial meningioma	Functional independent measure

Table 2: Study variables

3.10 Materials

The materials required for the study included printed questionnaires, stationary and SPSS data analysis software.

3.11 Quality Control

To ensure quality throughout the study the following measures were taken:

1. The research assistant was trained by the principal investigator to ensure data collected was accurate and verifiable.
2. All surgeries to resect meningioma were be done by qualified consultant neurosurgeon from the KNH/ UoN.
3. Radiologic imaging reporting was done by a qualified radiologist.
4. The histopathologic assessment and WHO grading of the resected meningioma was out by a qualified pathologist at KNH / UoN

3.12 Ethical Consideration

The KNH/UoN Ethics, Research, and Standards Review Committee's ethical permission was requested before the study may be carried out.

A thorough explanation of the study was made to the patients and or next of kin and an informed consent sought for participation in the study.

Confidentiality was of utmost import by non-disclosure of the participants information and data to any third party.

Data was utilized only for research reasons, and names or other personal identifiers were not used; instead, anonymity was ensured by using codes.

The data was stored securely at the Department of Surgery University of Nairobi for future reference and the digital copy password protected.

Participants in the study did not accrue any further cost apart from standard hospital treatment costs whilst they participated in the study.

3.13 Data management and Analysis

IBM SPSS version 26.0 shall be used for data analysis.

Descriptive statistics such as mean, median, and standard deviation were used to characterize continuous variables and proportions used for categorical variables.

To correlate the FIM score, and the independent variables such as sex, extent of resection, WHO grade of meningioma, Student T was used if the independent variable had two categories with Analysis of Variance (ANOVA) if more than two categories in the independent variable.

To compare the FIM score before and after surgery, paired t test was used.

Multivariate analysis using logistic regression was used to assess the independent risk factors for sub-optimal FIM score.

P values of less than 0.05 were considered statistically significant.

Results obtained were presented in tables, figures, relative frequencies graphs, charts and group percentages.

3.14 Study results dissemination

The study results will be published as a dissertation as required for the degree of Masters in Medicine Neurosurgery.

The published results will be distributed to Chair of the Department of Surgery University of Nairobi, the Head of Thematic Unit Neurosurgery university of Nairobi, Head of Surgery KNH, Head of Neurosurgery Unit KNH, Ethics and Research Committee UoN/KNH, the College of Health Sciences Library.

Results shall also be presented in webinars, seminars, workshops and conferences. A soft copy of copy of the final dissertation will be available at the UoN e-repository platform <http://erepository.uonbi.ac.ke>

Final manuscript will be presented for publication in peer reviewed journals and publications

3.15 Limitations of the Study

Missing data – some data was retrieved retrospectively such as the extent of resection and WHO histological grade of meningioma. Therefore, when such data was missing from the file the patients were excluded from the study.

Recall bias – some patients did not remember their function (Functional score) prior to surgery. However, medical records were counterchecked as well as interview for more information from the next of kin by telephone or in person.

CHAPTER FOUR

RESULTS

4.0 Background:

IBM SPSS version 26.0 was used for data analysis.

Descriptive such as mean, median, and standard deviation were used to characterize continuous variables and proportions used for categorical variables.

To correlate the FIM score, and the independent variables such as sex, extent of resection, WHO grade of meningioma, Student T test was used if the independent variable had two categories with Analysis of Variance (ANOVA) if there were more than two categories in the independent variable.

To compare the FIM score before and after surgical intervention, paired t-test was used. Multivariate analysis using logistic regression was used to assess the independent risk factors for sub-optimal FIM score.

P values of less than 0.05 were considered statistically significant.

Results obtained were presented in tables, figures, relative frequencies graphs, charts and group percentages

4.1. Demographic and clinical characteristics

4.1.1 Age

The mean of the patients was 46.8 years with a standard deviation of 13.1 years with a range of 12 to 74.

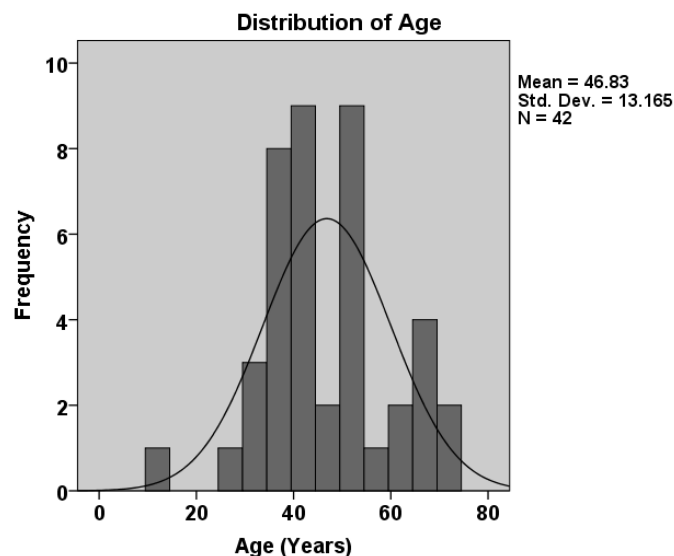


Figure 9: Age distribution

4.1.2 Sex

In the study, there were 34 (81%) female patients and 8 (19%) male patients.

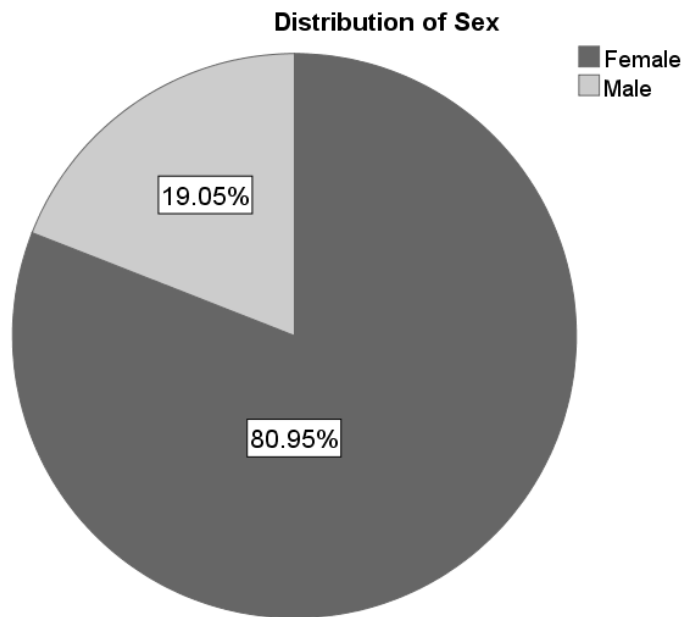


Figure 10: Sex distribution

4.1.3 County of residence

Majority of the patients resided in Kiambu county (19%), followed by Machakos at 16.7%.

