UNIVERSITY OF NAIROBI

ASSESMENT OF MULTIPARAMETRIC MAGNETIC RESONANCE IMAGE QUALITY FOR PROSTATE CANCER DETECTION USING PI-QUAL SCORING SYSTEM AT KENYATTA NATIONAL HOSPITAL & THE NAIROBI HOSPITAL

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STUDENT'S DECLARATION

I, **Dr. Gichuki Edwin,** 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.

Dr. Gichuki Edwin

Signature: _____   **Date:** <u>11/10/2023</u>

SUPERVISORS' APPROVAL

This dissertation has been submitted with my approval as the supervisor

Dr. Omamo Eunice,

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Signature: …………………………………… **Date:** 11/10/2023

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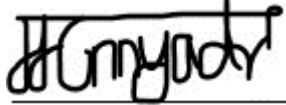
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DEPARTMENTAL APPROVAL

This dissertation has been presented and approved by the Department of Diagnostic Radiology and Radiation Medicine.

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Chairperson, Department of Diagnostic Imaging and Radiation Medicine, Faculty of Health Sciences, University of Nairobi.

Signature: _____ **Date:** 02/11/2023

DEDICATION

I would like to dedicate this thesis to my family, and all those impacted by prostate cancer.

ACKNOWLEDGEMENT

First, I would like to thank God for His never-ending love and grace. I would also like to express my warmest gratitude to my supervisor **Dr. Omamo Eunice,** for her continued support throughout the development of this thesis. Further, I am indebted to my friends and family their love and support have sustained me throughout my academic journey.

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LIST OF ABBREVIATIONS

3T   3 Tesla

ADC -   Apparent diffusion coefficient

DCE-MRI -   Dynamic contrast-enhanced magnetic resonance imaging

DW-MRI -   Diffusion-weighted magnetic resonance imaging

DRE -   Digital Rectal Exam

DWI -   Diffusion Weighted Imaging

FOV -   Field of view

KNH -   Kenyatta National Hospital

Mp –   Multiparametric

mpMRI -   Multiparametric magnetic resonance imaging

MRI –   Magnetic Resolution Imaging

MRS -   Magnetic Resonance Spectroscopy

NICE -   National Institute of Health and Care Excellence

PCa -   Prostate cancer

PiRADS -   Prostate Imaging and Reporting and Data System

PI-QUAL –   Prostate Imaging Quality

PSA -   Prostate Specific Antigen

SNR -   Signal-to-noise ratio

TRUS -   Transrectal Ultrasound Scan

T -   Tesla

T1W –   T1 weighted

T2W -   T2 weighted

DEFINITION OF TERMS

Multiparametric Magnetic Resonance Imaging - Multiparametric (mpMRI) of the prostate is magnetic resonance that includes the basic anatomical T1 and T2- weighted imaging and additional functional sequences of choice that include but not limited to dynamic contrast enhanced (DCE) MRI and diffusion-weighted imaging (DWI), including the calculation of apparent diffusion co-efficient (ADC) maps

Diffusion Weighted Imaging - Is a form of functional magnetic resonance imaging sequence that allows mapping of the diffusion process of molecules, mainly water, in biological tissues.

Dynamic Contrast Enhanced – Is an MRI technique that calculates perfusion parameters by evaluating T1 shortening induced by introducing gadolinium-based contrast bolus

Benign Prostate Hyperplasia – This is enlargement of the prostate resulting from proliferation of normal prostatic cellular elements.

Biopsy – Is a tissue sample extracted from the body for physical and chemical analysis.

Diagnostic Accuracy - Is the ability to detect, quantify, characterize, and classify disease and is the most traditional measure of the quality of an image.

Resolution – is a term that describes the ability of an imaging system to differentiate between structures, images, or events and display them as separate entities.

Image Contrast –   Is the degree of density difference between two areas on an image

Artefact -   Something observed in a scientific investigation or experiment that is not naturally present but occurs as a result of the preparative or investigative procedure.

ABSTRACT

Background: Prostate Cancer is the most prevalent non-cutaneous neoplasm of males in Kenya with an age standardized rate of 40.6/100000.

Multi parametric magnetic resonance imaging of the prostate (T2, DWI, DCE) is currently recommended in international guidelines as an indispensable tool for detection, risk stratification and image guided biopsy of clinically significant prostate cancer.

To attain the best out of this validated tool within the patient management pathway, several standardizing measures have been published and implemented globally. The first being Prostate Imaging Reporting and Data System (PIRADS– 2012/2015) for internationally standardized image acquisition and reporting then most recently Prostate Imaging Quality (PIQUAL) (2020) for evaluation of magnetic resonance image quality.

PIQUAL is derived from the PIRADS guidelines and it in cooperates minimal technical parameter for acquisition and a visual assessment criterion used to evaluate MR image quality prior to interpretation. Adherence to the PIRADS guidelines have been shown to produce good diagnostic quality images and vice versa.

Objective: Multi parametric magnetic resonance imaging of the prostate is currently used for prostate cancer management in Kenyatta National Hospital and The Nairobi Hospital. The purpose of this study was to evaluate the quality of multi parametric magnetic resonance prostate images, using PIQUAL criteria, of patients with clinical suspicion of Prostate Cancer.

Methods and Materials: This Prospective cross-sectional study was conducted in Kenyatta National Hospital and Nairobi Hospital following approval by KNH/UON ERC and NH ERC during a 6-month period from January 2022– June 2022. Study subjects that met the inclusion criteria were 63 patients suspected to have prostate cancer, selected by simple random sampling. All images were acquired using 3 Tesla Phillips MRI scanner KNH (Phillips Ingenia 2018 model) and NH (Phillips Achieva 2013 model). The pelvic phased array coil was used in both study centres and none utilized an endorectal coil The MRI scans were evaluated and scored using the PI-QUAL scoring check list. The collected data was checked for completeness and free of error prior to entry into Excel 2017. Thereafter the data was exported to Statistical Package for social services version 26 for analysis. The adherence to PIQUAL criteria was summarized as frequencies and percentages for categorical data and as means. All statistical tests were considered significant where the p value <0.05.

Results: The lowest adherence to PIQUAL technical parameters in the T2W sequence was in-plane resolution frequency encoding ≤0.4mm KNH 0% NH 0%; Slice Gaps (0) KNH 38.5 %, NH 0 %. Only KNH n=8 (31%), NH n=0 (0%) T2W images evaluated were independently of diagnostic quality. In both study sites there was excellent 100% adherence in acquiring the DWI Axial planes that were synchronous with the T2W; Multiple b values (0,500,1000 s/mm²); High b values acquired 1600 s/mm²; DWI Slice thickness <4mm; DWI In-plane resolution frequency and Phase encoding <2., 2. 5mm.The commonest artefact degrading DWI image quality was magnetic field in-homogeneity at the air/tissue interface caused by a distended rectum. The lowest adherence to PIQUAL criteria in the DCE sequence was seen in Slice thickness(3mm) KNH (0%) mean 5.9 mm and the inter slice gap (0) KNH (0%) mean -3.0mm, NH (0%) mean 1.5 mm. Adherence to the PIQUAL criteria of minimal technical parameters was seen highest in the DWI sequence 89.5 %, followed by DCE 83.5 % and lowest seen in T2WI 68.3%. The overall PIQUAL score was average with majority of the scans scoring PIQUAL 3 n=53 (84%) which has a clinical implication in that it is possible to rule in all significant lesions but as the same time not possible to rule out all significant lesions.

Conclusion: Optimal diagnostic image quality can be achieved by applying technical guidelines achieved documented from past and current research like the PIQUAL criteria which forms a basis for standardization of prostatic mpMR image quality.

Continuous application, education and research around optimization of the multiparametric magnetic resonance prostate imaging is important and necessary as it is now recognized as the future of prostate cancer management. PIQUAL is the first of its kind but revisions, driven by research, may be required in its future.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Cancer of Prostate

In Kenya, cancer of the prostate is the most prevalent non-cutaneous neoplasm in males. There were 3,412 new cases diagnosed in 2020(1). The Age-Standardized Incidence Rate (ASR) in Kenya of 40.6 per 100,000)(2) and 39.9 per 100,000 worldwide(1) . Cancer of prostate has a high significant contribution to the public health burden in Africa (clinical, economic and humanistic) and it is predicted to continue increasing with continued urbanization and population growth (3).
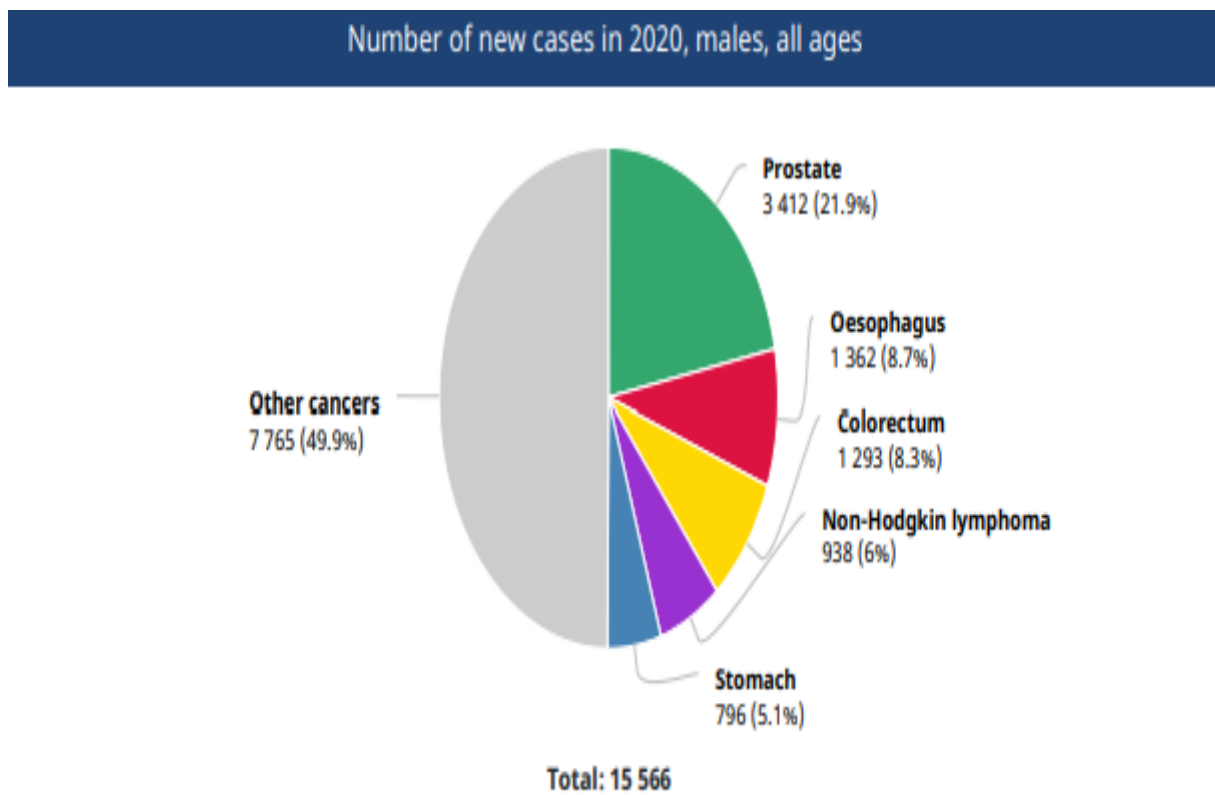
Figure 1 : Number of new Cancer of prostate cases in 2020 compared to other types of common cancers in Kenya(4)

Figure 2: Age standardized (world) incidence rates per sex, top 10 cancers(4)

In Africa, mortality mainly attributed to late diagnosis in relation to Cancer of prostate has been on the rise. Early diagnosis of cancer is noted as one of the key pillars in the cancer control strategy 2017–2022 in Kenya(5).

The prostate gland has three anatomical zones.

- Central zone – Is the regional around the ejaculatory ducts and amounts to 25% of total volume of the gland.

