THE USE OF BRACHIO-BASILIC ARTERIO-VENOUS FISTULAE FOR HAEMODIALYSIS - A SINGLE CENTRE DESCRIPTIVE STUDY

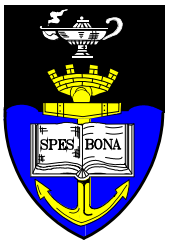
by

Dr Kenward Chibuye
MBChB (UNZA)
Student Number: CHBKEN001

Submitted in fulfilment of the requirements for the degree:

Master of Medicine (Surgery)
by minor-dissertation

Department of Surgery: Transplant Unit
Faculty of Health Sciences, Groote Schuur Hospital
University of Cape Town



Supervisor: Dr Johannes Marthinus du Toit
MBChB, FCS (SA), MMed (UCT), FEBS
Consultant: Transplant Unit, Groote Schuur Hospital

8 March 2021

University of Cape Town

The copyright of this thesis vests in the author. No quotation from it or information derived from it is to be published without full acknowledgement of the source. The thesis is to be used for private study or non-commercial research purposes only.

Published by the University of Cape Town (UCT) in terms of the non-exclusive license granted to UCT by the author.

University of Cape Town

TABLE OF CONTENTS

Declaration of authenticity p 3

Abstract p 4

Acknowledgments p 6

List of tables and figures p 7

Abbreviations p 8

Introduction p 9

Part A: LITERATURE REVIEW

Objectives of literature review p 11

Literature search strategy p 11

References p 28

Part B: MANUSCRIPT IN ARTICLE FORMAT

Title page p 34

Abstract p 34

Main text p 35

References p 48

Part C: ADDENDA

a. Target journal information and Instructions to Authors p 52

b. Research Protocol p 54

c. Data capture instruments p 59

d. HREC approval letter p 60

DECLARATION OF AUTHENTICITY

I, Dr Kenward Chibuye, hereby declare that the work on which this dissertation is based, is my own. I have fully and specifically acknowledged sources from which material has been sourced and adapted. Furthermore, the information contained within this document, was gathered and utilised specifically to fulfil the purposes and objectives of this study and has not been previously submitted to any other university for a higher degree or any journal for publication.

I understand that, if at any time it is shown that I have significantly misrepresented material within this document, any degree or credits awarded to me may be revoked.

Signed by candidate

Signature: ……..

K Chibuye

Date: 8 March 2021

Signature:

JM du Toit

Date: 8 March 2021

ABSTRACT

THE USE OF BRACHIO-BASILIC ARTERIO-VENOUS FISTULAE FOR HAEMODIALYSIS - A SINGLE CENTRE DESCRIPTIVE STUDY

Authors: Kenward Chibuye, Tinus du Toit

Corresponding author: Tinus du Toit

tinus.dutoit@uct.ac.za

Department of Surgery, University of Cape Town

Groote Schuur Hospital, Anzio Road, Observatory, Cape Town, 7925

Tel +27 829289546

Affiliations: Department of Surgery, University of Cape Town, Groote Schuur Hospital, Cape Town, South Africa (KC, TdT)

Author contributions: All authors made a substantial contribution to the conceptualisation, design, analysis and interpretation of data. All authors had the opportunity to approve the final version of the manuscript prior to submission.

Conflicts of interest: None to declare

Aim: To report on our local experience with the use of brachio-basilic arteriovenous fistulae (BBAVFs) and to encourage wider local acceptance of the procedure in accordance with international guidelines. The primary aim of the study was to report on access patency, including primary, assisted-primary and secondary patency at 30 days, 1 year and 3 years. The secondary aims were to report on complications and functional outcomes with this technique.

Methods: This is a retrospective, descriptive study of 41 consecutive haemodialysis patients that underwent BBAVF creation at Groote Schuur Hospital, from 1 January 2014 to 24 April 2020.

Results: The median age of the patients was 45 years (IQR 32-54). Twenty females and 21 males were included in the study. Of the 41 BBAVFs that were performed, 24 (58.5%) were performed as a one-stage procedure and 17 (41.5%) as a two-stage procedure. The primary patency rates at 30 days, 1-and 3-years were 95.1% (95% CI 81.9-98.8), 48.8% (95% CI 32.9-62.9) and 19.5% (95% CI 9.2-32.7). Assisted-primary patency rates at 30 days, 1-and 3-years were 100%, 67.7% (95% CI 50.0-80.1) and 24.3% (95% CI 12.1-38.8). Secondary patency rates at 30 days, 1-and 3-years were 100%, 70.3% (95% CI 52.8-82.3) and 27% (95% CI 14.1-41.8). Of the 41 patients that underwent BBAVF creation, 4 (9.8%) presented with minor complications within 30 days. The median interval from creation to use was calculated as 46 days (IQR 38-51). The median interval from BBAVF creation to catheter removal was calculated as 73 days (IQR 57-79).

Conclusion: BBAVFs can successfully be performed in a resource constraint environment by surgeons with limited prior experience with the technique. However, careful monitoring, well-established referral pathways for dysfunctional fistulae and access to surgical or endovascular revision seem to be key factors in ensuring long-term patency.

ACKNOWLEDGEMENTS

First and foremost, I would like to thank my family for their unwavering emotional and financial support during my studies. I would not have been able to complete this study without their support. I will always be indebted to them.

My supervisor, Dr JM du Toit, has been extremely supportive during this process and I would like to thank him once again for his support and guidance throughout the study period and after.

To Mrs Katherine Manning, thank you for your statistical support and for ensuring that the data presented in this study, has been rigorously checked and checked again.

To the Head of the Division of General Surgery at Groote Schuur Hospital, Prof EM Muller, thank you for creating and nurturing an environment conducive to research.

LIST OF TABLES AND FIGURES

Part A: LITERATURE REVIEW

Figure 1: Arterial anatomy of the upper arm

Figure 2: Venous anatomy of the upper arm

Figure 3: Venous anatomy of the forearm

Figure 4: Forest Plot depicting the pooled estimate of the immediate arterio-venous fistula failure rate in patients that underwent routine pre-operative Doppler ultrasound mapping (US) versus clinical examination alone.

Figure 5: Forest Plot depicting the pooled estimate of the early/midterm adequacy for haemodialysis and /or maturation in patients that underwent routine pre-operative Doppler ultrasound mapping (US) versus selective US.

Part B: MANUSCRIPT IN ARTICLE FORMAT

Table 1: Demographic and baseline characteristics of 41 patients that underwent BBAVF

Figure 1: Kaplan-Meier analysis of BBAVF patency rates at 1, 2 and 3 years

Figure 2: Histograms depicting time (in days) from AVF creation to first use (a) and catheter removal (b).