Table 3: : Distribution of patients by county

County	Count	Percentage
Embu	1	2.4
Homabay	1	2.4
Isiolo	1	2.4
Kiambu	8	19
Kilifi	1	2.4
Kisii	6	14.3
Machakos	7	16.7
Makueni	2	4.8
Meru	2	4.8
Muranga	1	2.4
Nairobi	5	11.9
Nakuru	1	2.4
Nyeri	6	14.3

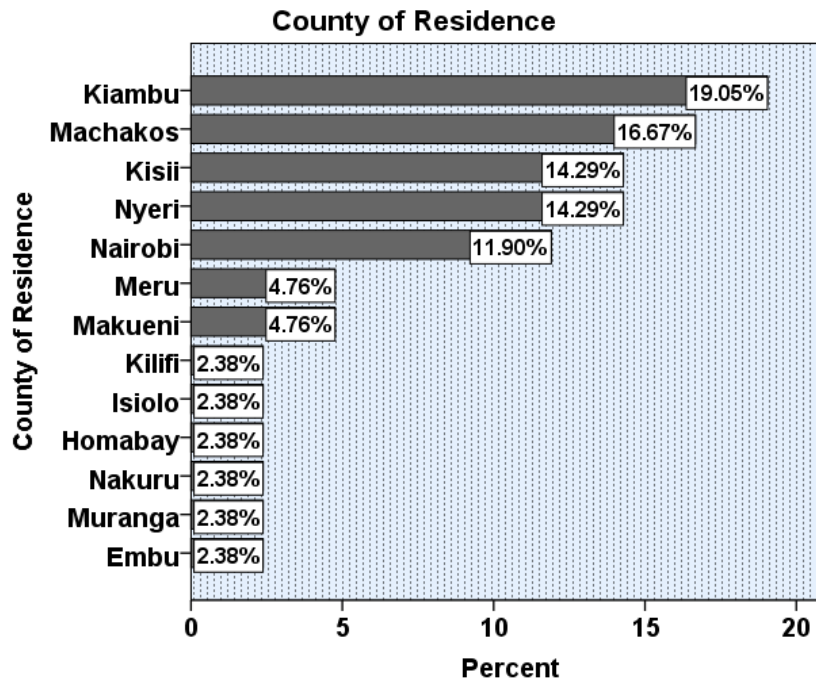


Figure 11: Distribution of patients by county

4.1.4 Signs and Symptoms

Headache was the commonest presenting complaint with 42 (97.7%) patients complaining of the same. Seizures occurred in 18 (41.9%) patients.

Table 4: Counts & percentages of signs and symptoms

Signs and Symptoms	Counts, N=43	Percentages
Headaches	42	97.7
Seizures	18	41.9
Loss of vision	15	34.9
Weakness of the limbs	8	18.6
Hemiparesis	7	16.3
Personality changes	7	16.3
Reduced level of consciousness	6	15.4
Memory problems	4	9.3
Dysphasia	3	7.7
Cranial Nerve palsy	2	5.1
Cerebellar symptoms	2	5.1
Anosmia	2	5.1
Proptosis	2	5.1
Sensory Deficit	1	2.6
Painless lump on the head	1	2.6

4.1.5 Duration of the symptoms

The mean duration of the symptoms was 13.6 with a standard deviation of 13.7, the median was 7.5 months with a range of 2 to 60.

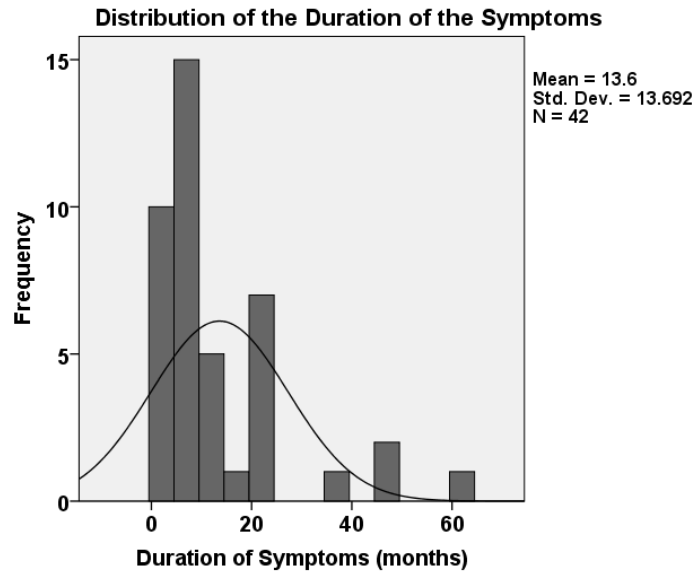


Figure 12: Histogram of duration of symptoms

4.1.6.1.1 Meningioma Location

Convexity meningiomas comprised the commonest meningioma type by location (31%). Parasagittal meningiomas comprised 16.7% and olfactory groove meningioma were 16.7%. the least common were Falcine, petrous, clival and petro-clival meningiomas. Occurrence of meningiomas by location is shown in Table 3.

Table 5: Location of meningiomas

Meningioma Location	Count, N=42	Percentages
Convexity	13	31
Parasagittal	7	16.7
Olfactory Groove	6	14.3
Sphenoid Wing	5	11.9
Spheno-orbital	3	7.1
Foramen Magnum	2	4.8
Tentorial/Falcotentorial	2	4.8
Tuberculum Sella	2	4.8
Falcine	1	2.4
Petrous / Clival / Petro-clival	1	2.4

4.1.7 Size of the tumor in centimeters

The size of tumor was reported radiologically in 20 cases. The mean size of the tumor was 138.4cm³ with a standard deviation 100. The median size was 106.5cm³, and range of 16cm³ to 419cm³

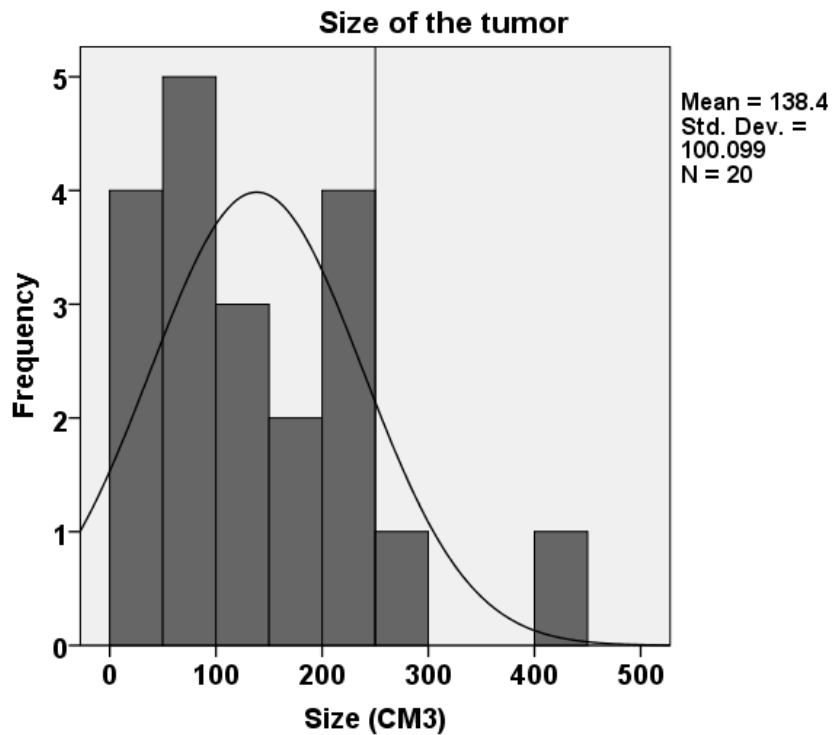


Figure 13: Tumor size distribution

4.1.8 Peri-lesional Edema

Radiologic comment regarding perilesional edema was done for 32 cases. Out of this number there were 29 (90.6%) radiologically reported cases with peri-lesional edema while 3 (9.4%) had no peri lesional edema.

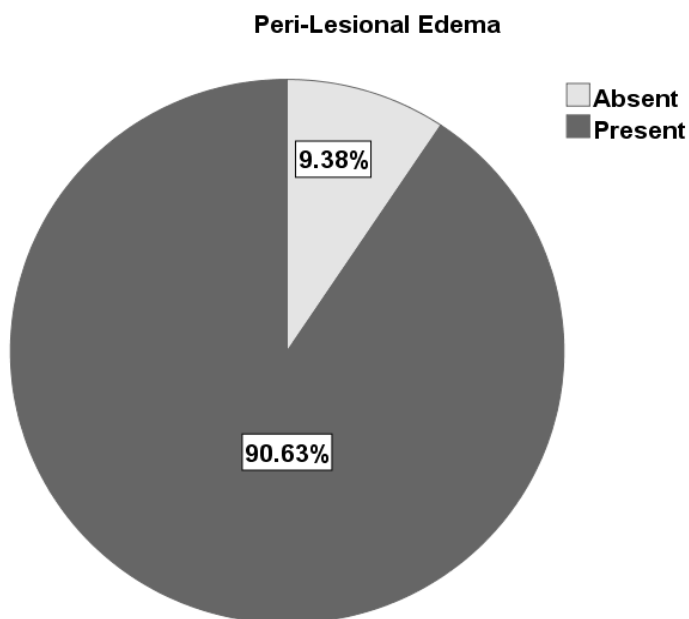


Figure 14: Presence of perilesional edema

4.1.9 Vascular Encasement

Out of 32 radiological reports there were 11 (34.4%) patients who had the vascular encasement by the tumor while 21 (65.6%) did not have the vascular encasement.