- The transitional zone – This zone surrounds the urethra and amounts to 5-10% of total gland volume. The dominant magnetic resonance sequence recognized for assessing this zone is T2 Weighted sequence.(6)

- Peripheral zone – makes up majority of the glandular tissue (approximately 65%) and is located posterior and lateral. The dominant Magnetic resonance sequence for assessing this zone is Diffusion weighted sequence (DWI)(6) The Peripheral zone is often involved more than transition zone or central zone.

Adenocarcinoma is the commonest type of cancer of prostate. It accounting for 95 - 99% of all cancer of prostate cases. This type tends to increase PSA levels and usually arises in the posterior/peripheral zone (70%) more commonly compared to anterior gland and central zone (30%)(7)

Cancer of prostate clinically presents as:(8)

i. Early Symptoms - Lower Urinary Tract Symptoms including: Nocturia, Hesitancy, Urgency, Dribbling, Incomplete bladder emptying, Weak urinary stream.

ii. Hematuria, unexplained weight loss and back pain are symptoms commonly evident in advanced disease and metastases.

Severity of symptoms of cancer of prostate are graded using the (IPSS). A high International Prostate Symptoms Score (IPSS) score combined with suspicious PSA levels i.e., elevated more than 4 ng/dL and an abnormal digital rectal examination usually prompts further investigations of which includes radiological imaging (ultrasound, MRI) and biopsy.

1.2 Multiparametric Magnetic Resonance Imaging and Image Quality of the Prostate - PIQUAL

Prostatic Multi-parametric MRI (MP-MRI) combines the following sequences

- Anatomical - T1 and T2 weighted images
- Functional - Diffusion-Weighted Sequence (DWI),
              Dynamic Contrast Enhanced sequence (DCE)

Information on images from all 3 sequences are combined and features typical for cancer of prostate sought out for a final diagnosis to be made.

Prostate Imaging Quality (PI-QUAL) score is a novel (2020) and the first image quality evaluation system graded prostatic multiparametric MRI (mpMRI) scans quality after acquisition prior to radiological interpretation. It is designed to gauge the MR scan quality using technical recommendations derived from PIRADS guidelines, together with visual information extracted from the image.(9)

Optimal diagnostic mpMR image quality is imperative because interpretations made from sub-optimal scans are bound to be erroneous and can easily lead to flawed patient care. Diagnostic accuracy errors directly associate with poor image qualities have been approximated to transpire in as much as 30% of image interpretations. Insufficiency in image quality and display has a direct correlation with both false positive and negative interpretation inaccuracies. (10). Overall, high PIQUAL scores bolster confidence in decision making and improves efficiency in prostate cancer treatment (31)

PIQUAL score is a Likert scale from 1-to-5 and has clinical implications attached to each score. It is essential for experienced academic/tertiary referral center radiologists for assessment of the adequacy of the MR images acquired within and outside their institution to gauge whether they are optimal for reporting or should be reacquired, that is before making decision of clinical nature (e.g. defer biopsy, treatment vs active surveillance)(9).

Table 1:PI-QUAL Score(9)

PI-QUAL Score	CRITERIA	CLINICAL IMPLICATIONS
1	All mpMRI sequences are below the minimum standard for diagnostic quality	It is not possible to rule in all significant lesions
2	Only one mpMRI sequence is of acceptable diagnostic quality.	It is not possible to rule out all significant lesions
3	At least two mpMRI sequences taken together are of diagnostic quality.	It is possible to rule in all significant lesions It is impossible to rule out all significant lesions
4	Two or more mpMRI sequences are of diagnostic quality	It is possible to rule in all significant lesions
5	All mpMRI sequences are of optimal diagnostic quality.	It is possible to rule out all significant lesions

This international system score should be included in the cancer of the prostate management algorithms within the Kenyan radiological centers to improve early cancer of prostate detection and generally reduce the public health burden.

Kenyatta National Hospital and The Nairobi Hospital are leaders in medical advancement and utilize the 3 Tesla magnetic resonance scanners for prostate imaging which is a necessity for this PIQUAL study and that is why the two centers have been chosen for this research. The study will help to pinpoint the strengths and pitfalls affecting the quality of prostatic resonance images within the two institutions.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Screening Cancer of Prostate

The primary reason for screening cancer of prostate is early detection of cancer and as such, allow for earlier intervention to help reduce and prevent morbidity and mortality(11).

The multiple treatment modalities available for cancer of prostate depend on the stage of the disease as such early detection of cancer of prostate, by applying screening methods, will invariably result high cure rates with treatment, if the disease has not spread outside the prostate. On the contrary, diagnosis at later stages of the disease result in relatively poor outcomes, mortality and higher treatment cost.

The current widely used screening and diagnostic tools for cancer of prostate following an abnormal digital rectal examination are DRE (Digital rectal examination), PSA (Prostatic surface antigen) and TRUS (Transrectal ultrasound) Biopsy for confirmation. Imaging of the prostate using Magnetic resonance imaging is the latest addition to the cancer of prostate screening methods.

 MpMRI has been rated as the best modality of imaging for detecting and staging cancer of prostate, especially after a failed biopsy, by the American college of radiology appropriateness (2013)and they have recommended its inclusion in low risk patients' active surveillance.(12)

In 2019, the National Institute of Health and Care Excellence (NICE)(UK) published guidelines endorsing the utility of mpMRI in assessment, diagnosis and biopsy in cases of localized prostate disease (13).

The National Health Service (NHS) of England recommends that patients suspected to have Cancer of prostate deserve a confirmed diagnosis of the same within 28 days and mpMRI performed before biopsy(14).

These endorsements, validations and recommendations of mpMRI of the prostate have initiated the need for internationally standardized image acquisition and reporting (PIRADs) and optimal image quality (PIQUAL).

2.1.1 Prostate Surface Antigen

Prostatic Specific Antigen is made by normal cells, hyperplastic and neoplastic cells within the prostate and it is considered specific for the prostate gland but not specific for cancer of prostate (15). This brings about a diagnostic overlap among normal prostate, prostatic benign lesions, and cancer of prostate diagnosis in the setting of raised prostatic surface antigen levels (PSA). PSA test results are interpreted as follows:

- 0 and 4 ng/mL: normal

- 4 to 10 ng/mL: There is a 25- 45 % chance of cancer of prostate

- >10 ng/mL: Cancer of prostate risk is >50%.

Factors, other than neoplastic, that may lead to change in PSA levels are listed

Table 2: Factors affecting PSA Levels (16)

Factors	Increasing PSA Level	Decreasing PSA Level
An enlarged prostate (BPH)	X	
Older age	X	
Prostatitis (infection or inflammation of prostate gland)	X	
Ejaculation (causes PSA increase for a short time)	X	
Riding a bicycle (not all studies found this effect)	X	
Certain urologic procedures (DRE, prostate biopsy, cystoscopy)	X	
Testosterone or medicines that raise testosterone levels	X	
Finasteride, dutasteride		X
Herbal (saw palmetto)		X
Obesity		X
Aspirin (daily usage)		X

The concern of multiple factors affecting the prostate surface antigen levels has led to the conclusion that PSA testing can result in erroneous diagnosis, and the estimated rate is 17% to 50% (17) (U.S. Preventive Services Task Force)(USPSTF)

2.1.2 Transurethral Ultrasound Prostate Biopsy

Transrectal ultrasound guided (TRUS) biopsy is usually performed in patients with PSA blood test >4 ng/dl. TRUS biopsy as the main diagnostic pathway of Cancer of prostate remains suboptimal and plagued with a lot of inaccuracies because the process is pegged on the finding of elevated PSA levels and the process is nonspecific in the location of the disease on the gland. This pathway leads to a lot of unnecessary biopsies, over diagnosis or under-diagnosis of cancer of prostate. Pre-biopsy MP-MRI is now recommended as a triage test for patients who present with an elevated serum PSA and this measure has been shown to reduce unnecessary biopsies by up to 25% of men at risk (18). The MP-MRI scans therefore need to be of optimal quality for the patients to gain this advantage of avoiding unnecessary biopsies and this is where PIQUAL system score is utilized.

PROstate MRI Imaging Study [PROMIS] 2017 is a prospective multi-center study that compared mpMRI and TRUS biopsy diagnostic accuracy. The findings published showed that mpMRI has greater sensitivity and a higher negative predictive value for the detection of cancer

of prostate in comparison to TRUS biopsy. (18). In addition, Spajic et al. reported that there is a 40% chance of TRUS examination missing detection of prostate malignancy based on sonographic attenuation of the neoplastic lesions. (19)

2.2 Multiparametric Magnetic Resonance Imaging and Image Quality of the Prostate - PIQUAL

MRI, especially mpMRI, remains the only imaging modality known to clearly localize prostatic cancer because of the exceptional spatial resolution and soft tissue contrast. PIQUAL is the first and only recognized system score available for grading prostatic multiparametric magnetic resonance images. Multiple international radiological centers with different levels of expertise were involved in producing multiple sets of prostate MR scans that were essential in production of the PI-QUAL system score (2020) (9)

MpMRI Image quality generally depends on resolution (field of view, matrix size and slice thickness), Signal-to-Noise Ratio (SNR), Image Contrast and Artefacts (19).

Several researchers have documented that mpMRI prostate imaging quality varies substantially between different medical centers, MR scanners as well as patient vulnerabilities and that the suboptimal image quality comes with a lot of uncertainty and lower diagnostic accuracy(20) with higher interobserver variability(21).

The Europe Society of Urogenital Radiology published the Prostate Imaging and Reporting and Data System (PI-RADs) (22)in 2012 and a recent version (PI-RADs v2) in 2015(23).

The main aim of the PI- RADs system is to offer technical outlines streamlining the acquisition prostatic MR Images and to construct a universal reporting system. It however does not evaluate the final product i.e., the final image quality after acquisition which is an important step before interpretation of the image hence the need for an image quality evaluation system like PIQUAL.

Some of the factors that may affect prostatic mpMRI image quality include:

- MR scanner Age – Increased scanner age has been shown to affect T2weighted image quality.(21)

- MR scanner strength – Greater MR strength scanners (3T) has shown to produce better signal to noise ratio in comparison to 1.5 T scanners and hence produces better image quality.

- Patient bowel preparation – Studies have shown that rectal dilatation and presence of rectal gas is inversely proportional to DWI image quality.(21)

- Patient motion – Patient motion/movement during image acquisition can cause ghosting artefacts that distort image quality.(24)

- Local field inhomogeneity – Metal prosthesis present within the patient is a common source of artefacts brought about by signal loss due to de-phasing and distortion that eventually distorts the final image acquisition.(24)

- Biopsy induce hemorrhage – Hemorrhage induced post-TRUS biopsy has been reported to decrease staging accuracy and distort image quality or prostatic MR scans.(25)

Most panelists (ESUR/ESUI expert panel 2020) were in favor of external and objective MR scan evaluations every 6 months or even longer intervals. They concluded that image quality evaluation should be performed on a randomly selected sample of cases, preferably 5% of total MR exams, but this percentage is rather dependent on the number of cases per center(26).

2.3 PI-QUAL

The PIQUAL checklist (Appendix 1) used for scoring the images encompasses subjective as well as objective details under each sequence (T2, DWI, DCE), that are used to judge the overall image quality as good enough for interpretation

2.3.1 MR Sequences in the PIQUAL Checklist

a) T2W:

The T2-weighted anatomical imaging is the is the sequence which is dominantly used for evaluation of the zone of transition. Cancer of prostate appears as a region of hypo intensity on the scan.

PI-RADS v. 2.1 recommends axial plane to be used in obtaining images and an additional coronal or sagittal plane.

• Field of view: It should cover the whole prostate gland including both seminal vesicles. Ideally 12 – 20 cm

• In-plane resolution: the dimensions for phase should be equal or less than 0.7 mm and range of frequency should be equal or less than 0.4 mm

• Slice thickness: Is 3 mm and gapless.

• Z-axis: The z-axis is in line of the main magnetic field.

• Anatomical structures: Clear delineation of the structures listed in the score checklist is necessary to deem the scan optimal.