ABBREVIATIONS

ACC	American College of Cardiology
AHA	American Heart Association
AV	Arterio-venous
AVF	Arterio-venous fistula
AVG	Arterio-venous graft
BBAVF	Brachio-basilic arterio-venous fistula
CI	Confidence interval
CKD	Chronic kidney disease
ESKD	End-stage kidney disease
mm	Millimetres
NKF-KDOQI	National Kidney Foundation Kidney Disease Outcomes Quality Initiatives
NYHA	New York Heart Association
OR	Odds' ratio
PTA	Percutaneous transluminal angioplasty
RR	Risk ratio
SPSS	Social Package of Statistical Sciences
THC	Tunnelled haemodialysis catheter

INTRODUCTION

An exponential rise in chronic kidney disease (CKD) in Sub-Saharan Africa (SSA) has been projected over the next decade due to the escalating dual burden of communicable and non-communicable diseases.[1] For the majority of patients who have progressed to end-stage kidney disease (ESKD), kidney transplantation will improve survival, decrease cost and improve quality of life compared to dialysis.[2] However, with a low annual kidney transplant rate of 0.7 per million population (pmp), predominantly limited by a low annual deceased donor rate of 0.1 pmp, most patients with ESKD on the African continent depend heavily on the safe and effective administration of dialysis to achieve long-term survival.[3] Within this context, the implementation of clinical practice guidelines, quality assessment, research and education in the field of dialysis access may be considered even more crucial and relevant than in regions with better access to transplantation.

The goal of vascular access is to provide repetitive and reliable access to the circulation, while minimising complications. Practice guidelines from several international vascular access societies endorse the radio-cephalic AV fistula as the first site of peripheral vascular access creation, followed by the brachio-cephalic AV fistula.[4-6] Based on superior outcomes, *brachio-basilic arterio-venous fistulae (BBAVF)* should be considered before AV grafts (AVG) in cases where superficial AV fistula sites have been exhausted or where the target vessels have been assessed as unsuitable for superficial AV fistula creation.[4-6] Despite these guidelines, AVGs are at times performed inappropriately early and may, in some instances, decrease the likelihood of future successful BBAVF creation. The perceived complexity of the BBAVF procedure may be the reason why some access surgeons prefer AVG creation.

By reporting on our local experience with the use of BBAVFs, and by reviewing the technical aspects of this procedure as well as the pitfalls, we anticipate wider local acceptance of this procedure for suitable candidates in accordance with international guidelines.

Part A: LITERATURE REVIEW

OBJECTIVES OF LITERATURE REVIEW:

The *objectives* of the literature review were to appraise the current body of evidence in AV access surgery in terms of:

- The anatomical considerations relevant to upper extremity AV access surgery
- The role of pre-operative assessment prior to AV access creation
- Reporting on AV access surgery outcomes
- The place of brachio-basilic arterio-venous fistulae in the modern haemodialysis unit
- Outcome comparison between one- versus two- stage brachio-basilic arterio-venous fistulae

LITERATURE SEARCH STRATEGY:

A computerised search of the National Library of Medicine and the National Institutes of Health MEDLINE database was undertaken using the PubMed (*www.pubmed.gov*) interface, followed by a secondary manual search of the article reference lists. The primary search strategy was developed to retrieve English language articles published between 2008 and 2018 that focused on the above aspects of AV access surgery. The following *key words* were used to facilitate a logical and structured review of the literature.

- Anatomy arterio-venous fistula
- Pre-operative arterio-venous access
- Arterio-venous outcome

- Brachio-basilic fistula
- One-stage two-stage brachio-basilic fistula

The following publications were *excluded*:

- Letters to the editor, editorials and other items of general commentary.
- Publications describing the diagnosis or management of traumatic arterio-venous fistulae.
- Publications reporting on arterio-venous access that were utilised for purposes other than haemodialysis (for instance administration of long-term total parental nutrition).
- Case series reporting on AV access in the paediatric population (aged 13 or less).
- Publications that reported on / or included lower extremity AV access outcomes in their analysis.
- Case reports.

Societal guidelines, meta-analyses, randomised control trials, review articles and case series were further reviewed and analysed. Sufficient literature pertaining to the anatomical considerations relevant to AV access surgery could not be identified during the literature review and textbook chapters had to be included as part of the search strategy for this section only.

ANATOMICAL CONSIDERATIONS IN UPPER EXTREMITY AV ACCESS SURGERY:

A thorough working knowledge of upper extremity vascular anatomy is essential when AV access creation is being considered and when complications of AV access surgery are being investigated and managed.

Relevant arterial anatomy

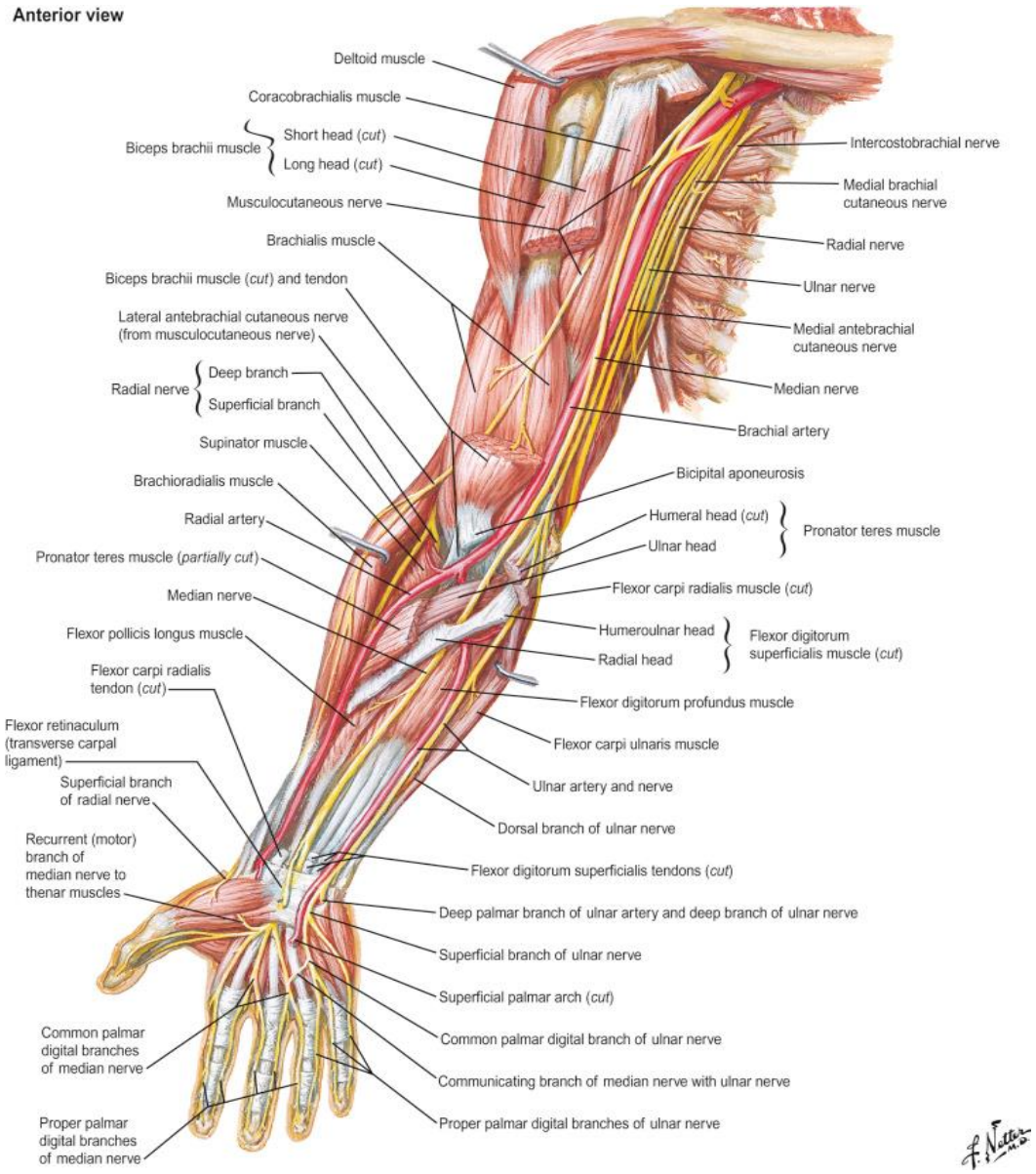
The most common arterial segments targeted for inflow to the AV access include the distal brachial artery, the proximal radial artery and the distal radial artery. Infrequently, the ulnar artery may be used during the creation of an ulnar-basilic AVF.[7] Appropriate arterial selection is a key component of the pre-operative evaluation and may result in complications, including primary failure or delayed maturation of the AVF if not adequately assessed pre-operatively. In extreme cases, upper limb viability may be threatened where the presence of pre-existing arterial occlusive disease were not recognised pre-operatively.[8]