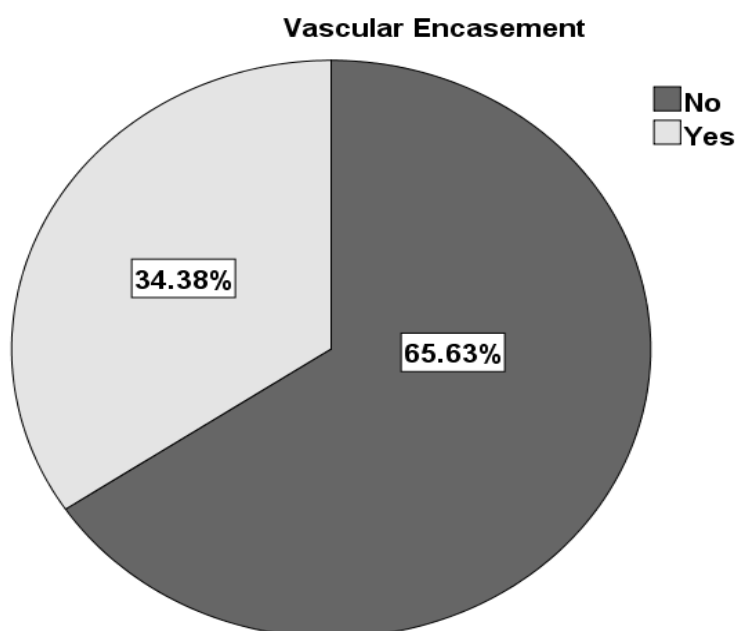


Figure 15: Vascular encasement

4.1.10 Histologic Type

Meningothelial variant was the most common histologic variant found following histopathologic evaluation of resected specimens at 61.9% of all meningiomas

Table 6: Histologic categories of meningioma

Histologic Type	Count	Percentages
Angiomatous	2	4.8
Atypical	2	4.8
Fibroblastic	3	7.1
Meningothelial	26	61.9
Microcystic	2	4.8
Psammomatous	3	7.1
Transitional	4	9.5

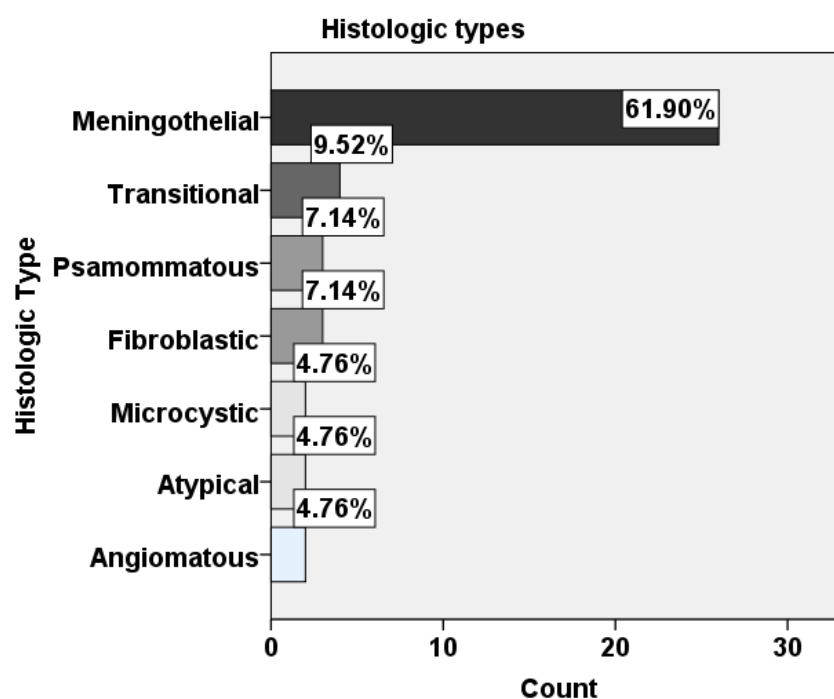


Figure 16: Distribution of histologic subtypes

4.1.11 WHO Grading

Majority of the meningiomas were WHO Grade I tumors. These accounted for 95.2% of the examined specimens while 4.8% were WHO Grade II tumors. There were no WHO grade III tumors at histological examination.

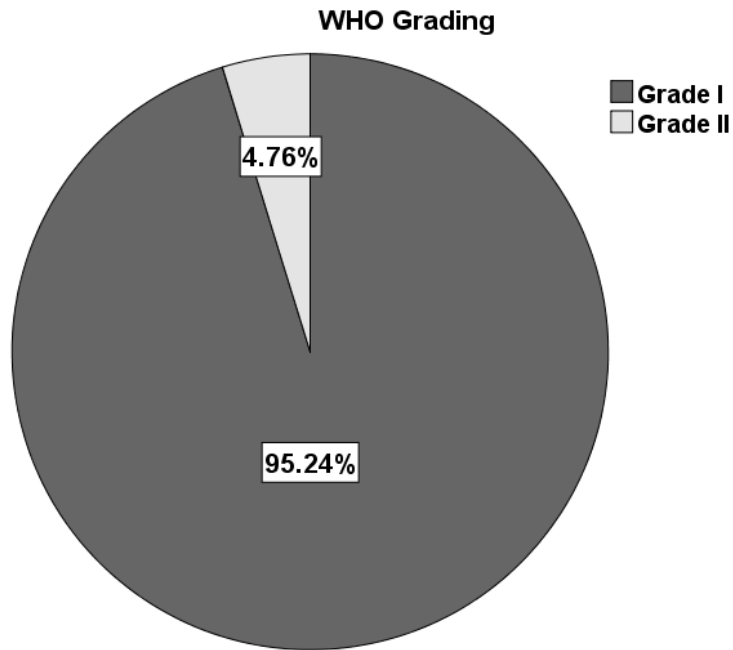


Figure 17: WHO grade of resected meningiomas

4.1.12 Complications

Overall occurrence of complications was 24/43 patients representing 55.8%.

There were various complications experienced by the patients as shown by the table below

Table 7: Rates of complications

Complications	Counts, N = 43	Percent
Hemorrhage requiring transfusion	7	16.3
Transient post craniotomy headache	4	9.3
Transient Hemiparesis	4	9.3
Persistent post craniotomy headache	4	9.3
Cranial nerve deficit	4	9.3
Deep venous thrombosis	3	7
Surgical site infection	2	4.7
Loss of vision	2	4.7
Focal Limb Weakness	2	4.7
Intestinal Obstruction	1	2.3
Dysphagia	1	2.3
Gangrene of pinna of ear	1	2.3
Drug reaction	1	2.3
Transient Diabetes Insipidus	1	2.3

4.1.3 Post-operative Mortality

There were 9 patients who died after operation for meningioma during the study period. These represented 21.4% of all patients operated during the study period. 78.6% survived.