• Artefacts: the commonest artefacts arise from motion during acquisition and previous prosthetic surgeries around the pelvis.
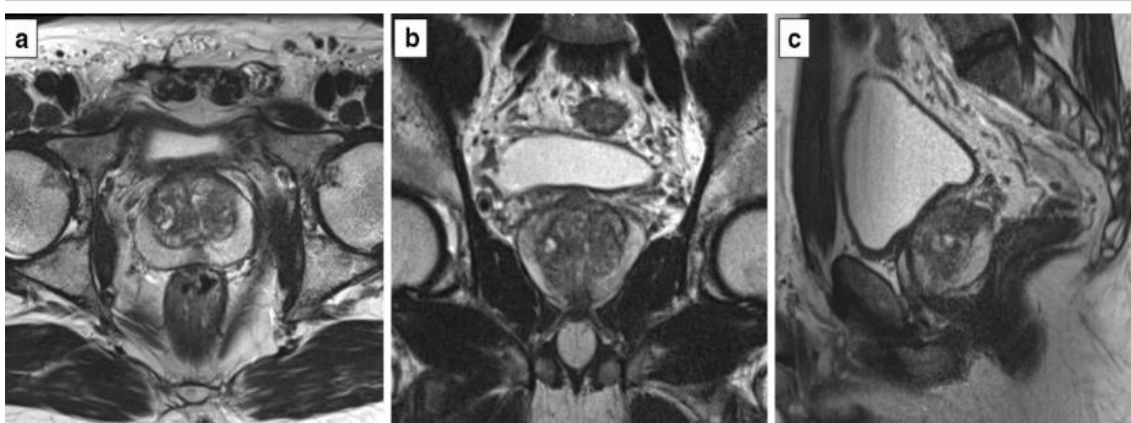
Figure 3:Optimal T2W images in the Axial plane, Coronal plane and Sagittal plane(9)
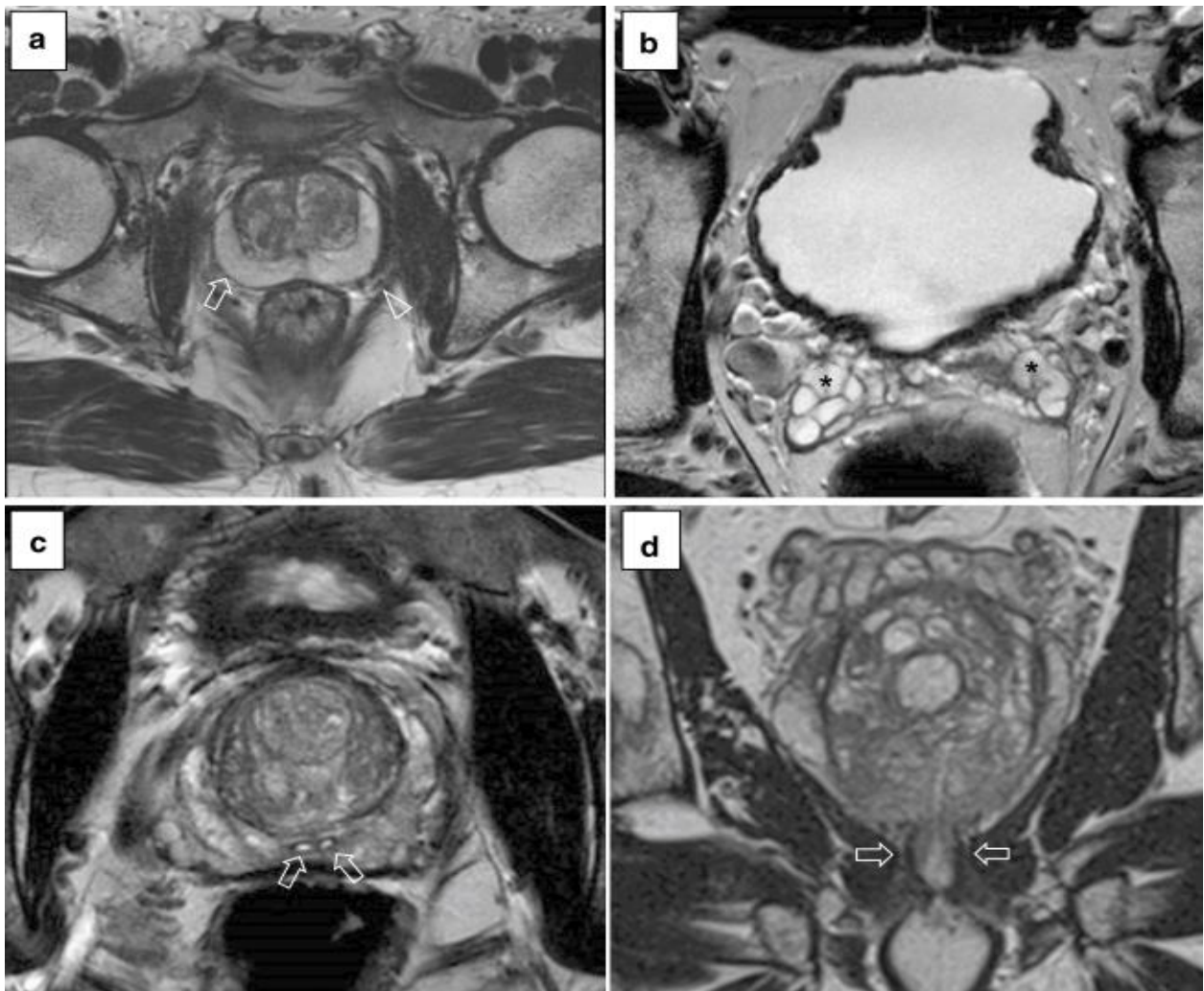
Figure 4: Axial (a–c) and coronal (d) Optimal Prostatic T2W scans depicting (a) Hypointense capsule (arrow) and the Internal Pudendal vessels within the Alcock canal (arrowhead), (b) bilateral seminal vesicles, (c) The ejaculatory ducts and (d) The external sphincter

b). DWI:

Diffusion-weighted imaging is a visual representation of Brownian motion and is a crucial sequence in prostate mpMRI. It is accompanied by apparent diffusion coefficient (ADC) map which is acquired by use of multiple b values.

B Values

- Are measures of the diffusion weighting degree applied. They indicate the duration between the paired gradients (Δ), amplitude (G), and time of applied gradients (δ) (27)

High cellularity lesions (as in cancer of prostate) appear as hyper intense on the high b-value diffusion-weighted images (bright on DWI) but appear hypointense on the ADC map acquisition.

The technical parameters recommended for these sequences include:

- Field of view: FOV ranges span 16 to a maximum of 22 cm
- In-plane resolution: the dimensions for phase and frequency should be ≤ 2.5 mm
- Slice thickness: Is equal or less than 4 mm and gapless.
- Multiple b values are recommended i.e., a low – 50 to100 s/mm2 and an intermediate b value 800 to 1000 s/mm2.

  The maximum b value, in order to avoid diffusion kurtosis effect, used to calculate ADC should be ≤ 1000 s/mm2.

- High b value sequences (1000- 2000 s/mm2) are used to detect molecules of water that are moving slowly and smaller distances of diffusion. The images of the scan can be acquired directly using a high b value sequence of ≥ 1400 s/mm2 or could be extrapolated from the lower b values to construct the ADC map. Higher *b*-values provide higher accuracy whilst still minimizing perfusion and T2 weighted effects (28)

- Adequate ADC map: Data acquired from different b values is used to compute ADC values. Higher ADC values appear hyperintense and indicate low diffusion restriction. Low ADC values appear hypointense indicating increased diffusion restriction.
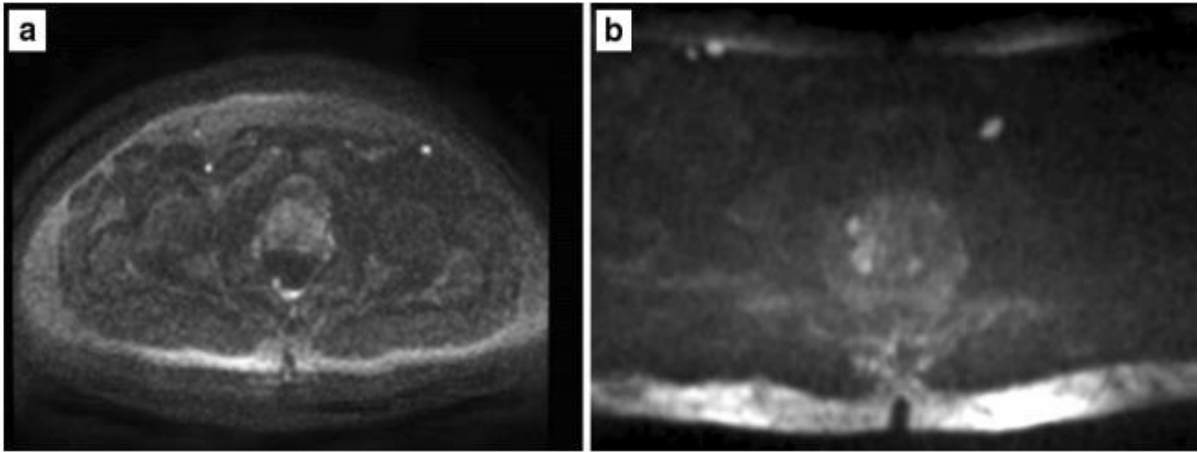
Figure 5:DWI of suboptimal (38x40cm) (a) and optimal (17x20cm)(b) field of view according to the PI-RADS v.2.1 guidelines (9)
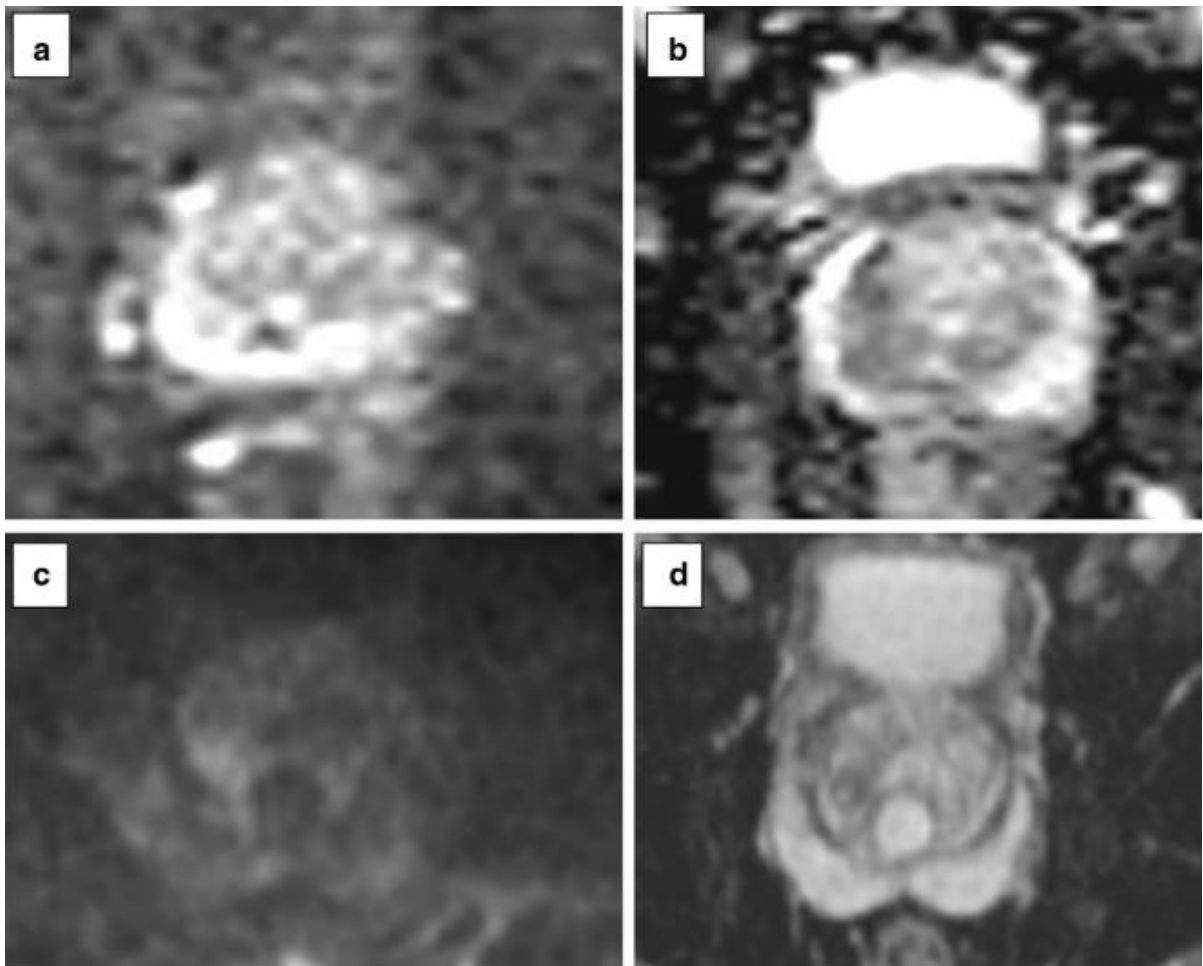
Figure 6: DWI suboptimal (a, b) and optimal (c, d) in plane resolution for the high b sequence (a, c) and ADC map (b, d) respectively ((9)
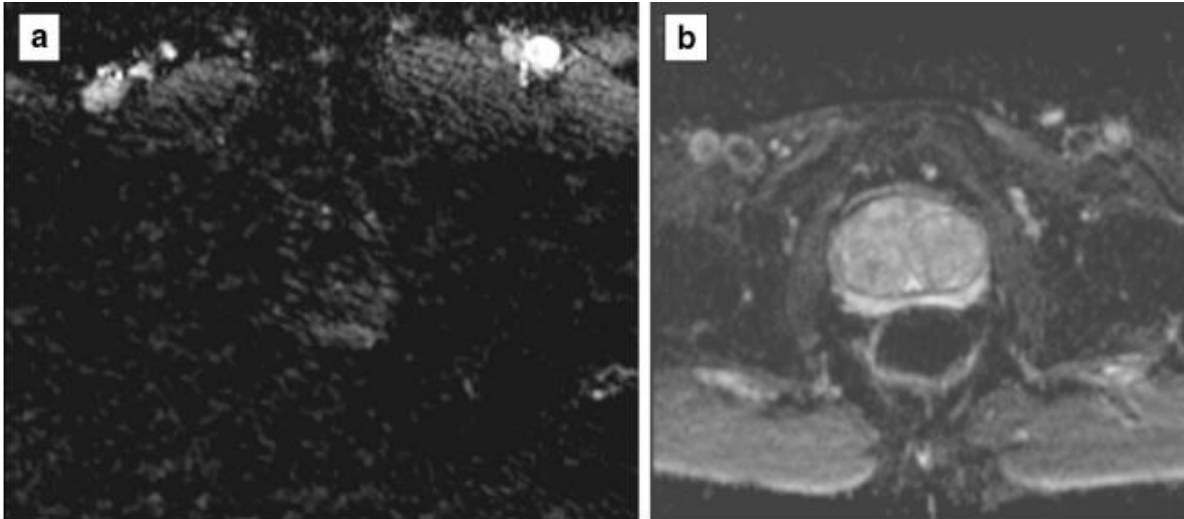
Figure 7: ADC maps of suboptimal(a) and optimal (b) quality (9)
 c) Dynamic Contrast Enhanced Sequence (DCE)