The axillary artery, which continues as the brachial artery, is the main arterial supply to the upper limb.[9] During subclavian artery occlusion (even in the most acute setting), perfusion of the upper limb should be maintained via multiple collateral vessels in most cases.[10] Brachial artery occlusion, particularly in the setting of acute thrombosis, seldomly display the same degree of collateralisation and may present with acute upper limb ischaemia more frequently.[10] The brachial artery usually bifurcates below the level of the bicipital aponeurosis. However, in 15-20% of individuals, the brachial artery bifurcation may occur more proximally, as high up as the axilla.[9] The first 3-4cm of the radial artery is regarded as the proximal radial artery and may be used as inflow during the creation of a proximal radio-cephalic AVF. During this procedure, care must be taken to prevent injury to the recurrent radial artery and superficial radial nerve. [9]

At the level of the wrist, the radial artery lies deep to the antebrachial fascia. This region is particularly favourable for AVF creation, as the cephalic vein is usually situated nearby and only a short incision and minimal mobilisation is required for radio-cephalic AVF creation. The proximal ulnar artery is larger in diameter than the proximal radial artery and gives rise

to a large interosseous branch close to its origin. Beyond this point, the ulnar artery tends to be of smaller calibre than the radial artery.[9] Some authors have attributed the higher primary failure and delayed maturation rates of ulnar inflow AVFs to the large proximal interosseous branch and smaller distal calibre, as compared to the radial artery.[11]

Figure 1: Arterial anatomy of the upper limb[9]



Relevant venous anatomy

The upper limb veins are divided into the superficial and deep venous systems and represent the prospective cannulation segments of mature AVFs. The cephalic vein forms part of the superficial venous system and originates at the web space between the first and second finger, where it crosses the anatomical snuff box. While ascending along the anterio-lateral aspect of the forearm, the cephalic vein drains a dorsal tributary (approximately 7-10cm proximal to the wrist) resulting in a larger calibre at the confluence of the two veins.[9] In cases where the cephalic vein is of particularly small calibre at the wrist, a more proximal site of anastomosis may be selected to make use of the larger calibre and to spatulate the confluence of the two veins to ensure a larger calibre anastomosis.[12] The vein continues medially towards the cubital fossa, anterior to the proximal radial artery. At the junction of the proximal third and middle third of the forearm, the cephalic vein drains a lateral tributary referred to as the lateral cephalic vein, which can serve as additional outflow should stenosis or occlusion of the main cephalic vein occur. In the cubital fossa the cephalic vein branches into the median cubital vein and the upper arm cephalic vein. A perforating vein pierces the deep fascia at this point to join the deep venous system via the brachial veins. This perforating vessel has the potential to maintain AVF flow should stenosis or occlusion of the upper arm cephalic vein occur. The median cubital vein courses medially and joins the basilic vein on the medial aspect of the lower third of the upper arm. By maintaining the median cubital vein during a first stage BBAVF, additional outflow may be ensured. However, the median cubital vein is often sacrificed during the second-stage procedure to maximise length and to facilitate tunnelling away from the neuro-vascular bundle. The upper arm cephalic vein ascends along the deltopectoral groove towards the infraclavicular fossa, where it forms a section referred to as the cephalic arch (a segment prone to stenosis) before draining into the axillary vein.[9]

The basilic vein is superficially situated in the forearm and originates from the ulnar aspect of the dorsal venous arch of the hand. It ascends along the medial aspect of the forearm and is always anterior to medial epicondyle of the humerus, an important anatomical landmark. The basilic vein pierces the brachial fascia and joins the brachial veins (at a variable distance from the medial epicondyle) to form the axillary vein. Therefore, the basilic vein should be elevated and transposed to ensure that it is accessible as haemodialysis access. The BBAVF procedure requires a more extensive incision in the bicipital groove, compared to superficial AVFs and AVGs. The basilic vein is dissected free from its bed by ligation and division of all tributaries up to the point of confluence with the brachial vein to form the axillary vein. The more proximal the junction between the basilic and brachial veins, the longer the segment of basilic vein that can be transposed. In some patients the basilic vein may continue as an independent deep vein to the level of the axilla. This anatomy is ideal for transposition of the basilic vein.[9]

Figure 2: Venous anatomy of the upper arm[9]