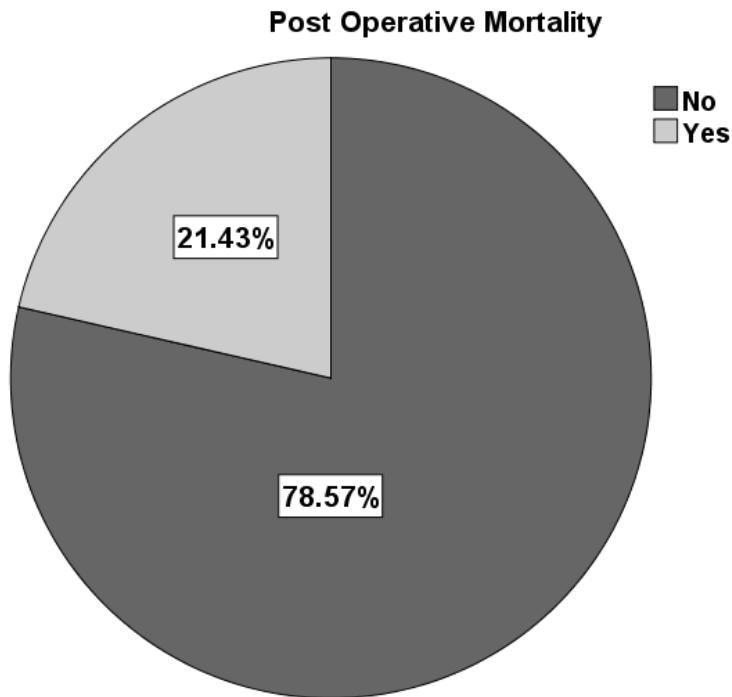


Figure 18: Perioperative mortality

4.2.0 The extent of resection (Simpson Grade) of intracranial meningioma

4.2.1 Simpson Grade

A Simpson grade II resection was achieved in 22 patients (52.4%). Grade I resection was achieved in 38.1% and 9.5% had grade III and IV resection.

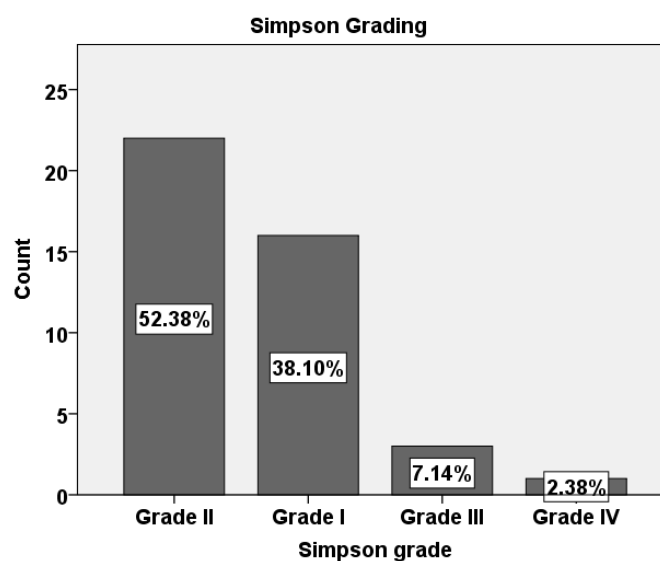


Figure 19: Distribution of Simpson Grade

Table 8: Distribution of Simpson Grade

Simpson Grading	Counts	Percentages
Grade I	16	38.1
Grade II	22	52.4
Grade III	3	7.1
Grade IV	1	2.4

4.2.2 Correlation between FIM gain and Simpson grade

One-way analysis of variance (One-way ANOVA) was used to correlated the FIM gain and Simpson grade.

4.2.2.1 FIM total gain by Simpson grade

In the relationship between FIM total score and Simpson grade,

Table 9: FIM total gain by Simpson grade

Simpson grade	N	Mean	St Dev	95% CI	P value
Grade I	12	49.2	40.4	(27.5, 70.8)	0.272
Grade II	17	57.82	36.05	(39.64, 76.01)	
Grade III	3	16.00	10.15	(-27.28, 59.28)	
Grade IV	1	83.00	*	(8.03, 157.97)	

Pooled St Dev = 36.6550

Therefore, for Total FIM gain, the differences between the groups are not statistically significant ($p = 0.272$)

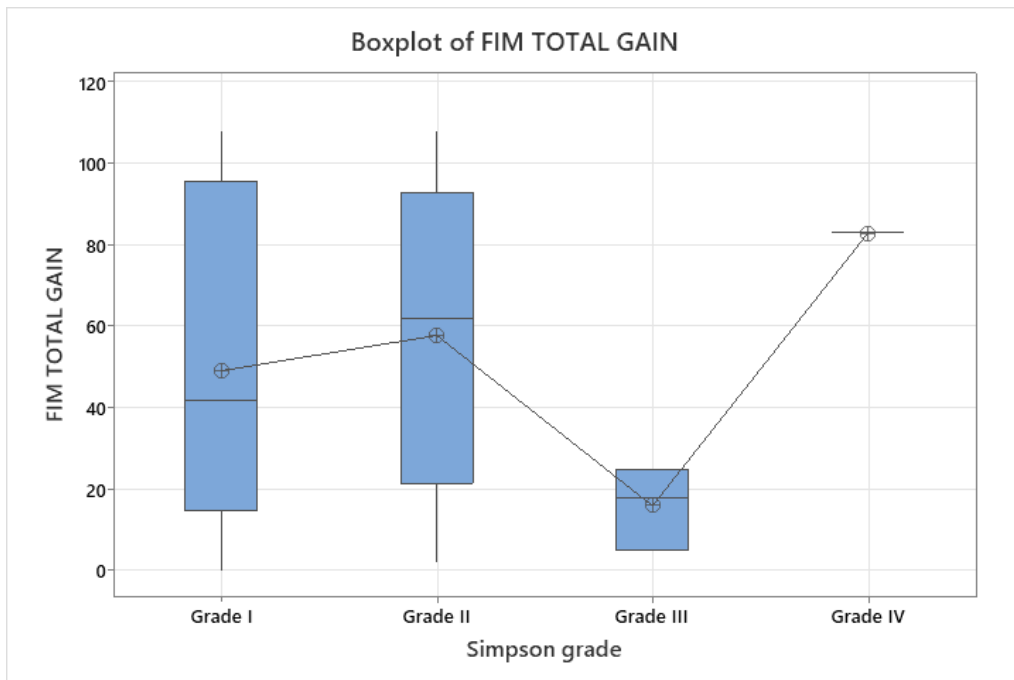


Figure 20: Boxplot of FIM Total gain by Simpson grade

The table below (Table 8) indicates the specific group differences of FIM

Table 10: Fisher Individual Tests for Differences of Means

Difference of Levels	Difference of Means	SE of Difference	95% CI	T-Value	Adjusted P-Value
Grade II - Grade I	8.7	13.8	(-19.6, 36.9)	0.63	0.536
Grade III - Grade I	-33.2	23.7	(-81.6, 15.2)	-1.40	0.172
Grade IV - Grade I	33.8	38.2	(-44.2, 111.9)	0.89	0.382
Grade III - Grade II	-41.8	23.0	(-88.8, 5.1)	-1.82	0.079
Grade IV - Grade II	25.2	37.7	(-52.0, 102.3)	0.67	0.510
Grade IV - Grade III	67.0	42.3	(-19.6, 153.6)	1.58	0.124

Simultaneous confidence level = 80.48%

4.2.2.2 FIM motor gain by Simpson grade

In the relationship between FIM motor gain and Simpson grade, Thus the differences between the groups is **not** statistically significant ($p = 0.218$) for FIM motor gain

Table 11: FIM Motor gain by Simpson Grade

Simpson grade	N	Mean	StDev	95% CI	P value
Grade I	12	35.42	28.77	(19.62, 51.21)	0.218
Grade II	17	43.41	26.87	(30.14, 56.68)	
Grade III	3	10.00	7.00	(-21.59, 41.59)	
Grade IV	1	59.00	*	(4.28, 113.72)	