This is rapid (time scale acquisition every so often-determined by institution 6 milliseconds, 8 milliseconds) acquisition of a series of T1-weighted MR scans in rapid succession following intravenous administration of a contrast agent.

Cancer of the prostate features angiogenesis and the new tumor vessels are thin, irregular in shape, poorly organized and highly permeable as such they usually exhibit early enhancement and early washout.

DCE sequence acts as a tie breaker when prior sequences (T2w imaging and DWI) are inconclusive.

The DCE technical parameters include:

- Field of view: the FOV for DCE sequences by PIRADS v2.1 guidelines should be small enough to include the whole prostate gland and both seminal vesicles and still retain optimal spatial resolution.

- In-plane resolution: For phase and frequency should be equal or less than 2 mm.

- Slice thickness: It should be 3 mm, gapless and matching T2-weighted axial scans.

- Pre-contrast T1-WI scan: This is necessary to identify post-biopsy hemorrhage, which degrades prostate MRI images notably during staging. These regions appear hyperintense the pre-contrast T1 images. The PI-RADS V2.1 advice a post-biopsy duration of 6 weeks or more before scanning. This sequence should be evaluated for diagnostic quality before contrast administration.

- Temporal resolution: PI-RADS v. 2.1 advices that temporal resolution should be equal or less than 15 s to detect early enhancement and early washout of cancer of prostate lesions.

- Fat suppression: Fat suppression techniques like the short tau inversion recovery (STIR) are recommended to improve visual assessment of enhancement and better define the prostate capsule.
- Pudendal artery and capsular vessels: Small blood vessels adjacent to the gland, when clearly visualized, they are used as objective markers of image quality. These vessels include - prostate capsular vessels, internal pudendal artery and veins.

Artefact: Metallic prosthesis, inadequate fat suppression and motion during the procedure are some of the commonest causes of artefacts during DCE sequence acquisition.
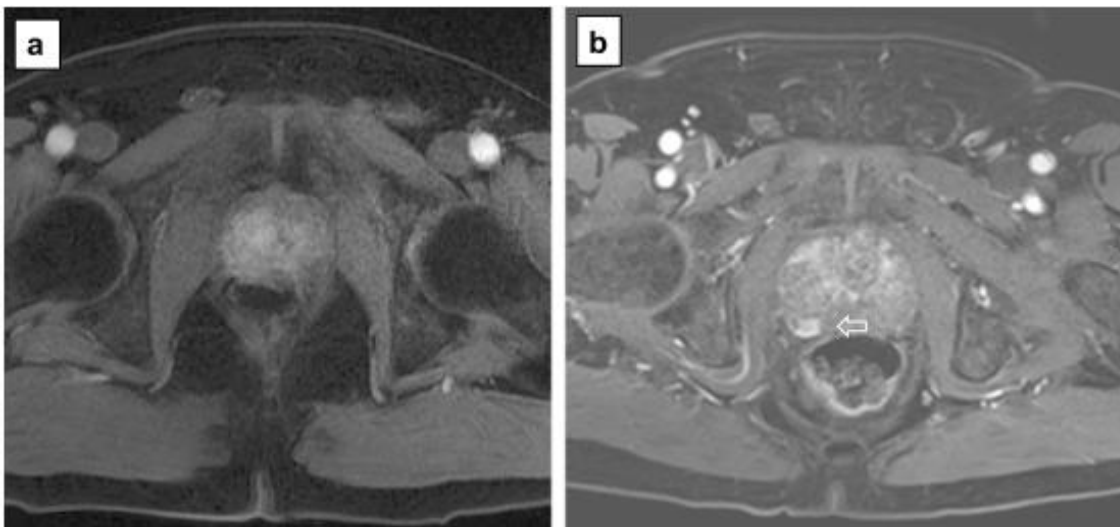
Figure 8: DCE of suboptimal (a) and optimal (b) in plane resolution. The arrow in (b) indicates an enhancing lesion in the right peripheral zone (9)
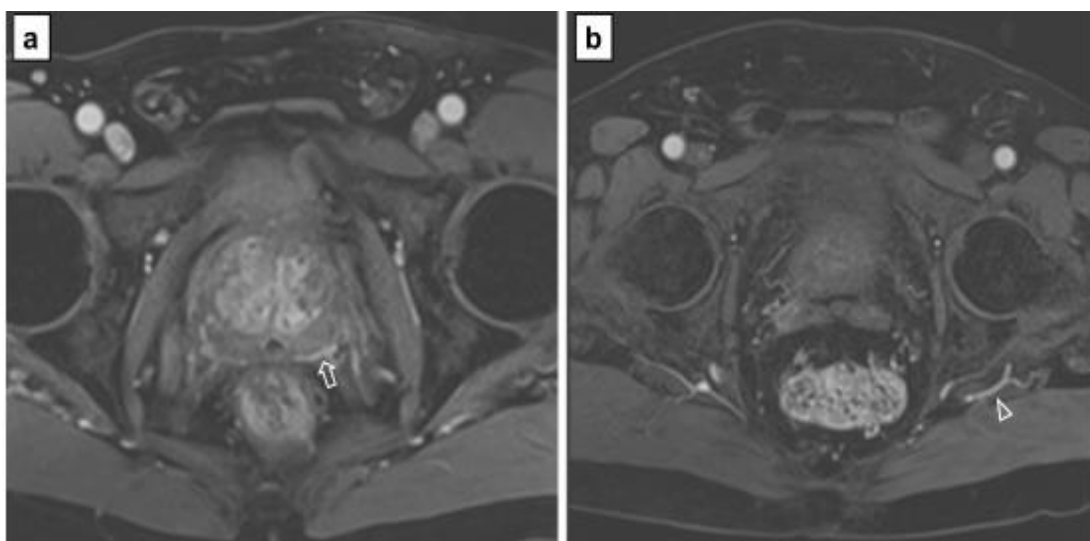
Figure 9: DCE adequate diagnostic quality images showing the capsular vessels (a, arrow) and the vessels in the Alcock's canal (b, arrowhead) (9)
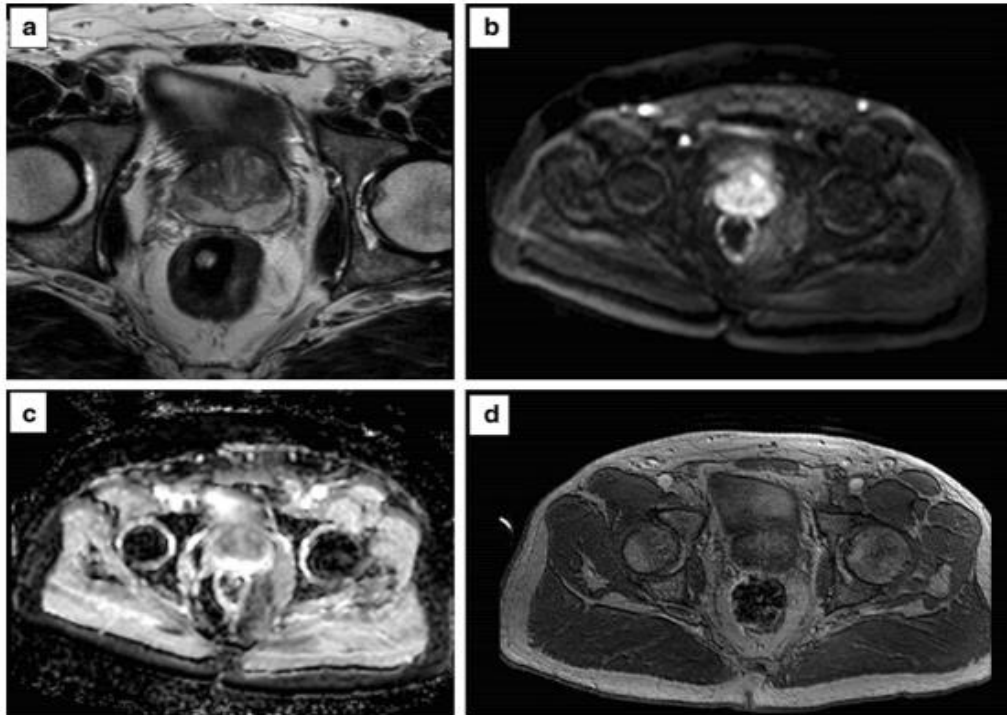
Figure 10: Axial T2w imaging(a) DWI with a b value of 150s/mm2(b), ADC map (c) and DCE acquisition(d) of a study that was given a PI-QUAL score of 1. All MR sequences are below the minimum standard of diagnostic quality as per PI-RADSv.2.1 technical recommendations. In particular, T2w imaging and DWI(a-c) show motion artefacts, no high b value has been acquired(b), the field of view is too large on DWI (21x35cm, in b, c) and on DCE sequences (21x33cm in d), and there is no fat suppression of DCE sequences (9)

2.4 Justification

The gold standard for definitive diagnosis of Prostatic cancer is through TRUS & histopathological assessment which is invasive and costly. MRI machines are currently widely available in most parts of Kenya both in private and public facilities. This has helped in evaluation and diagnosis of prostatic diseases including cancer. Despite the advances in MRI imaging, there are still concerns about image quality of scans derived from multiple factors causing varied interpretations. Magnetic resonance scans, especially prostatic multiparametric magnetic resonance, should be that of optimal quality because it greatly impacts the cancer of prostate management pathway and hence reduces the burden of cancer of prostate.