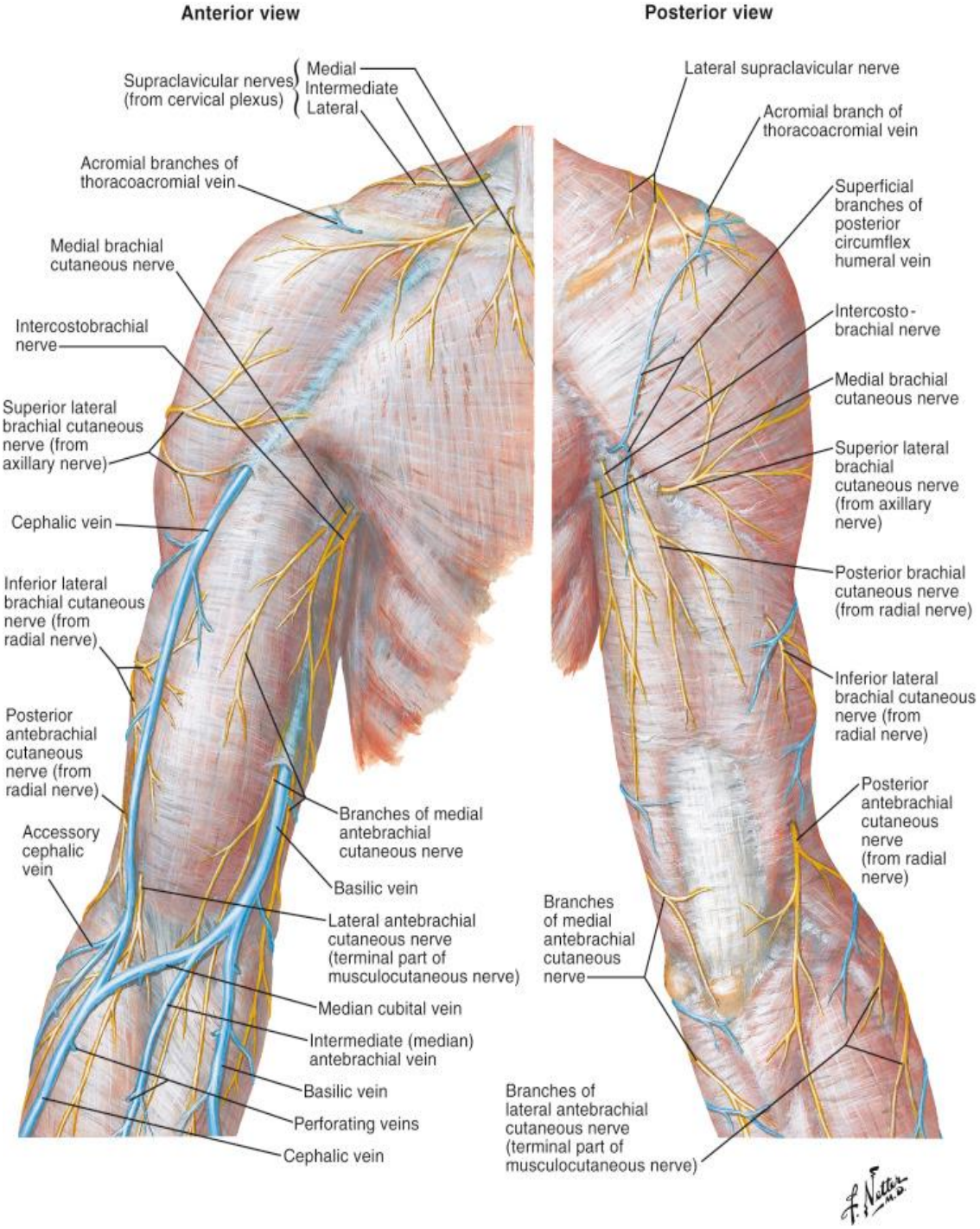
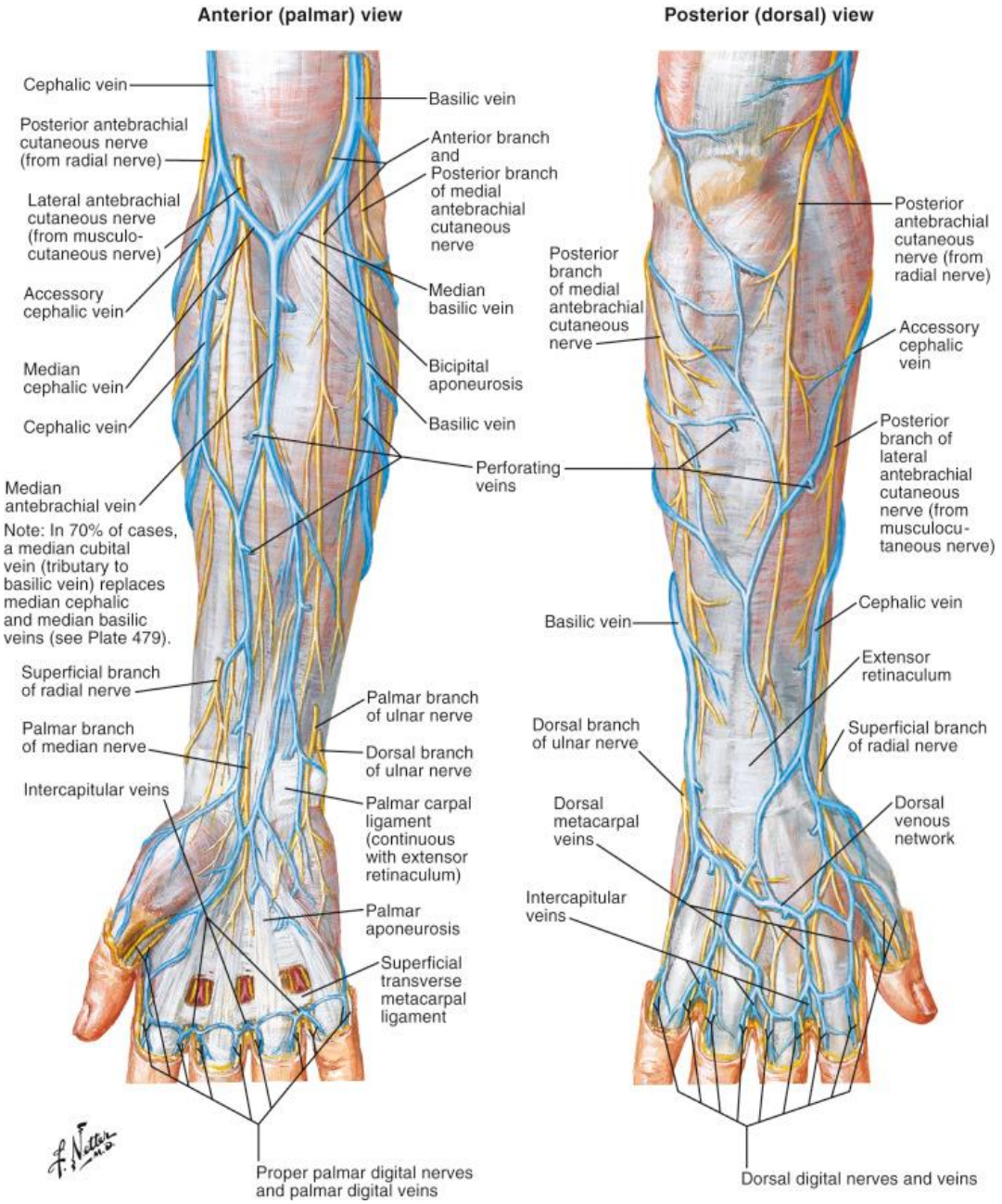


Figure 3: Venous anatomy of the forearm[9]



PRE-OPERATIVE ASSESSMENT PRIOR TO AV ACCESS CREATION:

Patient evaluation in preparation for peripheral AV access surgery should always include a detailed medical, surgical and occupational history, physical examination and ultrasound assessment of the target vessels. The evaluation should focus on the detection of contra-indications and the identification of factors that could predict primary failure of surgically created AV access. An appropriate AV access site, with an acceptable chance of success and lowest chance of complications, should be selected based on a thorough pre-operative evaluation. Importantly, AV access sites should be selected with a long-term view of future access options and should not adversely affect prospective AV access sites.[4]

Identifying the patient who does not stand to benefit from AV access creation:

The benefit of peripheral AV access, compared to tunnelled haemodialysis catheters (THCs), are often only realised after about 1 year post-creation. Therefore, in patients with a life expectancy of 1 year or less, or in patients scheduled for living donor kidney transplant within 3 months of starting dialysis, placement of a THC may be more appropriate than AV access creation.[4]

Identifying the patient with cardiac dysfunction:

A cautious approach to patients with significant cardiac dysfunction is advised. In practise, it is important to ensure that cardiac dysfunction is not due to inadequate haemodialysis and chronic fluid overload, as this cause may be potentially reversible. High-flow brachial artery-based AV access (including brachio-cephalic AVFs, brachio-basilic AVFs and brachio-axillary AVGs) may exacerbate pre-existing cardiac dysfunction due to an increase in preload and venous return. In cardiac failure patients classified within the New York Heart Association (NYHA) Class III and the American College of Cardiology (ACC) / American

Heart Association (AHA) Stage C, the decision to create an AVF or to insert a THC should be individualised according the degree of systolic and / or diastolic dysfunction.[13] In cardiac failure patients with a significant impairment of systolic function (ejection fraction lower than 30%) or classified within the NYHA Class IV and the ACC/AHA Stage D, THC placement is advised.[13] Infrequently, patients with THCs in-situ, may present with significant tricuspid valve regurgitation when the catheter tip is positioned too deep. This clinical scenario may result in a giant c-v wave within the internal jugular vein that may be palpable (Lancini's sign).[14]

Identifying the patient with underlying central vein stenosis / occlusion:

A major consequence of long-term THC use is the development of central vein stenosis or occlusion. This complication has appropriately been referred to as the Achilles heel of haemodialysis access and often has a crippling effect on prospective vascular access options. The development of central vein stenosis is based on an interplay of mechanical forces, generated by dynamic mediastinal structures and turbulent flow.[15] Vein-wall thickening, proliferation of smooth-muscle cells and focal catheter attachment to the vein wall are consequences of prolonged catheter use.[16] Areas of natural anatomical narrowing have been described and render the vessel wall vulnerable to direct, repetitive mechanical trauma. In the upper extremities, these areas include the subclavian vein at the costoclavicular junction and the left brachiocephalic vein as it crosses a relatively fixed, pulsatile fulcrum of brachiocephalic artery and aorta.[17,18]

During pre-operative assessment, patients need to be specifically asked about a recent change in phonation, the occurrence of chronic headaches or a history of difficult THC insertion, as they may not always volunteer this information. Clinical signs of central vein stenosis are dependent on the anatomical segment(s) affected and may be subtle in patients who do not

have functioning AV access. All patients referred for AV access creation, especially those with a history of previous THC use, should be carefully evaluated for the presence of upper extremity, neck and facial swelling, conjunctival oedema and tortuous collateral veins in the region of the shoulder joint and / or the anterior chest wall. In patients with functioning AV access, central vein stenosis may result in difficult cannulation as a result of arm swelling, poor dialysis adequacy, high venous pressure with prolonged bleeding on decannulation, aneurysm formation and thrombosis of the access.[19]

Venography is viewed as the gold standard in detecting central vein stenosis or occlusion in those suffering from CKD, but is invasive in nature.[19] In one study, a more than 50% stenosis of the central veins during venographic assessment could be demonstrated in 10 to 13% of patients referred for vein mapping.[20] Duplex ultrasound (DUS) may be used to evaluate the internal jugular and subclavian veins for the presence of respiratory phasicity and cardiac pulsation, which are viewed as indirect or surrogate markers of central vein patency.[19] In one study, the overall sensitivity, specificity, positive predictive value and negative predictive value of DUS compared to venography to identify central vein pathology were, 80.9%, 79.3%, 73.9% and 85.1%, respectively.[21] CT venography is an effective tool in defining central vein pathology in selected cases, especially when aggressive recanalisation procedures are being considered. Magnetic resonance venography has a limited role in this subset of patients due to the potential risk of nephrogenic systemic fibrosis from gadolinium.[19]

The creation of AV access may unmask the presence of pre-existing central vein stenotic lesions that were subclinical or not successfully identified at pre-operative evaluation. Swelling may be self-limiting and may improve with time in some cases, but in those with persistent or progressive swelling, further assessment and endovascular intervention may be

necessary as primary failure and wound complications may occur if treatment is delayed for too long. Percutaneous transluminal angioplasty (PTA) is recommended as the initial approach, but the reported results are variable and the technical failure rate ranges from 10% to 30%.[19] Patency rates after PTA alone are generally poor (28.9% at 6 months and 25% at 1 year).[19] Elastic recoil of the central veins, as demonstrated by intravascular ultrasound or delayed venogram, is probably responsible. PTA with high pressure balloons has resulted in improved primary patency rates (60% at 6 months and 30% at 12 months).[19] Secondary patency approaching 60% at 12 months can be achieved with repeated angioplasty without stent placement. Close surveillance and repeated interventions are required to maintain patency. Marginal outcomes of angioplasty alone have prompted a recommendation of primary stent placement for central vein stenosis. However, stent shortcomings make this practice a rather aggressive approach and stent grafts are mostly recommended for elastic vein recoil leading to significant residual stenosis after PTA or for lesions recurring within 3 months after angioplasty.[19]

Identifying the patient with pre-existing peripheral arterial lesions:

The goals of the arterial evaluation are to identify an inflow artery that would be capable of delivering adequate blood flow to support the prescribed haemodialysis dose and to identify pre-existing peripheral arterial lesions that may increase the likelihood of vascular complications post-AV access creation. These complications may include the development of acute upper limb ischemia (based on Vascular-Access associated Steal Syndrome or thrombo-embolism), anastomotic pseudo-aneurysm formation and primary failure of the AV access. In patients with multiple risk factors for atherosclerosis, or those where other vascular beds have already been affected by atherosclerosis (cerebrovascular incidents, ischaemic heart disease, peripheral arterial disease of the lower extremities), a thorough peripheral

arterial assessment is warranted to exclude pre-existing atherosclerotic occlusive disease of the upper extremities. The radial artery may be affected and is often heavily calcified in uncontrolled or longstanding Diabetics. Under these circumstances, it is essential to establish the presence of a patent ulnar artery and intact palmar arch. The Allen test is used to evaluate the blood supply of the hand. The presence of an optimally functioning dual circulation to the hand, as represented by the radial and ulnar arteries communicating distally through the superficial and deep palmar arches, is an important safeguard against post-operative hand ischemia.[9] When performed with the aid of a pulse oximeter or DUS, the Allen test has been found to be reliable in 95% to 100% of patients being evaluated for the creation of future haemodialysis access.[22] Asymmetrical or absent pulses on physical exam and / or a discrepancy in non-invasive blood pressure between upper limbs are all indicators of pre-existing upper extremity arterial disease and need to be interrogated further.