Pooled StDev = 26.7550

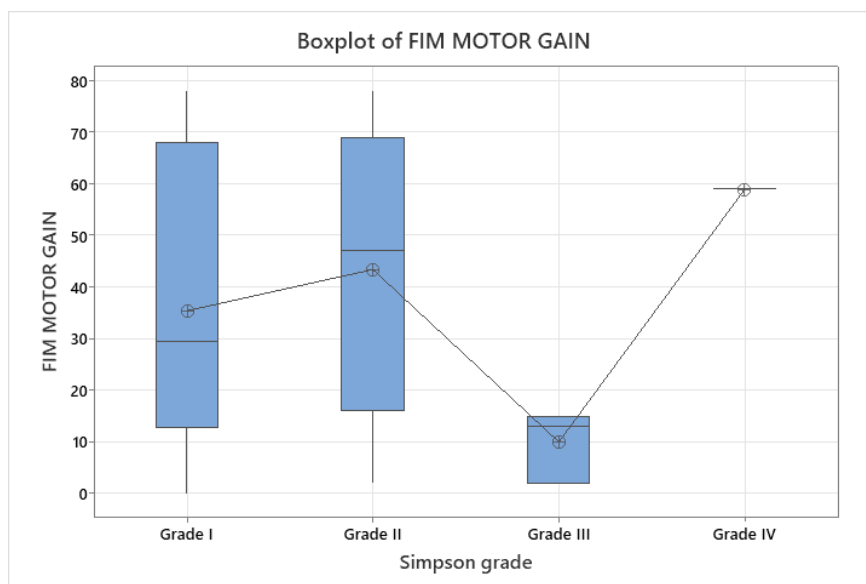


Figure 21: Boxplot of FIM Motor gain by Simpson grade

The table below (table 10) indicates specific group differences for FIM motor scores.

Table 12: Fisher Individual Tests for Differences of Means

Difference of Levels	Difference of Means	SE of Difference	95% CI	T-Value	Adjusted P-Value
Grade II - Grade I	8.0	10.1	(-12.6, 28.6)	0.79	0.434
Grade III - Grade I	-25.4	17.3	(-60.7, 9.9)	-1.47	0.152
Grade IV - Grade I	23.6	27.8	(-33.4, 80.5)	0.85	0.404
Grade III - Grade II	-33.4	16.8	(-67.7, 0.9)	-1.99	0.056
Grade IV - Grade II	15.6	27.5	(-40.7, 71.9)	0.57	0.576
Grade IV - Grade III	49.0	30.9	(-14.2, 112.2)	1.59	0.124

Simultaneous confidence level = 80.48%

4.2.2.3 FIM Cognitive gain by Simpson grade

In the relationship between FIM cognitive gain and Simpson grade, Thus the differences between the groups is **not** statistically significant ($p = 0.427$) for FIM cognitive gain

Table 13: FIM Cognitive by Simpson Grade

Simpson grade	N	Mean	StDev	95% CI	P value
Grade I	12	13.75	11.79	(7.76, 19.74)	0.427

Grade II	17	14.53	9.46	(9.49, 19.56)	
Grade III	3	6.00	3.61	(-5.99, 17.99)	
Grade IV	1	24.00	*	(3.24, 44.76)	

Pooled StDev = 10.1514

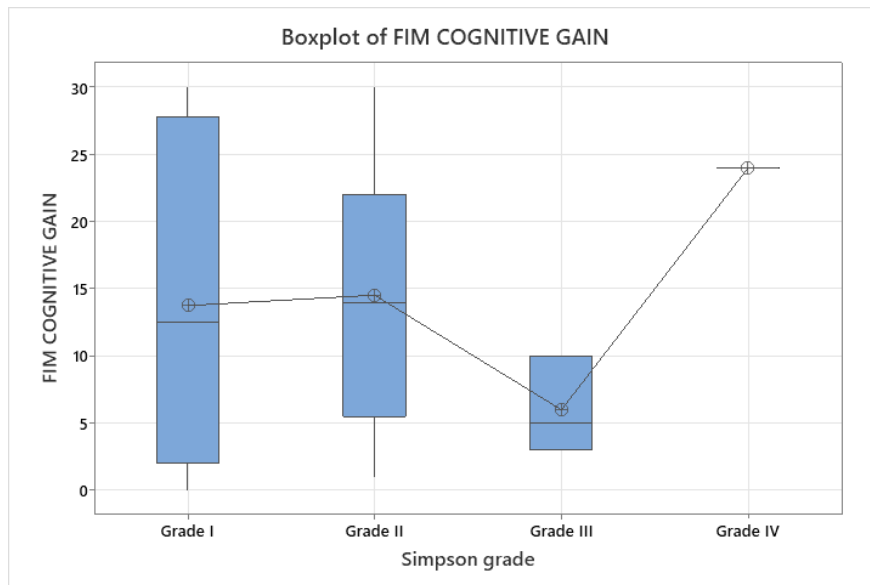


Figure 22: Boxplot of FIM Cognitive gain by Simpson grade

The table below (table 10) indicates specific group differences for FIM cognitive scores.

No specific group differences exist.

Table 14: Fisher Individual Tests for Differences of Means

Difference of Levels	Difference of Means	SE of Difference	95% CI	T-Value	Adjusted P-Value
Grade II - Grade I	0.78	3.83	(-7.05, 8.61)	0.20	0.840
Grade III - Grade I	-7.75	6.55	(-21.15, 5.65)	-1.18	0.247
Grade IV - Grade I	10.3	10.6	(-11.4, 31.9)	0.97	0.340
Grade III - Grade II	-8.53	6.36	(-21.53, 4.47)	-1.34	0.190
Grade IV - Grade II	9.5	10.4	(-11.9, 30.8)	0.91	0.372
Grade IV - Grade III	18.0	11.7	(-6.0, 42.0)	1.54	0.135

Simultaneous confidence level = 80.48%

4.3: The change (Gain) in Functional Independent Measure (FIM) before and after surgery for intracranial meningioma

The gain in FIM score is indicated in table 4.

Table 15: FIM Score Before and After Surgery

FIM	Variable	Obs	Mean	Standard Deviation	P value*
Total FIM	Before Surgery	33	72.7	37.5	<0.001
	After Surgery	33	124.3	5.9	
FIM Motor	Before Surgery	33	51.8	27.6	<0.001
	After Surgery	33	89.8	4.3	
FIM Cognitive	Before Surgery	33	20.9	10.2	<0.001
	After Surgery	33	34.6	1.8	

*T test p value

FIM gain in function

Absolute and percent gains are indicated in Table 5

Table 16: FIM Gain

Type of FIM score	Absolute gain (Mean+SD)	Percent gain (mean+SD)
Total score	51.6 +37.3	161.9 +206.5
Motor score	37.9 +27.5	174 +219
Cognitive score	13.8 +10.1	149.6 +204.5

4.4 Associations of FIM gain

Table 17: Associations of FIM gain

Variable	Coefficient	P value	Test statistic
Duration of symptoms	0.2	0.415	regression
Tumor size	-0.020	0.804	regression
Tumor location		0.291	ANOVA
Histology		0.013	ANOVA
Perilesional edema		0.674	T test
Vascular encasement		0.792	T test
Complications		0.632	T test
Hemiparesis		0.469	
Headache		0.820	
Cranial nerve deficit		0.117	
Hemorrhage		0.740	
DVT		0.385	

4.4 Total FIM gain vs tumor histology

Table 16 indicates associations of FIM gain with specific tumor histologies.

The overall p value is **significant** at 0.013. Specific group differences are indicated.