PI-QUAL system score bolsters confidence in prostate MRI as a crucial tool in management of cancer of prostate. PI-QUAL is the first standardizing measure of prostatic magnetic resonance images internationally and acts as a basis for future research. This study will aid to identify strengths and pitfalls of prostatic magnetic resonance imaging and the findings will be used to positively influence future prostatic imaging within Kenyan institutions.

2.5 Research Question

What is the spectrum of image quality of mpMRI prostate scans, using PIQUAL system score, in patients with clinical suspicion of Cancer of prostate at Kenyatta National Hospital and The Nairobi Hospital?

2.6 Hypothesis

Multiparametric magnetic resonance images of the prostate produced in Kenyatta National Hospital and The Nairobi Hospital radiology departments are of optimal diagnostic quality for cancer of prostate diagnosis and management.

2.7 General Objective

The purpose of this research is to evaluate the quality of multiparametric magnetic resonance prostate images using PI-QUAL scoring system of patients suspected to have Cancer of prostate at Kenyatta National Hospital and The Nairobi Hospital.

2.8 Specific Objectives

a) To assess the quality of the T2 weighted sequence scans utilized in mpMRI for cancer of prostate detection.

b) To assess the quality of the Diffusion Weighted Imaging sequence scans utilized in mpMRI for cancer of prostate detection.

c) To assess the quality of the Dynamic Contrast Enhanced sequence scans utilized in mpMRI for cancer of prostate detection.

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study Design

This was an analytic cross sectional study design. The study assessed image quality using the PI-QUAL checklist.

3.2 Study Site

In collaboration with the University of Nairobi, the study was conducted at two sites:

a) Kenyatta National Hospital which is a national referral hospital under the ministry of health which also is the teaching hospital for the University of Nairobi, specifically its radiology department. The institution utilizes a 3Tesla Phillips MRI scanner for image acquisition and a Phillips ISP PACS system.

b) The Nairobi Hospital which is a private imaging and teaching facility that works in collaboration the University of Nairobi. The institution is utilizing a 3Tesla Phillips MRI scanner for image acquisition and Fujifilm Synapse RIS PACS system.

3.3 Study Period

The study period was from January 2022 to June 2022.

3.4 Study Population

The study population were multi-parametric magnetic resonance prostate scans of patients with suspected to have Cancer of prostate (Elevated PSA levels more than 4 ng/dl or abnormal DRE), referred for magnetic resonance imaging at the Department of Radiology in Kenyatta National Hospital and The Nairobi Hospital.

3.4.1 Inclusion Criteria

MR scans of patients undergoing mpMRI imaging on a 3T MRI scanner with:

- Clinical suspicion of cancer of prostate i.e., Lower urinary tract symptoms, Advanced disease symptomatology (Bone pain, weight loss, Hematuria), Elevated PSA levels >4ng/dl and Abnormal DRE

3.4.2 Exclusion Criteria

- Images of patients who have undergone radical prostate surgery or Trans urethral prostatectomy.

- Images of patients with mpMRI scans from < 3tesla strength MRI scanner.
- Images of patients with concurrent pelvic diseases e.g., any other disease of the rectum.
- Patients with claustrophobia.

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

3.5 Recruitment and Sampling Procedure

Simple random sampling method was used, whereby every subject that fit the inclusion criteria in Kenyatta National Hospital and The Nairobi Hospital was selected until the required sampling size was achieved. The study did not in any way affect or influence the treatment plan.

3.6 Sample Size Determination

- Sample size calculation is via Fisher□s formula (29)

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

- Whereby,

n = Desired sample size

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

- P = expected true proportion (estimated at 50.0%, as no studies have reported image quality, it is assumed 50.0% of the image quality will be good.)

d = desired precision (0.05

- $n_0 = \frac{1.96^2 x\, 0.50(1-0.50)}{0.05^2} = 384$

- Kenyatta National Hospital and The Nairobi Hospital records indicate an approximate of 80 images per annum. The sample size was adjusted for finite populations less than 10,000 in the formula below.

- $nf = \frac{n_0}{1+\frac{n_0-1}{N}} = \frac{384}{1+\frac{384-1}{80}} = 66$

- Sixty-six images will be required for the study.

3.7 Data Collection and Image Analysis

63 prostatic MR scans of patients that meet the inclusion criteria and were within the study period were selected by simple random sampling. Images were reviewed on local picture

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archiving and communication system (PACS) workstation (KNH - Phillips ISP & NH - Fujifilm Synapse RIS). The image analysis included manual extraction (e.g., FOV, spatial resolution) of technical parameters from the metadata and visual assessment of anatomical structures

Two radiologists (1 senior, 1 junior) assessed in consensus the image quality of multi parametric scans (all without endorectal coil) from 3T MRI scanners of same vendor (Phillips). The image quality was determined against the requirements listed in the PIQUAL checklist and assigned a score according to the quality of T2, DWI and DCE sequences using the 5-point Likert scale. The readers also recorded whether the three primary mpMRI prostate sequences were independently of diagnostic quality. For each scan, a record was kept of artifacts observed and the readers agreed in advance on the types of artifacts that would be noted and their definitions.

3.8 Ethical Considerations

Ethical approval was obtained from UON/KNH and NH research ethics boards before commencing the study. Patients' confidentiality and privacy was ensured by using numerical identifiers and safe and restricted data storage was maintained throughout the study. No additional cost was incurred by the participants for this study.

3.9 Data Management and Analysis

The raw image data was manually extracted from image metadata and visual assessment was exported into Excel and counter checked for completeness and inconsistencies. The data was then transferred to Statistical Package for Social Sciences version 23.0 for analysis.

4.0 CHAPTER FOUR: RESULTS

A total of 63 image samples were sampled KNH n=26 NH n=37. All images were acquired using 3 Tesla Phillips MRI scanner, in KNH (Phillips Ingenia 2018 model) and in NH (Phillips Achieva 2013 model). The pelvic phased array coil was used in acquisition all images acquired 63/63 in both study centres and none utilized an endorectal coil. Total :time taken to review and score each MRI scan was an average 35 min.

4.1 T2W

A total of 63 mpMRI images evaluated had T2W images. Adherence to the PIQUAL criteria technical parameters in acquisition of axial, coronal and sagittal planes was excellent KNH 100%, NH 100%. Minimal variability seen in adherence to Slice thickness (ST) 3mm KNH 92.3%, NH 100% p value 0.034. Poor adherence in the slice gap (0 mm) KNH 38.5%, NH 0% <0.001; Field of view (FOV) 12-20 cm KNH 88.5%, NH 100% p value 0.034; Similarly poor adherence to in-plane resolution - *Frequency encoding* ≤4mm KNH 0%, NH 0% p value <0.001; Variability in the in-plane resolution - *Phase encoding* ≤7mm KNH 10% NH 100% p value <0.001. Z axis direction in KNH 77% scans were perpendicular to the table and 13% matching the long axis of the prostate, NH had all scans n=100% perpendicular to the MR table.

There was clear delineation of the prostate capsule, sphincter musculature and neurovascular bundles around the prostate in 100% of T2W images acquired in both study sites. The ejaculatory ducts were clearly delineated in KNH 81 %, NH 54 %. The seminal vesicles clear delineation in KNH 92%, NH 100%. No major image quality degrading artefacts were visualized in the T2W images from both study sites. The total number of T2W images noted to be independently of diagnostic quality KNH (n=8) 31% NH (n=0) 0%.
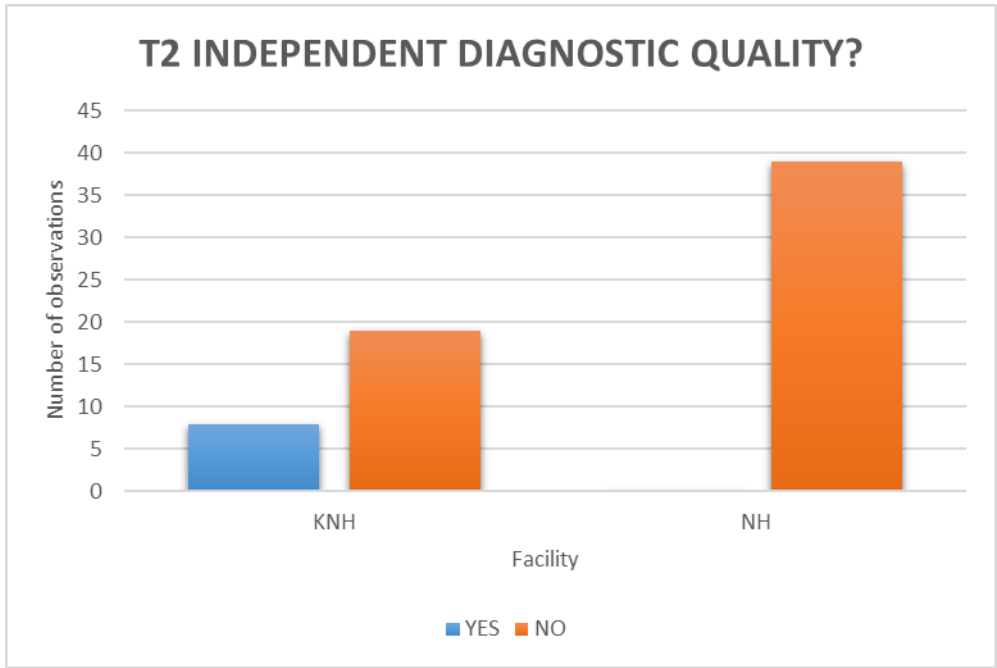
Figure 11: T2 Independent Diagnostic quality

4.2 DWI/ADC

A total of 63 mpMR scans evaluated had DWI and ADC images. Adherence to the PIQUAL criteria technical parameters during acquisition of the axial plane that should be synchronous to the T2W images was KNH 100%, NH 100%; Slice thickness (ST) 2.5 mm KNH 100%, NH 97.3%. There was a significant difference in adherence of Slice Gap 0mm KNH 96 %, NH 0% p value <0.001 and Field of View 16-22 cm KNH 100% NH 37.8% p value <0.001.