Reactive hyperaemia has been described as a measure of the artery's ability to dilate and accommodate the increased blood flow demands of an AV fistula. The reactive hyperaemia test is performed by first obtaining a spectral Doppler waveform of the arterial blood flow and comparing it with the waveform obtained after the patient has clenched his or her fist very tightly for two minutes. The effect is mediated by nitric oxide released from the vascular endothelium. One study reported that the lack of an appropriate reaction to unclenching the fist was significantly associated with an increased rate of primary AV fistula failure.[22]

Numerous studies have investigated the minimum radial artery internal diameter associated with an acceptable primary success rate. According to the 2018 Clinical Practice Guidelines of the European Society for Vascular Surgery, a minimum pre-operative internal diameter of

2.0 millimetres (mm) is recommended to maximise the success of radio-cephalic AV fistula creation.[23]

Identifying the patient with pre-existing peripheral venous lesions:

Detailed evaluation of the venous anatomy is an important aspect of the pre-operative evaluation. The most significant advance in pre-operative evaluation in recent years, have been the validation of pre-operative mapping of peripheral target vessels. No longer should we base the selection of an AV access site on physical examination alone. Specific ultrasonographic evaluations are performed to identify (and avoid) pre-existing venous lesions that may increase the likelihood of primary failure. Phlebitic and stenotic lesions of the cephalic veins are often caused by repeated venepuncture or prolonged cannulation with peripherally inserted venous cannulas and may be subtle on physical examination. Presence of these lesions will almost certainly result in primary failure unless sufficient venous tributaries exist to maintain patency. The minimum venous internal diameter threshold most often used is 2.0 mm at the point of the anastomosis and has been endorsed by the European Society for Vascular Surgery.[23]

Several studies have compared physical examination and ultrasound mapping with physical examination alone and have reported a superior success rate where mapping is performed. The highest quality evidence on the usefulness of pre-operative mapping takes the form of a meta-analysis that included five randomised controlled trials. Primary failure rates were compared in the following 3 groups: clinical examination alone, selective ultrasound and routine ultrasound.[24]

Figure 4: Forest plot depicting the pooled estimate of immediate arteriovenous fistula failure rate in patients that underwent routine pre-operative Doppler ultrasound mapping (US)

versus patients that underwent clinical examination alone. Odds ratio (OR) is shown with 95% confidence intervals (CI). [24]

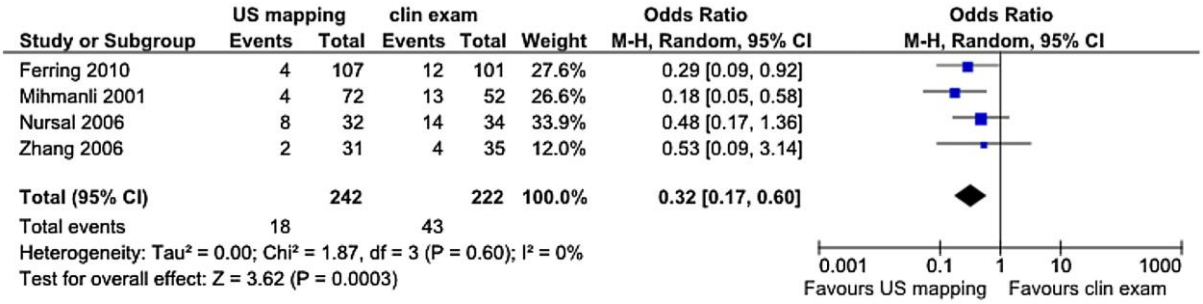
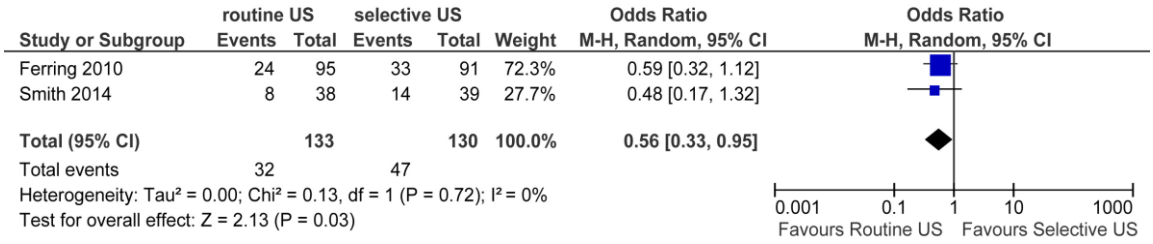


Figure 5: Forest plot depicting the pooled estimate of early/midterm adequacy for haemodialysis and/or maturation in patients that underwent routine pre-operative Doppler ultrasound mapping (US) versus patients that underwent selective US. Odds ratio (OR) is shown with 95% confidence intervals (CI). [24]



The role of pre-operative mapping prior to the creation of a BBAVF:

A prospective study on the role of pre-operative venous and arterial mapping prior to BBAVF creation indicated that a basilic vein diameter of 3.0 mm was associated with a shorter maturation time (21-34 days), compared to 32-92 days if the diameter was less than 3mm. The primary patency at 1-year was 58.9% for patients whose brachial artery flow rates were below 70cm/sec and 93.3% when the flow exceeded 70cm/sec. No minimum arterial internal diameter that would result in an increased likelihood of primary failure could be identified.[25]

REPORTING ON AV ACCESS OUTCOMES:

Despite some inconsistency in the literature, outcomes of peripheral vascular access are predominantly described in terms of 30-day, 1-, 3- and 5- year patency rates. Primary patency is defined as the interval from access creation to the first intervention intended to maintain or re-establish blood flow/reaching a censored event (including transfer to peritoneal dialysis, transplant, loss to follow-up and death). Assisted primary patency refers to the interval from access creation to thrombosis (including intervention /reaching a censored event). Secondary patency refers to the interval from access creation to abandonment of access (including interventions). Other important outcomes measures include the time to cannulation, time to haemodialysis catheter –free dialysis, complications as well as dialysis adequacy.[4]

THE PLACE OF BRACHIO-BASILIC ARTERIO-VENOUS FISTULAE IN THE MODERN HAEMODIALYSIS UNIT:

The order of preference for AV fistula creation, according to the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines, is as follow:[4]

1. Distal radio-cephalic AV fistula
2. Proximal radio-cephalic AV fistula
3. Brachio-cephalic AV fistula
4. Brachio-basilic AV fistula (transposed basilic vein)

In cases where the above options have been exhausted, or where a suitable venous conduit cannot be identified on preoperative mapping, an AV graft may be considered. Compared to patients dialysing through an AVG, those dialysing through a tunnelled haemodialysis catheter have been shown to have a higher risk of mortality (risk ratio 1.38, 95% CI 1.25-1.52), fatal infections (risk ratio 1.49, 95% CI 1.15-1.93) and cardiovascular events (risk ratio 1.26, 95% CI 1.11-1.43).[26] Several prosthetic AV graft options have been described and can

be classified according to the material used (synthetic, biosynthetic, biological), configuration of the conduit (straight, loop) as well as the target vessels used (brachio-axillary, brachio-basilic). The primary failure rates for AVGs are lower than that of native vein AVFs and do not need time to mature (only to incorporate), but graft sepsis and neo-intimal hyperplasia at the graft-vein interface are well known complications of these AV access options.[26]