Table 18: Fisher Individual Tests for Differences of Means

Difference of Levels	Difference of Means	SE of Difference	95% CI	T-Value	Adjusted P-Value
Atypical - Angiomatous	-36.5	37.0	(-112.8, 39.8)	-0.99	0.334
Fibroblastic - Angiomatous	-97.5	37.0	(-173.8, -21.2)	-2.63	0.014
Meningothelial - Angiomatous	-67.7	31.0	(-131.6, -3.8)	-2.18	0.039
Microcystic - Angiomatous	-23.0	37.0	(-99.3, 53.3)	-0.62	0.540
Psammomatous - Angiomatous	-5.5	37.0	(-81.8, 70.8)	-0.15	0.883
Transitional - Angiomatous	-35.3	33.8	(-104.9, 34.4)	-1.04	0.307
Fibroblastic - Atypical	-61.0	30.2	(-123.3, 1.3)	-2.02	0.054
Meningothelial - Atypical	-31.2	22.5	(-77.5, 15.1)	-1.39	0.177
Microcystic - Atypical	13.5	30.2	(-48.8, 75.8)	0.45	0.659
Psammomatous - Atypical	31.0	30.2	(-31.3, 93.3)	1.03	0.315
Transitional - Atypical	1.3	26.2	(-52.7, 55.2)	0.05	0.962
Meningothelial - Fibroblastic	29.8	22.5	(-16.5, 76.1)	1.33	0.197
Microcystic - Fibroblastic	74.5	30.2	(12.2, 136.8)	2.46	0.021
Psammomatous - Fibroblastic	92.0	30.2	(29.7, 154.3)	3.04	0.005
Transitional - Fibroblastic	62.3	26.2	(8.3, 116.2)	2.38	0.025
Microcystic - Meningothelial	44.7	22.5	(-1.6, 91.0)	1.99	0.058
Psammomatous - Meningothelial	62.2	22.5	(15.9, 108.5)	2.77	0.010
Transitional - Meningothelial	32.4	16.6	(-1.8, 66.7)	1.95	0.062
Psammomatous - Microcystic	17.5	30.2	(-44.8, 79.8)	0.58	0.568
Transitional - Microcystic	-12.3	26.2	(-66.2, 41.7)	-0.47	0.644
Transitional - Psammomatous	-29.8	26.2	(-83.7, 24.2)	-1.14	0.267

Simultaneous confidence level = 59.48%

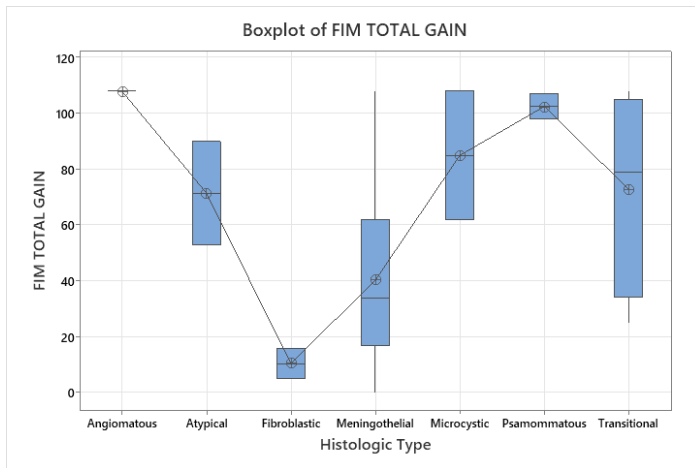


Figure 23: Boxplot of FIM total gain by Histologic type

CHAPTER FIVE

DISCUSSION

Meningioma is a common type of brain tumor that is frequently operated on at Kenyatta National Hospital. During the study period, 42 patients underwent surgery for meningioma at this hospital (1). The incidence of meningioma at Kenyatta National Hospital ranges from 34.4% to 41.4%, and it has been increasing due to the widespread use of neuroimaging techniques (2). A 12-year review of the neuro-pathology database at the University of Nairobi by Magoha et al revealed that 44.8% of the histologies were meningioma, making it the most prevalent brain tumor type (63).

The findings of a different study by Wahome et al., who reported a mean age of 43.97 years, are similar to those of our study, where the mean age of meningioma presentation was 46.8 years. (3). Consistent with both local and international data, there was a higher incidence of meningioma in females compared to males, with a male to female ratio of 1:4.25. (1,3)

Machakos County was found to have the highest number of meningioma referrals, but the reasons for this were not investigated in this study. However, Wahome et al. found that factors such as ethnic background and geographic variables play a significant role in access to neurosurgical care in the local setting (3).

The majority of patients in this study (97.7%) presented with headaches, and 41.9% experienced seizures. These findings align with previous studies conducted at Kenyatta National Hospital (1, 2). On average, it took 13.6 months for patients in this study to seek medical attention at Kenyatta National Hospital from the onset of symptoms. However, this time period did not have a statistically significant impact on the functional outcome as measured by the Functional Independence Measure (FIM) gain in function ($p = 0.415$).

In terms of histology, seven different meningioma types were identified in this study group. The most common histological subtype was Meningothelial, accounting for 61.9% of cases. Transitional, Psammomatous, and Fibroblastic subtypes comprised 28.26% of cases. A one-way ANOVA analysis established a relationship between the histologic subtype and the functional outcome. The overall p-value was 0.013, indicating statistical significance. Histologies such as angiomatous, psammomatous, microcystic, and transitional were associated with a better functional outcome, while fibroblastic histology had the least functional gain and, therefore, a poorer functional outcome.

Upon histological examination, 95.2% of the specimens were classified as World Health Organization (WHO) grade 1 meningioma. The mean size of the operated meningiomas at Kenyatta National Hospital was found to be 138.4 cm³. However, the correlation between tumor size and functional outcome was not statistically significant ($p = 0.804$).

Regarding radiological findings, 90.6% of the cases with mention of perilesional edema exhibited this condition. However, the analysis using the T-test to evaluate the influence of perilesional edema on the functional outcome was not statistically significant ($p =$

0.674). Vascular encasement was observed in 34.45% of the radiology reports, but it did not significantly impact the functional outcome after meningioma resection ($p = 0.792$).

The Functional Independence Measure (FIM) scores before and after surgery were evaluated using the T-test. There was a statistically significant improvement in FIM scores after surgery for meningioma in this study. The initial FIM score before surgery was 72.7, which increased to 124.5 after surgery ($p < 0.001$). The mean gain in functional outcome, comparing the total FIM scores before and after surgery, was 161.9%. The mean motor FIM sub-score after surgery was 89.8, compared to the pre-operative motor FIM sub-score of 51.8, and this improvement was statistically significant ($p < 0.001$). The percentage gain for the motor sub-score was 174%. The mean cognitive FIM sub-score improved from 20.9 before surgery to 34.6 after surgery, and this improvement was also statistically significant ($p < 0.001$). The percentage mean gain in the FIM cognitive subscale was 149.6%. Meling et al found that over the past 2 decades there was functional improvement after meningioma surgery (37). In their study they found that surgeries were becoming more aggressive with better or no untoward influence on the functional outcome after resection

Simpson grade II resection was achieved in 22 patients (52.4%), while grade I resection was achieved in 38.1% of cases. Grade III and IV resections were performed in 9.5% of cases. Grade III meningioma showed a lesser total functional gain compared to other Simpson grades. However, there was no statistically significant difference among the different Simpson grades regarding the total gain in FIM scores. With the exception of grade III, significant improvements were observed in the mean total FIM, FIM motor sub-score, and FIM cognitive sub-score. However, the differences between the different Simpson grades were not statistically significant. Similarly, Gousias et al found that the degree of resection was not a predictor of functional outcome as measured by the Karnofsky Performance Scale (KPS) score. They however found younger age, higher preoperative Karnofsky Performance Scale (KPS) score and convexity tumor location to be independent predictors of a good functional outcome (38). The Simpson grade has however been associated with the rates of tumor recurrence on long term follow up (39)

The complication rate for meningioma surgery in this study was 55.8%. Most of the reported complications were mild, including intraoperative hemorrhage requiring transfusion (16.3%), transient post-craniotomy headache (9.3%), transient paresis (9.3%), and transient diabetes insipidus (2.3%). None of these complications influenced the functional outcome after resection, as assessed by the T-test analysis, which was not statistically significant.