Similarities were seen in adherence to in plane resolution *Frequency encoding* ≤2.5 mm KNH 100%, NH 100%; In plane resolution *Phase encoding* ≤2.5 mm KNH 100% NH 100%; Multiple b values KNH 100%, NH 100%; Dedicated High b value >1400s/mm² KNH 100%, NH 100%. Adequate ADC map available KNH 100%, NH 58%. There were image degrading artefacts seen mostly secondary to magnetic field in-homogeneity (due to air/tissue interfaces) KNH 50%, NH 14 %. The total number of DWI images noted to be independently of diagnostic quality KNH (n=13) 50% NH (n=0) 0%.
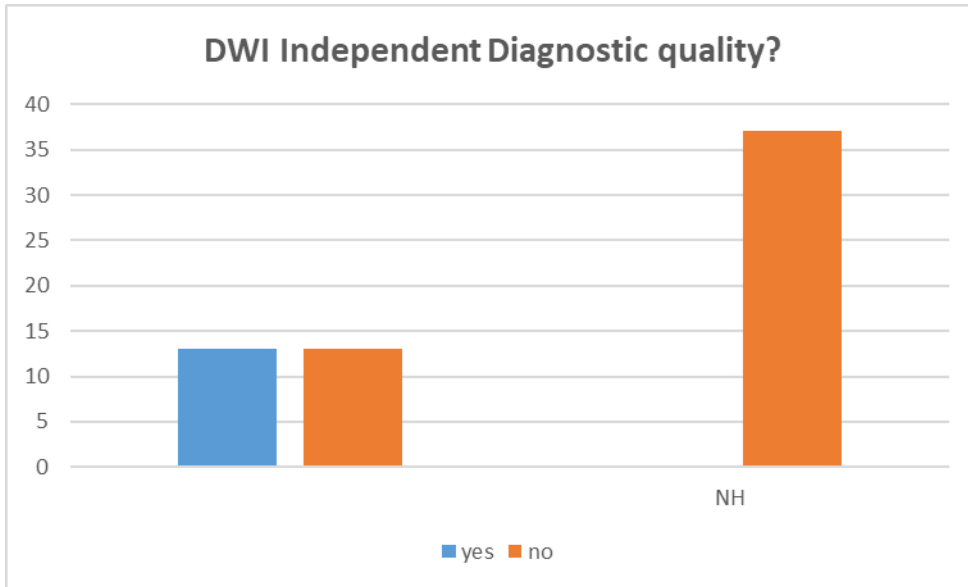
Figure 12 : DWI Diagnostic quality

4.3 DCE

A total of 63 scans evaluated had DCE images. Adherence to the PIQUAL criteria technical parameters during acquisition of the axial plane that should be synchronous to the T2W images was KNH 100% NH 100%. Slice thickness (ST) 3 mm KNH 100%, NH 100%; Slice Gap 0 KNH 0 %, NH 0%; In plane resolution *Frequency encoding* ≤2.5 mm KNH 100%, NH 100%; In plane resolution *Phase encoding* ≤2.5 mm KNH 100% NH 100%; Pre - contrast T1WI available KNH 100% NH 100%; Fat suppression KNH 100% NH 100%; Temporal resolution <15s KNH 100%, NH 100%; Total Acquisition time >2min KNH 96 %, NH 100%

The visual assessment included clear delineation capsular vessels KNH n=22 (85%) NH n=27 (73%); Clear delineation of vessels in the Alcock□s canal KNH n=26 (100%) NH n=37 (100%) There were image degrading artefacts seen mostly secondary to poor fat suppression and motion. Overall DCE images with artefacts KNH n=13 (50%), NH n=26 (70%) ; Poor fat suppression KNH n=10 (44%) NH n=25 (68%), Motion artefacts KNH n=3 (12%), NH n=1 (3%). The total number of DCE images noted to be independently of diagnostic quality KNH (n=0) 0% NH (n=0) 0%.
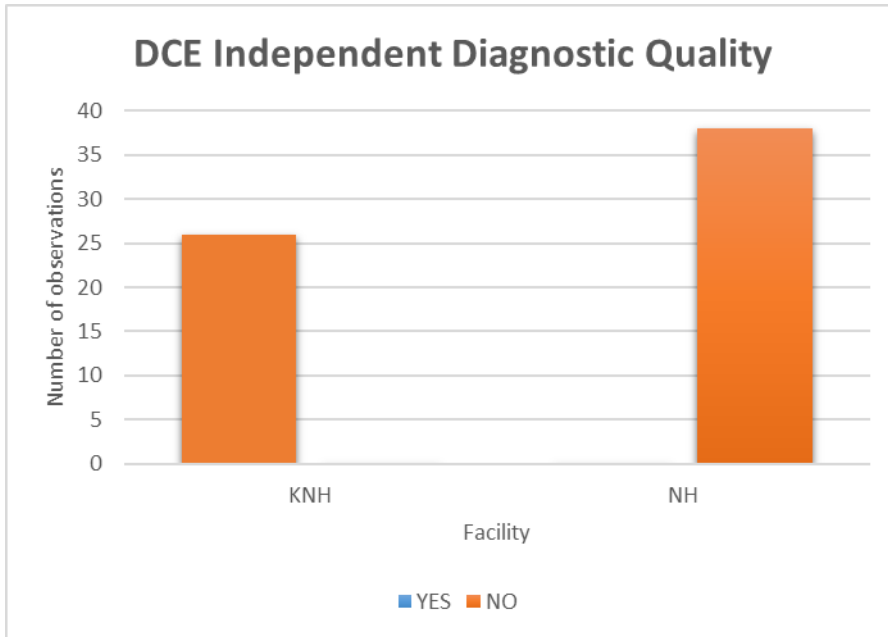
Figure 13: DCE Independent diagnostic quality

4.4 Overall PIQUAL Score

The overall the prostate mpMR Images in the two study centers (n=63) in this study were noted to be of at least sufficient diagnostic quality (PIQUAL ≥ 3) for n=61 97% score; n=8 (13%) were of optimal diagnostic quality (PIQUAL≥4); n=53 (84%) had a score of 3; n= 0 (0%) scored PIQUAL 5; n=2 had a PIQUAL score of <3

Table 3:Adherence to technical parameters

T2W	KNH (n=26, %)	NH (n=39, %)
Axial T2	26 (100)	37 (100)
Sagittal T2	26 (100)	37 (100)
DWI		
Axial	26 (100)	37 (100)
Mul. b. v	26 (100)	37 (100)
High b Val	26 (100)	37 (100)
DCE		
Axial	26 (100)	37 (100)
T1 W	26 (100)	37 (100)
FAT S.	26 (100)	37 (100)

Table 4:Kenyatta National Hospital (KNH) Technical parameters Adherence

T2W:		Mean	Min-Max	Adherence n=26 %
	Slice thickness	3.03	3.0-3.5	23 (92.3)
	Gap	0.8	0.3-2.0	10 (38.5)
	Field of view (cm)	15.8	10-20	23 (88.5)
	Frequency voxel size (mm)	1.1	0.47-1.7	0 (0)
	Phase voxel size (mm)	0.8	0.47-1.1	10 (37)
DWI:				
	Slice thickness (mm)	2.5	2.5-3	26 (100)
	Gap	0.01	0.0-0.5	25 (96)
	Field of view (cm)	18.1	15-21	26 (100)
	Frequency voxel size (mm)	1.4	1.31-1.41	26 (100)
	Phase voxel size (mm)	1.4	1.31-1.41	26 (100)
DCE:				
	Temporal resolution (ms)	177	143-427	26 (100)
	Slice thickness (mm)	5.9	5.0-6.0	26 (100)
	Gap	-3.0	-3.0-2.5	0 (0)
	Frequency voxel size (mm)	0.69	0.40-0.86	26 (100)
	Phase voxel size (mm)	0.69	0.40-0.86	26 (100)
	Acquisition time (mins)	3.5	1.47-4.53	25 (96.2)

Table 5:Nairobi Hospital (NH) Technical Parameters Adherence

Axial T2:		Mean	Min-Max	Adherence n=37 %
	Slice thickness	3.0	2.8-3.0	37 (100)
	Gap	3.6	2.8-4.0	0 (0)
	Field of view (cm)	18.2	14.4-19.4	37 (100)
	Frequency voxel size (mm)	0.54	0.54-0.54	0 (0)
	Phase voxel size (mm)	0.54	0.54-0.54	37 (100)
Diffusion				
	Slice thickness (mm)	3.0	3.0-4.5	36 (97.3)
	Gap	3.4	3.3-4.5	0 (0)
	Field of view (cm)	24.8	18-32	14 (37.8)
	Frequency voxel size (mm)	1.69	1.69-1.69	37 (100)
	Phase voxel size (mm)	1.69	1.69-1.69	37 (100)
Dynamic				
	Temporal resolution (ms)	257.6	257.6-257.6	
	Slice thickness (mm)	3	3.0-3.0	37 (100)
	Gap	1.5	1.5-1.5	0 (0)
	Frequency voxel size (mm)	1.59	1.59-1.59	37 (100)
	Phase voxel size (mm)	1.58	1.58-1.58	37 (100)
	Acquisition time (mins)	3.3	2.15-4.53	37 (100)

Table 6:Technical parameters Adherence Comparisons

Parameters/Adherence	KNH (n=26), %	NH (n=37), %	P value
T2 Slice thickness	23 (92.3)	37 (100)	**0.034**
T2 Gap	10 (38.5)	0 (0)	**<0.001**
T2 FOV	23 (88.5)	37 (100)	**0.034**
T2 Voxel (Frequency)	0 (0)	0 (0)	-
T2 Voxel (Phrase)	10 (37)	37 (100)	**<0.001**
DWI Slice thickness	26 (100)	36 (97.3)	**0.398**
DWI Gap	25 (96)	0 (0)	**<0.001**
DWI FOV	26 (100)	14 (37.8)	**<0.001**
DWI Voxel (frequency)	26 (100)	37 (100)	-
DWI Voxel(phase)	26 (100)	37 (100)	-
DWI maximum b value			
DCE Slice thickness	26 (100)	37 (100)	-
DCE Gap	0 (0)	0 (0)	-
DCE voxel (frequency)	26 (100)	37 (100)	-
DCE voxel (phase)	26 (100)	37 (100)	-
DCE temporal resolution (15 s)	26 (100)	37 (100)	-
DCE total duration	26 (100)	37 (100)	**-**

Chi-square test for significant difference

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

5.1.1: T2 W:

T2w imaging is useful to study the anatomy of the prostate and surrounding structures and is the dominant sequence for the transition zone. There was excellent (100%) adherence to PIQUAL criteria of acquisition of synchronous axial, coronal and sagittal planes which are necessary to avoid limitations caused by volume averaging in single plane use.

This study demonstrated though that only KNH n=8 (31%), NH n=0 (0%) T2W images evaluated were independently of diagnostic quality. This was primarily due to improperly inputted technical parameters i.e., slice gaps and in plane (spatial) resolution. The lowest adherence compliance was seen in in-plane resolution frequency encoding KNH 0% NH 0%; Slice Gaps KNH 38.5 %, NH 0 %. These results were comparable to previous study by Mehmet Coskun et al (32) T2W in plane resolution frequency encoding adherence rate of 9.8% (2019) and Esses et al 16.8 % in-plane frequency dimension. (33) (2017).

There was however noted better overall image quality with a slight deviation in the T2W in-plane resolution i.e., PIQUAL criteria recommends a frequency encoding <0.4 mm, it was noted within this study that when varied up to <0.6 mm, the final image produces less noise/graininess without affecting final overall image resolution. The choice of Z axis did not affect the overall diagnostic quality of the MR images and it was replicated within the other sequences (DWI/DCE).

The prostate capsule, surrounding neurovascular bundles and sphincter muscles were clearly delineated in n =63 100 %. Non visualization of the seminal vesicles KNH n=2 (8%) was solely due to anatomical distortion by extra-prostatic tumor extension; The commonest cause of poor Ejaculatory ducts delineation in KNH n=5 (19.2%) NH n= 17 (46%) scans was seen to be abnormally large slice gaps (range 2 - 4 mm) and anatomical distortion. The overall average adherence to the T2W minimal technical requirements under the PIQUAL criteria was KNH 65.1% NH 71.4 %.

5.1.2: DWI/ADC:

Diffusion weighted imaging is the dominant sequence for assessing the peripheral zone and within this study produced the highest rate of adherence with the PIQUAL technical parameters. Both study sites had excellent 100% adherence in acquiring the Axial planes (that

were synchronous with the corresponding T2W images), Multiple b values (0,500,1000 s/mm2), High b values acquired (1600 s/mm2), Slice thickness and In-plane resolution (Frequency and Phase encoding <2.5mm). The lowest adherence compliance to PIQUAL criteria was seen with the inter-slice gap in NH n=0 (0%), the mean gap distance was 3.4mm. The ADC map adequacy varied at KNH 100% NH 58%. There is an added advantage seen in using the same PACS workstation brand as the acquisition machine (I.e., Phillips ISP workstation for Phillips 3T MRI) because of the post processing functions provided. This difference was especially seen with ADC images viewed better with the Phillips Intellispace PACS viewer (KNH) as compared to the Fujifilm Synapse RIS PACS viewer (NH) viewer; both sets of images were acquired using a Phillips 3T MRI machine. The NH MRI scanner also happens to be past the 7-year cutoff for scanner age a defining factor to the final image quality as noted by Burn et al (2019)(21).