A meta-analysis of 11 relevant studies (including 1 509 patients with previous failed radio-cephalic and / or brachio-cephalic AVFs) compared outcomes of BBAVFs (in 602 patients) with that of upper limb AVGs (performed in 907 patients).[27] Meta-analysis techniques were applied to identify differences in outcome between the two groups in terms of primary and secondary failure rates at 1 year. The pooled odds' ratio (OR) estimate for the primary failure rate at 1 year was 0.67 (95% CI 0.41–1.09) indicating no significant difference in the outcome between the two groups ($p = 0.11$). The pooled OR estimate for the secondary failure rate at 1 year was 0.88 (95% CI 0.69–1.12) with no significant difference between the two groups ($p = 0.29$). In eight studies that reported the total number of re-interventions, 255 re-interventions in 470 BBAVFs (0.54 per BBAVF) and 922 re-interventions in 694 grafts (1.32 per graft) were reported, respectively. When the BBAVF and upper arm AVG subgroups were compared, the pooled OR estimates for primary and secondary failure rates at 1 year were 0.78 (95% CI 0.43–1.41) and 0.86 (95% CI 0.66–1.11), respectively, indicating no significant difference between the two groups. However, when the BBAVF and *forearm* AVG subgroups were compared, the pooled OR estimates for primary and secondary failure rates at 1 year were calculated as 0.3 (95% CI 0.15–0.58) and 0.75 (95% CI 0.33–1.72), respectively, indicating a significantly increased primary failure rate in the forearm AV graft subgroup ($p = 0.0004$). Therefore, forearm AVGs are viewed as inferior to BBAVFs due to a 3-fold higher risk of failure at 1 year.[27]

ONE-STAGE VERSUS TWO-STAGE BRACHIO-BASILIC ARTERIOVENOUS FISTULA CREATION:

A BBAVF can be created as a one–stage or two-stage procedure. During the one – stage procedure, the basilic vein transposition and brachio-basilic anastomosis are performed at the same operation. As part of the two-stage approach, the brachio-basilic anastomosis is created through a small incision, followed by a variable maturation period. A second operation is then performed to transpose the matured BBAVF. There is no consensus among authors regarding these two methods of constructing a BBAVF, despite one study showing improved patency rates[28] and another showing a lower complication rate[29] with the two-stage approach.

A meta-analysis of one randomised control trial and seven observational studies previously failed to show any difference in patency rates between the one-stage and two-stage procedures.[30] A more recent meta-analysis that included 3 randomised control trials (126 patients), reported that failure of two-stage BBAVFs (3/47, 6.4%) was less likely than failure of one-stage BBAVFs (16/79, 20.3%; risk ratio 0.27; P=0.02).[31] The complication rates of two-stage and one-stage BBAVFs were reported as being similar (risk ratio 0.80; P=0.54). However, on sensitivity analysis these were less likely to occur with two-stage BBAVFs (37% than with one-stage BBAVFs (69%; risk ratio 0.57; P=0.03). Two-stage BBAVFs were less likely to lose their functional secondary patency (21.3%) than one-stage BBVFs (31.6%; risk ratio 0.61; P=0.11). This non-significant trend became significant on sensitivity analysis (risk ratio 0.36; P=0.02).

In summary, there is evidence to suggest that two-stage BBAVFs may achieve higher maturation rates compared to one-stage BBAVFs, but the evidence for a difference in long-term secondary patency is less robust, calling for further research. Most access surgeons will opt for a two-stage procedure when dealing with a small diameter basilic vein. Nevertheless, any advantage of the two-stage procedure needs to be balanced against the 3-6 week (inter-stage) delay as well as the extra cost and inconvenience of a second trip to theatre.

REFERENCES:

1. Stanifer JW, Jing B, Tolan S, et al. The epidemiology of chronic kidney disease in sub-Saharan Africa: a systematic review and meta-analysis [published correction appears in Lancet Glob Health. 2014 May;2(5):266]. Lancet Glob Health. 2014;2(3):e174-e181. doi:10.1016/S2214-109X(14)70002-6
2. Purnell TS, Auguste P, Crews DC, et al. Comparison of life participation activities among adults treated by hemodialysis, peritoneal dialysis, and kidney transplantation: a systematic review. Am J Kidney Dis. 2013;62(5):953-973. doi:10.1053/j.ajkd.2013.03.022
3. http://www.transplant-observatory.org/export-database/
4. Lok CE, Huber TS, Lee T, et al. KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1-S164. https://www.ajkd.org/article/S0272-6386(19)31137-0/pdf
5. Gallieni M, Hollenbeck M, Inston N, et al. Clinical practice guideline on peri- and postoperative care of arteriovenous fistulas and grafts for haemodialysis in adults. Nephrology Dialysis Transplantation 2019; 34(suppl_2): ii1-ii42. doi:10.1093/ndt/gfz072

6. Schmidli J, Widmer MK, Basile C, et al. Editor's Choice – Vascular Access: 2018 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). European Journal of Vascular and Endovascular Surgery, Volume 55, Issue 6, 2018, Pages 757-818, ISSN 1078-5884. doi.org/10.1016/j.ejvs.2018.02.001

7. Al Shakarchi J, Khawaja A, Cassidy D, et al. Efficacy of the Ulnar-Basilic Arteriovenous Fistula for Hemodialysis: A Systematic Review. Annals of Vascular Surgery, 2016;32:1-4. doi.org/10.1016/j.avsg.2015.09.027

8. En I, Tripathi RK. Dialysis access-associated steal syndromes. Semin Vasc Surg. 2016 Dec;29(4):212-226. doi.org/10.1053/j.semvascsurg.2017.04.002

9. Bakri K. Clinical Anatomy and Recipient Vessel Selection in the Upper Extremity. Flaps and Reconstructive Surgery (Second Edition), 12, 89-114.

10. Du Toit T, Manning K, Naidoo NG. Upper limb ischaemia: a South African single-centre experience. Cardiovasc J Afr. 2018 Mar/Apr 23;29(2):88-92. doi.org/10.5830/CVJA-2017-049

11. Al Shakarchi J, Khawaja A, Cassidy D, et al. Efficacy of the Ulnar-Basilic Arteriovenous Fistula for Hemodialysis: A Systematic Review. Ann Vasc Surg. 2016 Apr;32:1-4. doi.org/10.1016/j.avsg.2015.09.027

12. Mousa AY, Dearing DD, Aburahma AF. Radiocephalic fistula: review and update. Ann Vasc Surg. 2013 Apr;27(3):370-8. doi: 10.1016/j.avsg.2012.07.012

13. Roca-Tey R. Permanent arteriovenous fistula or catheter dialysis for heart failure patients. J Vasc Access. 2016 Mar;17 Suppl 1:S23-9. doi: 10.5301/jva.5000511

14. Vigo V, Lisi P, Galgano G, et al. Lancisi's sign and central venous catheter tip position: a case report. J Vasc Access. 2018 Jan;19(1):92-93. doi.org/10.5301/jva.5000760