During the study period, the post-operative mortality rate for intracranial meningioma was 21.4%. The remaining 78.6% of patients who underwent surgery survived and were included in the subsequent analysis. Kallio et al observed cumulative survival rate was 91% at 3 months, 89% at 1 year, and 63% at 15 years. They found significant risk factors for mortality as poor preoperative clinical condition, absence of epilepsy, old age, incomplete tumor removal, pulmonary embolism, and an intracranial hematoma requiring evacuation (41). Such were not evaluated in this study.

Conclusion

42 participants were taken part in this study, with a male to female ratio of 1:4.25 and an average age of 46.8 years. Majority of the patients presented within 13.6 months with headaches 97.7% and seizures 41.9%. Neuroimaging revealed that the average size of meningioma was 138.4 cm³, and perilesional edema was observed in 90.6% of cases. Surgical resection achieved a Simpson grade II in 52.4% of cases and Simpson grade I in 38.1% of cases. Most meningiomas were classified as WHO grade 1 (95.2%), specifically the Meningothelial variant (61.9%). Following surgery, there was a noticeable improvement in functional status, as indicated by a mean total gain of 161.9% in the Functional Independent Measure (FIM), a motor sub score gains of 174%, and a cognitive sub score gain of 149.6%. However, there was no statistically relevant association between the functional outcome and extent of surgical resection.

Recommendation

1. A follow up study to evaluate the long-term functional outcome of patients operated at the Kenyatta National Hospital
2. Create a database for all meningioma patients that will improve clinical follow up and research for meningioma.

Table 1.1 Study Budget

ITEMS	DESCRIPTION	AMOUNT
Personnel	• 1 Research assistant	20, 000
	• Statistician	35, 000
Supplies	• Printing	10, 000
	• Photocopy	5, 000
	• Binding	5, 000
	• Stationery	3, 000
Miscellaneous		20,000
TOTAL		98000

Table 19: Study Budget

Table 1.2 Study Time frame

Timelines	January 2022 – March 2022	May 2022	August 2022	Sept 2022 - Jan 2023	March – April 2023	May 2023
Proposal Development						
Presentation						
Ethical Approval						
Data Collection						
Data Analysis						
Dissertation Submission						

Table 20: Study Time frame

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APPENDICES

Appendix 1 : Data Collection Tool/ Questionnaire

Title: FUNCTIONAL OUTCOME AFTER INTRACRANIAL MENINGIOMA SURGERY AT THE KENYATTA NATIONAL HOSPITAL

STUDY NUMBER	
IP NUMBER	
DATE	

Demographics (Fill)

Age (years)	
Sex	
Occupation	
County of Residence	

Signs and Symptoms (Tick)

Headache	Anosmia
Seizure	Reduced level of consciousness
Limb weakness	Sensory deficit
Hemiparesis	Dysphasia
Visual loss	Cerebellar signs
Exophthalmos	Cranial Nerve Palsy
Personality change	
Painless lump	

Duration of Symptoms

Meningioma location

Convexity		Sphenoid Ridge	
Parasagittal		Spheno-orbital	
Falcine		CP Angle	
Olfactory Groove		Petrous/ Clival/Petro-clival	
Tuberculum Sella		Foramen Magnum	
Tentorial/Falco-tentorial		Other (Specify)	

Associated CT/ MRI features

Size (cm3)		Not reported	
Perilesional Edema	Yes	No	Not reported
Vascular Encasement	Yes	No	Not reported

Functional Independence Measure (FIM) before surgery

Self-Care	Score
A. Eating	
B. Grooming	
C. Bathing	
D. Dressing - Upper Body	
E. Dressing - Lower Body	
F. Toileting	
Sphincter Control	
G. Bladder Management	
H. Bowel Management	
Transfers	
I. Bed, Chair, Wheelchair	
J. Toilet	
K. Tub, Shower	
Locomotion	
L. Walk/Wheelchair	
M. Stairs	
Motor Subtotal Score	
Communication	
N. Comprehension	
O. Expression	
Social Cognition	
P. Social Interaction	
Q. Problem Solving	
R. Memory	
Cognitive Subtotal Score	
TOTAL FIM Score	

Modifiers

- 7- Complete independence Fully independent
 6- Modified independence Requiring the use of a device but no physical help
 5- Supervision Requiring only standby assistance or verbal prompting or help with set-up
 4- Minimal assistance Requiring incidental hands-on help only (subject performs > 75% of the task)
 3 -Moderate assistance Subject still performs 50–75% of the task
 2 -Maximal assistance Subject provides less than half of the effort (25–49%)
 1 -Total assistance Subject contributes < 25% of the effort or is unable to do the task

Simpson grade

I	
II	
III	
IV	
V	

WHO grade

Complications

Hemorrhage requiring transfusion	Cranial Nerve deficit (Specify)
Hemiparesis	Other (Specify)
Focal limb weakness	
Surgical site infection	
Seizure	
Deep venous thrombosis	
Loss of vision	

Functional Independence Measure (FIM) 2 months after surgery

Self-Care	Score
A. Eating	
B. Grooming	
C. Bathing	
D. Dressing - Upper Body	

E. Dressing - Lower Body	
F. Toileting	
Sphincter Control	
G. Bladder Management	
H. Bowel Management	
Transfers	
I. Bed, Chair, Wheelchair	
J. Toilet	
K. Tub, Shower	
Locomotion	
L. Walk/Wheelchair	
M. Stairs	
Motor Subtotal Score	
Communication	
N. Comprehension	
O. Expression	
Social Cognition	
P. Social Interaction	
Q. Problem Solving	
R. Memory	
Cognitive Subtotal Score	
TOTAL FIM Score	

Modifiers

- 7- Complete independence Fully independent
- 6- Modified independence Requiring the use of a device but no physical help
- 5- Supervision Requiring only standby assistance or verbal prompting or help with set-up
- 4- Minimal assistance Requiring incidental hands-on help only (subject performs > 75% of the task)
- 3 -Moderate assistance Subject still performs 50–75% of the task
- 2 -Maximal assistance Subject provides less than half of the effort (25–49%)
- 1 -Total assistance Subject contributes < 25% of the effort or is unable to do the task

FIM total gain (calculate FIM after minus FIM before surgery)

FIM motor gain (calculate)

FIM cognitive gain (calculate)

Appendix 2 : Informed Consent form (English Version)

CONSENT TO PARTICIPATE IN THE STUDY

Introduction

Dr Kagasi Travor is a Neurosurgery resident at the University of Nairobi. He is conducting research for his Masters of Medicine in Neurosurgery thesis. The purpose of this consent form is to provide you with the requisite details about the study to aid you in deciding whether or not to participate in the study. When you have satisfied that sufficient information has been provided to you and all your questions and queries have been answered Dr Kagasi will request for your signature agreeing to participate in his study. Your decision to be involved in the study will be completely voluntary.

Study number-

Title of the study:

FUNCTIONAL OUTCOME AFTER SURGERY FOR INTRACRANIAL MENINGIOMA AT THE KENYATTA NATIONAL HOSPITAL

Introduction

Thank you for considering participating in this study. This form will give you the information you need to decide on whether you want to participate in the study or not. Refusal to participate in the study will not affect the management of your condition. Feel free to ask any question whether related to the study or not.

Purpose of the study

The study entails being asked questions that assess your functional status on the current day to day basis.

This information is helpful to help us understand better the impact of the treatment we have been offering you on your day to day function.

The implications of the results will be explained to you by the principle investigator.

The benefits of evaluating your treatment will help better management of patients in the future.

You are free to ask any questions about the study at any point and can withdraw from the study in writing at any point without attaching any reason.