The commonest artefact degrading the final DWI image was due to distended rectum, caused by lack of patient preparation, resulting in magnetic field in-homogeneity at the air/tissue interface KNH 50%, NH 14 %. The has also been noted in prior research that the DWI sequence is more prone to artefacts from magnetic field inhomogeneity due to higher gradients used. M. Czarniecki et al. (34) (2013). The overall average adherence to the DWI minimal technical requirements under the PIQUAL criteria was KNH 99.5%, NH 79.4 %.
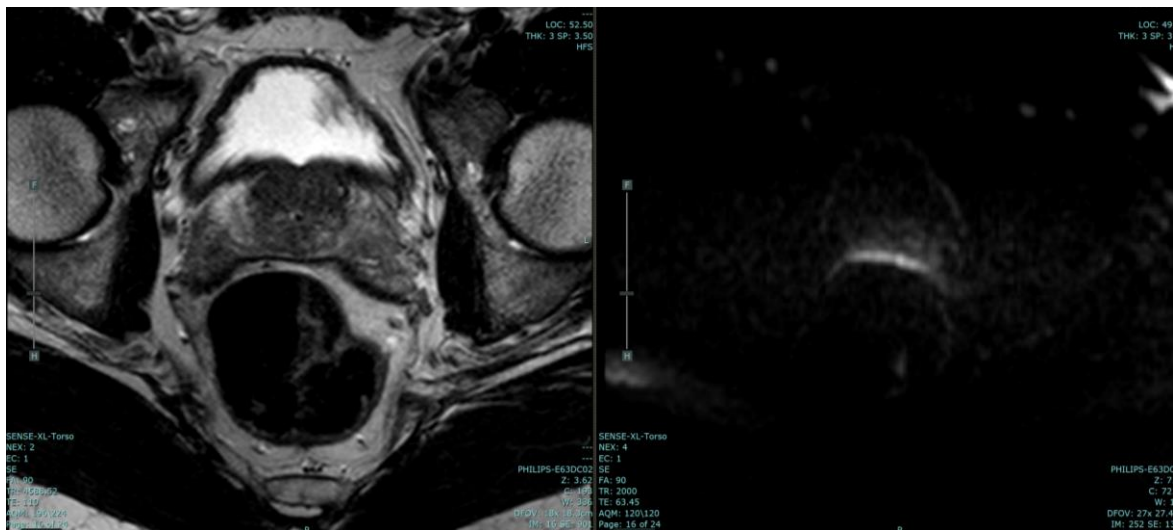

Figure 14: Commonest artifact encountered in DWI sequence- magnetic field

The figure above demonstrates the commonest artifact encountered in DWI sequence- magnetic field in-homogeneity at the air tissue interface in a case of poor patient preparation. Left - Accompanying T2W axial. Right- DWI b1000 s/mm²

5.1.3 DCE:

Dynamic contrast enhanced imaging is an important sequence used when the T2W and DWI sequences are unequivocal. Adherence to the PIQUAL criteria technical parameters was excellent (100%) in acquiring a matching axial plane; in-plane resolution for frequency and phase <2mm; Temporal resolution <15 sec and Total acquisition time >2min. The lowest adherence compliance was seen in Slice thickness(3mm) KNH (0%) mean 5.9 mm and Slice Gap (0) KNH (0%) mean -3.0mm, NH (0%) mean 1.5 mm

A dedicated Pre-contrast T1W image was acquired in KNH 7.6%, NH 100%. These images have been documented as essential to rule out hemorrhagic changes means prior to contrast injection in fat suppressed images. It was noted that this sequence (T1W) was omitted in KNH 92.4 % scans and rather the initial images of DCE used as alternatives, which is still validated within the original PIQUAL article Giganti et al. (9) (2021).

There is no documented optimal FOV range in the PIQUAL criteria but rather states that it should encompass the prostate gland and seminal vesicles. This was seen to be rather ambiguous because an extremely large FOV e.g., >24 cm still included include the anatomical features denoted but would compromise on the spatial resolution and produced blurred images. Fat suppression was applied in all scans KNH 100%, NH 100% but was rather insufficient in majority of scans KNH 44%, NH 68%, This high rate of incomplete fat suppression can lead to misinterpretation when the region around the prostate is affected.

Visual assessment of capsular vessels varied KNH 85% NH 73%. The delineation of these vessels was reduced in images with large FOV >24 cm, anatomical distortion causes by extra-prostatic tumorous growth and artefacts. The overall average adherence to the DCE minimal technical requirements under the PIQUAL criteria was KNH 77.7%, NH 88.8 %.
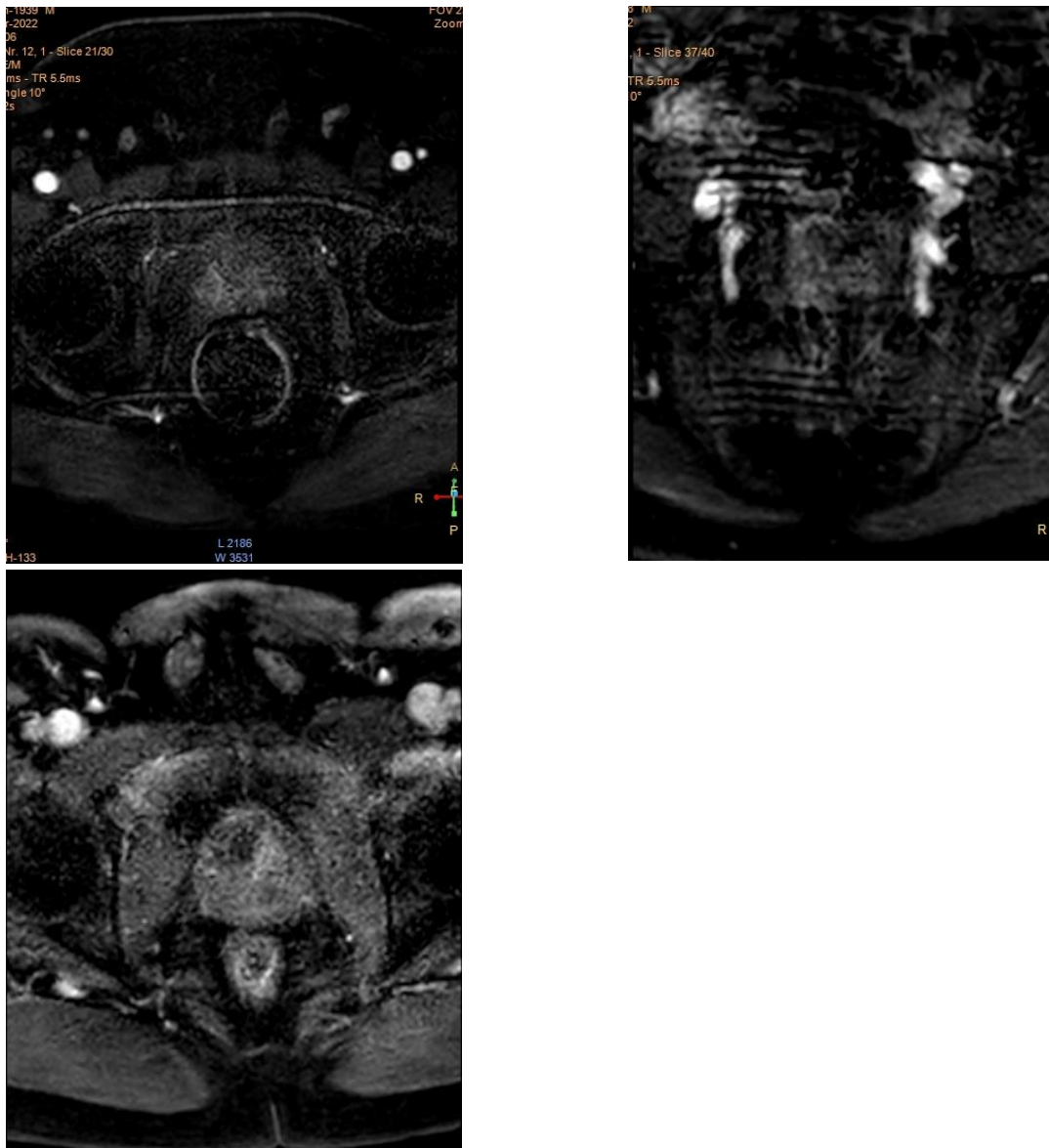
Figure 15: The commonest image degrading artifacts seen under DCE sequence

The images above depict the commonest image degrading artifacts seen under DCE sequence. **Top left**: Motion artefact brought on by patient breathing; **Top right**: Incomplete fat suppression and motion artifacts caused by patient movement; Bottom **left**: The image shows incomplete fat suppression in the periphery as well as the prostate region

5.1.4 Overall PIQUAL Score

There were multiple variations in the input of technical specifications for prostate mpMR image acquisition seen between the two study centers. These variations were influenced by radiologists' or radiographers' preference rather than by the recognized PIRADS/PIQUAL guidelines.

Adherence to the PIQUAL criteria of minimal technical parameters was seen highest in the DWI sequence 89.5 %, followed by DCE 83.5 % and lowest seen in T2WI 68.3%. Comparison between the two study centers showed a similar total percentage rate of compliance to PIRADS/PIQUAL guidelines KNH 80.7 %, NH 79.9%.

There were more image degrading artifacts observed in DCE 59%, followed by DWI sequence 31% and no significant degrading artifacts seen in T2W sequence.The overall PIQUAL score was average, with majority of the scans scoring PIQUAL 3 n=53 (84%) which has a clinical implication in that it is possible to rule in all significant lesions but as the same time not possible to rule out all significant lesions.
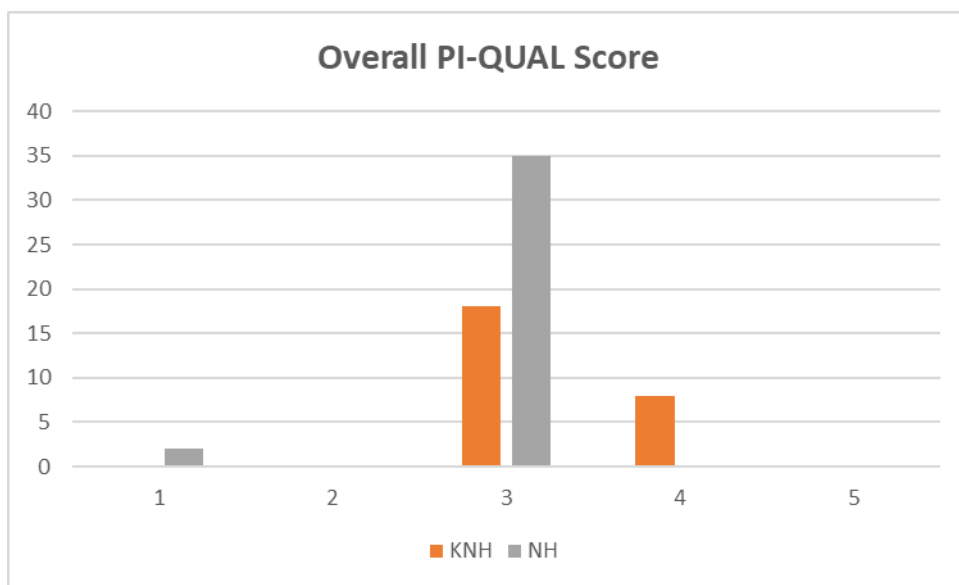
Figure 16: Overall PI-QUAL score

5.2 Limitations

Two radiologists analyzed the images in consensus, so inter-reader variability of the PI-QUAL score in this cohort cannot be provided. However, this has been recently investigated in another cohort, and the results have shown a strong reproducibility in the assessment of PI-QUAL between two radiologists (35)

Despite being of same magnetic strength, the age of the acquisition machines varied (NH - 2013, KNH - 2018) and this is noted as a defining factor in the final image quality referenced from previous studies - Burn et al. showed a significant difference in the quality of prostate MRI at a 7-year cutoff for scanner age (36)

5.3 Recommendations

Urogenital radiologists & radiographers need attend courses/Continuous medical education (CMEs), to familiarize with the PIQUAL/PIRADS criteria and how to use these tools to optimize prostate image quality. Regular assessment of the quality mp MR images of the prostate should be considered by the radiologist before interpretation and should be documented.

A 6 monthly retrospective audit of mp MR images is also recommended for tertiary institutions. These documented reviews should be shared within the larger community and act as a base for further refinements in prostate image quality optimization.

More research needs to be done on the PIQUAL criteria as it appears non-committal in certain parameters e.g., FOV of DCE sequence has no specified range yet this measurement weighs heavily on the final image quality especially the spatial resolution. Serious consideration should be put in patient education and preparation before prostate MRI procedures. It has been documented before and this study confirms that poor patient preparation has a direct correlation to poor PIQUAL scores and final image quality which is degraded by artefacts like magnetic field in-homogeneity and motion.

5.4 Conclusion

Adherence to the standardized minimal technical parameters should always be taken into consideration before every prostate MR scan. Improperly inputted technical parameters e.g., slice thickness, gaps, in-plane resolution frequency encoding accounted for most variation and from the recognized PIRADS guidelines and hence poorer PIQUAL scores.

Continuous application, education and research around optimization of the multi parametric magnetic resonance (MR) prostate imaging is important and necessary as it is now recognized as the future of prostate cancer management. PIQUAL is the first optimization tool of its kind but refinements, driven by research, may be required in its future.

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APPENDICES

Appendix I: Prostate Imaging Quality Control (PI-QUAL) Scoring sheet

Scan & site number: [   ]

⊙ PRECISION

Prostate Imaging QUALity control (PI-QUAL) scoring sheet

PI-QUAL score	Criteria	Clinical implications
1	All mpMRI sequences are below the minimum standard of diagnostic quality	It is NOT possible to rule in all significant lesions [‖]
2	Only one mpMRI sequence is of acceptable diagnostic quality	It is NOT possible to rule out all significant lesions [§]
3	At least two mpMRI sequences taken together are of diagnostic quality	It is possible to rule in all significant lesions / It is NOT possible to rule out all significant lesions
4	Two or more mpMRI sequences are independently of diagnostic quality	It is possible to rule in all significant lesions
5	All mpMRI sequences are of optimal diagnostic quality	It is possible to rule out all significant lesions

[‖] Therefore reports should not include PI-RADS or Likert scores

Please (✓) if present: (note: 'adequate' means compliant with the technical specifications reported in PI-RADS v. 2 guidelines) *

T2-WI

Technical parameters

Axial plane	
Sagittal or coronal plane	
Adequate field of view	
Adequate in-plane resolution	
Adequate slice thickness	
Z-axis correctly positioned	

Visual assessment

Capsule clearly delineated	
Seminal vesicles clearly delineated	
Ejaculatory ducts clearly delineated	
Neurovascular bundles clearly delineated	
Sphincter muscle clearly delineated	
Absence of artefacts (e.g. movement)	

Is T2-WI of diagnostic quality?

☐ Yes
☐ No

DWI

Technical parameters

Axial plane matching T2-WI	
Adequate field of view	
Adequate in-plane resolution	
Adequate slice thickness	
Multiple [> 2] b values acquired	
High b value (synthesised or acquired)	

Visual assessment

| Adequate ADC map | |
| Absence of artefacts (e.g. rectal air) | |

Is DWI of diagnostic quality?

☐ Yes
☐ No

DCE

Technical parameters

Axial plane matching T2-WI	
Adequate field of view	
Adequate in-plane resolution	
Adequate slice thickness	
Pre-contrast T1-WI available	
Fat suppression/subtraction	
Adequate temporal resolution [≤ 10 sec]	
Adequate total observation rate [≥ 2min]	

Visual assessment

Capsular vessels clearly delineated	
Vessels in the Alcock's canal clearly delineated	
Absence of artefacts (e.g. movement)	

Is DCE of diagnostic quality?

☐ Yes
☐ No

PI-QUAL score:
1 ☐
2 ☐
3 ☐
4 ☐
5 ☐

Comments:

[   ]

Date:

Reporting Radiologist:

Signed:

* Weinreb JC, et al. PI-RADS Prostate Imaging - Reporting and Data System: 2015, Version 2. Eur Urol 2016;69:16–40.

Appendix II: Prostate MRI Technical Considerations and Technical Parameters in Accordance with PIRADS V2.1

MRI Machine Details

1. **The Nairobi hospital**

   Machine Details: Type – Phillips 3.0 Tesla

   Brand - Achieva

   Y.O.M – 2012 Nov.

2. Kenyatta National Hospital: Type – Phillips 3.0 Tesla

   Brand – Ingenia

   Y.O.M - 2018

Clinical Considerations:

1. **Timing:**

   Prostate MR imaging for Staging should be done prior to or after a period of at least 6 weeks in patients that have undergone prostate biopsy (TURP).

2. **Patient Preparation**

   Patient should evacuate the rectum, if possible, prior to the MRI exam.

3. **Patient Details**

   The patients request form should include the following details:

   Recent serum PSA level.

   Date and results of prostate biopsy

   Digital rectal exam (DRE) findings, medications (hormones/hormone ablation), prior prostate infections, pelvic surgery, radiation therapy

TECHNICAL SPECIFICATIONS:

   T2W (FSE)

• Always obtain images in the Straight Axial and/or Oblique Axial Plane (perpendicular to the peripheral zone) + one additional plane i.e., Sagittal or Coronal Plane

• Slice thickness: 3mm, no gap. Imaging planes same as those for DWI & DCE

• FOV: 12-20 cm to encompass the entire prostate gland and seminal vesicles

• In plane dimension: ≤0.7mm (phase) x ≤0.4mm(frequency)

DWI

• Free-breathing spin echo EPI sequence combined with spectral fat saturation is recommended.

• TE: ≤90 msec; TR: ≥3000 msec

• Slice thickness: ≤4mm, no gap. Imaging planes should be same as those for T2W and DCE

• Field Of View: 16-22 cm

• In plane dimension: ≤2.5mm (phase and frequency)

• One low b-value set preferably at 50-100 sec/mm2

   One intermediate b-value set at 800-1000 sec/mm2

   One high b-value ≥1,400 sec/mm2 (produced separately or calculated from the low and intermediate b -values)

DCE

• Fat suppression and/or subtractions should be used.

• 3D T1W GRE sequence is preferred

• TR/TE:<100msec/ <5msec

• Slice thickness: 3mm, no gap. Imaging planes same as for DWI & DCE.

• FOV: encompass the entire prostate gland and seminal vesicles

• In plane dimension: ≤2mm X ≤2mm (Phase and sequence)

• Temporal resolution: ≤15sec

• Total observation rate:>2min •

• Dose: 0.1mmol/kg standard Gadolinium based contrast enhanced agent

• Injection rate: 2-3cc/sec starting with continuous image data acquisition (should be the same for all exams)

Appendix III: Nairobi Hospital Research Approval

THE NAIROBI HOSPITAL

REF: TNH/ADMIN/CEO/DMSR/07/04/2022   07 April 2022

TO:Dr. Gichuki Edwin Mwangi

Principal Investigator

Dear Dr. Gichuki,

RE:ASSESSMENT OE MULUPARAMETRIC MAGNENIC RESONANCE-IMAGE QUALITY FOR PROSTATE CANCER DETECTION USING PI-QUAL SCORING SYSTEM AT KENYATTA NATIONAL HOSPITAL & THE NAIROBI HOSPITAL

This is to inform you that The Nairobi Hospital Ethics & Research Committee has reviewed and approved your above research proposal. Your application approval number is TNH-ERC/DMSR/ RP/019/22. The approval period is 07th April, 2022 - 07th April, 2023.

A. Scientific design and conduct of the study.

This is a Prospective cross-sectional study from April 2022 -August 2022. The study will assess the multiparametric Magnetic Resonance Image qualities of scans produced in Kenyatta National hospital and The Nairobi Hospital. Selected MR Scans' image quality will be scored using the PI-QUAL scoring sheet.

B. Recruitment of research participants.

Total study participants will be 66 patients, who are suspected to have prostate cancer. Selection will be by simple random sampling, whereby every subject that fits the inclusion criteria in Kenyatta National Hospital and The Nairobi Hospital will be selected until the required sampling size is achieved.

C. Care and protection of research participants

Relevant data of eligible patients will be collected. No personal identifying information will be included from the images being evaluated. All research data will be preserved anonymously.

Healthcare with a difference

P.O. Box 30026-00100 Nairobi, Kenya | Tel: +254 020 2845000 | Fax: +254 020 2728003

Email:hosp@nbihosp.org|Website:www.nairobihospital.org

Ethical guidelines will be-employed in line with the World Medical Association Declaration of Helsinki (30).

- The name, religion and ethnicity of the patients will not be documented. Patients will be identified by MRI number only to safeguard confidentiality.

No additional cost will be incurred by the patient by participating in the study

- Identification of the patient and any other additional information will be kept anonymous by the investigator.

The information in the questionnaire will be known only to the investigator, supervisor radiologist, radiographer and bio-statistician.

This approval is subject to compliance with the following requirements;

i) Only approved documents including (informed consents, study instruments, MTA) will be used.

ii) All changes including (amendments, deviations, and violations) are submitted for review and approval by The Nairobi Hospital Ethics & Research Committee

iii) Death and life-threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to The Nairobi Hospital Ethics & Research Committee within 24 hours of notification.

iv) Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to The Nairobi Hospital Ethics & Research Committee within 72 hours

v) Clearance for export of biological specimens must be obtained from relevant institutions.vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.

vi) Submission of an executive summary report within 90 days upon completion of the study.to The Nairobi Hospital Ethics & Research Committee.

Prior to commencing you study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI)https://oris.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely

-FOR: THE NAIROBI HOSPITAL

jb0

James Nyamongo

CHIEF EXECUTIVE OFFICER

cC.Chairman, TNH-Ethics & Research Committee

.Director Medical Services & Research

Chief Radiologist

Chief Medical Records Officer

Team Leader, Oncology

Appendix IV: KNH/UoN-ERC Letter of Approval

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020)2726300 Ext 44355

KNH-UON ERC
Email:uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter:@UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel:726300-9
Fax:725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/56   15th February,2022

Dr. Edwin Gichuki

Reg. No. H58/32118/2019

Dept. Of Diagnostic Imaging and Radiation Medicine

Faculty of Health Sciences

University of Nairobi

Dear Dr.Gichuki,

RESEARCH PROPOSAL: ASSESSMENT OF MULTIPARAMETRIC MAGNETIC RESONANCE IMAGE QUALITY FOR PROSTATE CANCER DETECTION USING PI-QUAL SCORING SYSTEM AT KENYATTA NATIONAL HOSPITAL AND THE NAIROBI HOSPITAL (P702/08/2021)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is P702/08/2021.The approval period is 15th February 2022 - 14th February 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.

ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.

iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.

iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.

V. Clearance for export of biological specimens must be obtained from relevant institutions.

vi. Submission of a request for renewal of approval at least 60 days prior t expiry of the approval period. Attach a comprehensive progress report to support the renewal.

vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Protect to discover

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI)https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

B

DR. BEATRICE K.M. AMUGUNE

SECRETARY, KNH-UoN ERC

C.C. The Dean, Faculty of Health Sciences, UoN

The Senior Director, CS, KNH

The Chairperson, KNH-UoN ERC

The Assistant Director, Health Information, KNH

The Chair, Dept. of Diagnostic Imaging and Radiation Medicine, UoN

Supervisors: Dr. Alfred Odhiambo, Dept. of Diagnostic Imaging and Radiation Medicine, UoN

Dr. Omamo Eunice, Consultant Radiologist, Dept. of Radiology, KNH

Appendix V: Certificate of Plagiarism

Assessment of Multiparametric Magnetic Resonance Image Quality For Prostate Cancer Detection Using Pi-Qual Scoring System At Kenyatta National Hospital & The Nairobi Hospital

ORIGINALITY REPORT

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