Withdrawal from the study will not affect the management of your condition including the follow-up in our clinics. Participation in the study does not attract any financial benefits.

Study procedures

You will be taken to a quiet room where questions shall be asked about your condition.

Participation in this study will involve you as a patient being asked questions regarding you day to day performance of certain tasks.

Your data shall also be retrieved from the file records of our treatment to assess various parameter.

Are There Any Risks, Harms Discomforts Associated with This Study? 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 on the role of surgery and tumor characteristics on your ability to function optimally. This will further enable us to create feasible local guidelines guiding the same.

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.

Confidentiality

All information that identifies you to the data collected will be held in confidence. Standardized medical forms will be left in your file for future reference. The data extracted will be kept in lockable cabinets in the department of surgery and password enable computers accessible only to the principal investigator, academic supervisors and any support staff the principal investigator may deem necessary in conducting the study.

Cost and payment

All the costs of this study will be undertaken by the principal investigator and you shall not incur any costs to participate in this study other than standard hospital charges related to your treatment

Ethical consideration

This study has been reviewed and approved by the Kenyatta National Hospital-University of Nairobi Ethical review Committee (KNH-UON ERC). It fulfills all conditions set.

Do you have any questions?

Do you agree?

The study described above has been explained to me. I have had a chance to ask questions. I am aware that participating in this study is voluntary and my declining will not result in victimization whatsoever. Having understood the above

Signature / Thumb print..... Date.....

Signature of Investigator.....

Name of investigator.....

Withdrawal Priviledge

I understand that I will be free to withdraw from the study at any stage. Useful contacts: 1) KNH/UON/ERC. Telephone: 020726300 ext.: 44102

Email: uonknh_erc@uonbi.ac.ke, P. O Box 20723code 00202 CONSENT BY THE PATIENT

I..... Of..... hereby give consent to be included in this study. The nature of the study has been explained to be by Dr He has NEITHER coerced NOR has he forced me to be part of this study. I understand that there will be NO monetary gain in return.

Date..... Signed.....

I Dr..... confirm that I have explained to the patient the nature of the study.

Date..... Signed.....

PROBLEMS OR QUESTIONS:

Information on researchers and telephone numbers. Any concerns arising from this study should be directed to the following people:

Principle investigator:

Dr. Kagasi Travor 0722213593

Supervisors:

Dr Michael Magoha 0710388279

Dr Vincent Wekesa 0722881405

The KNH/UON ethics and research committee. 020-2726300 ext 4435

Appendix 3 : Informed consent form (Kiswahili version)

IDHINI YA KUJIHUSISHA NA UTAFITI.

Namba ya utafiti.....

Jina la Utafiti : Tathmini ya matokeo ya upasuaji wa wagonjwa wa Meningioma ya Ubongo katika hospitali kuu ya Kenyatta

Utafiti Huu Unahusu Nini?

Watafiti hapo juu wanawahoji wagonjwa ambao walifanya upasuaji wa meningioma ya ubongo. Utachunguza uthibiti wako wa kutekeleza mambo yanayohusika na wewe kila siku. Kutakuwa na takriban washiriki 45 katika utafiti huu ambao wamechaguliwa bila mpangilio. Tunaomba idhini yako kufikiria kushiriki katika utafiti huu.

Utangulizi

Asante kwa kuzingatia kushiriki katika utafiti huu. Fomu hii itakupa habari unayohitaji kuamua kama unataka kushiriki katika utafiti. Kukataa kushiriki katika utafiti hauathiri matibabu yako. Jisikie huru kuuliza swali lolote ikiwa linahusiana na utafiti. Kusudi la utafiti huu ni kujua saina za ishara katika ugonjwa wako. Ishara hii inatusaidia kujua ni vipi upasuaji wa Meningioma ya ubongo inawasaidia wagonjwa. Kwa hiyo utafiti huu unajaribu kutambua saina hizi za ugonjwa wa Meningioma ya bongo ili kusaidia kuboresha matibabu ya ugonjwa huu nchini Kenya.

Katika utafiti huu, fomu ya matibabu ya kawaida itajazwa na picha zako ziangaliwe na madaktari. Mpango wa upasuaji na uondoaji wa ugonjwa wako zitaendelea na daktari wa ubongo anayeitwa neurosurgeon. Vipande vya ugonjwa huo vitachukuliwa kwa madaktari wengine ambao watawachunguza chini ya darubini na pia kufanya uchunguzi wa ziada kuamua aina ya meningioma ambayo unayo. Utasimamiwa katika kata na kuzingatiwa kwa matatizo yoyote mpaka kutolewa.

Faida za kuchunguza matokeo ya upasuaji wako itasaidia matibabu bora wa wagonjwa katika siku zijazo. Ukona uhuru kuuliza maswali yoyote kuhusu utafiti wakati wowote na unaweza kujiondoa kwa njia ya maandishi kutoka utafiti huu wakati wowote bila kutupatia sababu yoyote. Kuondoka kwenye utafiti hautaathiri matibabu yako ikiwa ni pamoja na kufuatiliwa katika kliniki zetu. Hautapata fedha zozote kushiriki katika utafiti huu.

Usiri

Taarifa zote zinazokutambulisha, data zilizokusanywa zitafanyika kwa usiri. Fomu za matibabu zilizosimamiwa zitasalia katika faili yako kwa manufaa ya baadaye. Takwimu zilizochukuliwa zimehifadhiwa katika makabati yaliyohifadhiwa katika idara ya upasuaji ya chuo kikuu cha Nairobi

Nenosiri litatumika kwa tarakilishi itayotumika na mchunguzi mkuu, wasimamizi wa kitaaluma na wafanyakazi wowote wa msaada ambao uchunguzi mkuu atawaamini kumsaidia kufanya utafiti.

Gharamana / Malipo

Gharama zote za utafiti huu zitasimamiwa na mpelelezi mkuu.

Kuzingatia Maadili

Utafiti huu umepitiwa na kupitishwa na Kamati ya Kenyatta ya Taifa ya Kenyatta ya Kitaifa ya Ukaguzi wa Maadili (KNH-UON ERC). Inatimiza hali zote zilizowekwa.

Je! Una maswali yoyote?

Unakubali?

Kutenda Kin

Utafiti ulioelezwa hapo juu umeelezewa kwangu. Nimekuwa na nafasi ya kuuliza maswali. Ninafahamu kuwa kushiriki katika utafiti huu ni kwa hiari na kushuka kwangu hautafanya uonevu wowote. Baada ya kuelewa Ishara iliyo juu

Chapisha kuchapa... Tarehe

Saini ya uchunguziJina la mchunguzi.....

Ufunzo Wa Kutawa

Nitaelewa kuwa nitakuwa huru kujiondoa kwenye utafiti wakati wowote. Mawasiliano muhimu: 1) KNH / UON / ERC. Namba ya: 020726300 ext .: 44102 Barua pepe: uonknh_erc @ uonbi.ac.ke, P.O Sanduku 20723code 00202

Kwa Mgonjwa

Mimi Ntoa idhini ya

Kuingizwa katika utafiti huu. Hali ya utafiti imeelezwa na Daktari Kagasi Travor.

Hajanishurutisha au kunikandamiza ili kuingia kwa utafiti huu bali ni kwa hiari yangu. Ninaelewa kuwa hakutakuwa faida yoyote ya kifedha kwa kujishugulisha kwa utafiti huu.

Sahihi ya Mgonjwa ...

Tarehe

Kwa maswali kuhusu utafiti huu waweza kupiga nambari hizi

Mtafiti Mkuu:

Dr. Kagasi Travor 0722213593

Wanaosimamia mtafiti mkuu:

Dr Michael Magoha 0710388279

Dr Vincent Wekesa 0722881405

KNH/UON ethics and research committee. 020-2726300 ext 4435