15. Hernández D, Díaz F, Rufino M, et al. Subclavian vascular access stenosis in dialysis patients: Natural history and risk factors. J Am Soc Nephrol 1998;9(8):1507-1510. PMID: 9697674
16. Forauer AR, Theoharis C. Histologic changes in the human vein wall adjacent to indwelling central venous catheters. J Vasc Interv Radiol 2003;14(9):1163-1168. doi.org/ 10.1097/01.rvi.0000086531.86489.4c
17. Yevzlin AS. Hemodialysis catheter-associated central venous stenosis. Semin Dial 2008;21(6):522-527. doi.org/10.1111/j.1525-139X.2008.00496
18. Salik E, Daftary A, Tal MG. Three-dimensional anatomy of the left central veins: Implications for dialysis catheter placement. J Vasc Interv Radiol 2007;18(3):361-364. doi.org/10.1016/j.jvir.2006.12.721
19. Agarwal AK, Haddad NJ, Khabiri H. How Should Symptomatic Central Vein Stenosis be Managed in Hemodialysis Patients? Semin Dial 2014;27(3):278-81. doi.org/10.1111/sdi.12205
20. Tedla FM, Clerger G, Distant D, et al. Prevalence of Central Vein Stenosis in Patients Referred for Vein Mapping. Clin J Am Soc Nephrol. 2018 Jul 6;13(7):1063-1068. doi:10.2215/CJN.14001217
21. Rad MP, Kazemzadeh GH, Ziaee M, et al. Diagnostic value of color doppler ultrasonography in detecting stenosis and occlusion of central veins in patients with chronic kidney disease. Saudi J Kidney Dis Transpl. 2015 Mar;26(2):279-84. doi: 10.4103/1319-2442.152418
22. Distefano G, Zanoli L, Basile A. Arteriovenous fistula and pre-surgery mapping: Potential role of physical exercise on endothelial function. J Vasc Access. 2019 Nov;20(6):652-658. doi.org/10.1177/1129729819838180

23. Schmidli J, Widmer M, Basile C, et al. Vascular Access: 2018 Clinical Practice Guidelines of the European Society for Vascular Surgery. European Journal of Vascular and Endovascular Surgery 2018;55:757-818. doi.org/10.1016/j.ejvs.2018.02.001
24. Georgiadis GS, Charalampidis DG, Argyriou C, et al. The Necessity for Routine Pre-operative Ultrasound Mapping Before Arteriovenous Fistula Creation: A Meta-analysis. Eur J Vasc Endovasc Surg. 2015 May;49(5):600-5. doi.org/10.1016/j.ejvs.2015.01.012
25. Karakayali FY , Sevmis S, Basaran C , et al. Relationship of Preoperative Venous and Arterial Imaging Findings to Outcomes of Brachio-Basilic Transposition Fistulae for Hemodialysis: a Prospective Clinical Study. Eur J Vasc Endovasc Surg 35(2):208-213(2008). doi:10.1016/j.ejvs.2007.07.026
26. Ravani P, Palmer SC, Oliver MJ, et al. Associations between hemodialysis access type and clinical outcomes: a systematic review. J Am Soc Nephrol. 2013 Feb;24(3):465-73. doi: 10.1681/ASN.2012070643
27. Lazarides MK, Georgiadis GS, Papasideris CP, et al. Transposed brachial-basilic arteriovenous fistulas versus prosthetic upper limb grafts: a meta-analysis. Eur J Vasc Endovasc Surg. 2008 Nov;36(5):597-601. doi.org/10.1016/j.ejvs.2008.07.008
28. Gonzalez E, Kashuk JL, Moore EE, et al. Two-stage brachial-basilic transposition fistula provides superior patency rates for dialysis access in a safety-net population. Surgery. 2010 Oct;148(4):687-94. doi.org/10.1016/j.surg.2010.07.033
29. Kakkos SK, Haddad GK, Weaver MR, et al. Basilic vein transposition: what is the optimal technique? Eur J Vasc Endovasc Surg. 2010 May;39(5):612-9. doi.org/10.1016/j.ejvs.2010.01.006

30. Cooper J, Power AH, DeRose G, et al. Similar failure and patency rates when comparing one- and two-stage basilic vein transposition. J Vasc.2015; 61(3):809 -16. doi.org/10.1016/j.jvs.2014.11.083
31. Kakkos SK, Lampropoulos GC, Nikolakopoulos KM, et al. A Systematic Review and Meta-Analysis of Randomized Trials Comparing Two-Stage with One-Stage Brachio-Basilic Vein Fistulas. Vasc Specialist Int. 2018 Sep;34(3):51-60. doi.org/10.5758/vsi.2018.34.3.51

Part B: MANUSCRIPT IN ARTICLE FORMAT

THE USE OF BRACHIO-BASILIC ARTERIO-VENOUS FISTULAE FOR HAEMODIALYSIS - A SINGLE CENTRE DESCRIPTIVE STUDY

Authors: Kenward Chibuye, Kathryn Manning, Tinus du Toit

Corresponding author: Tinus du Toit

tinus.dutoit@uct.ac.za

Department of Surgery, University of Cape Town

Groote Schuur Hospital, Anzio Road, Observatory, Cape Town, 7925

Tel +27 829289546

Affiliations: Department of Surgery, University of Cape Town, Groote Schuur Hospital, Cape Town, South Africa (KC, KM, TdT)

Author contributions: All authors made a substantial contribution to the conceptualisation, design, analysis and interpretation of data. All authors had the opportunity to approve the final version of the manuscript prior to submission.

Conflicts of interest: None to declare

ABSTRACT:

Aim: To report on our local experience with the use of BBAVFs and to encourage wider local acceptance of the procedure in accordance with international guidelines.

Methods: Retrospective, descriptive study of 41 consecutive haemodialysis patients who underwent brachio-basilic arterio-venous fistula creation. The primary aim of the study was to report on access patency. The secondary aims were to report on functional outcomes and complications.

Results: The primary patency rates at 30 days, 1-and 3-years were 95.1%, 48.8% and 19.5%. Assisted-primary patency rates at 30 days, 1-and 3-years were 100%, 67.7% and 24.3%. Secondary patency rates at 30 days, 1-and 3-years were 100%, 70.3% and 27%.

Conclusion: BBAVFs can successfully be performed in a resource constraint environment by surgeons with limited prior experience with the technique. However, careful monitoring, well-established referral pathways for dysfunctional fistulae and access to surgical or endovascular revision seem to be key factors in ensuring long-term patency.

INTRODUCTION:

An exponential rise in chronic kidney disease (CKD) in Sub-Saharan Africa (SSA) has been projected over the next decade due to the escalating dual burden of communicable and non-communicable diseases.[1] For the majority of patients who have progressed to end-stage kidney disease (ESKD), kidney transplantation will improve survival, decrease cost and

improve quality of life compared to dialysis.[2] However, with a low annual kidney transplant rate of 0.7 per million population (pmp), predominantly limited by a low annual deceased donor rate of 0.1 pmp, most patients with ESKD on the African continent depend heavily on the safe and effective administration of dialysis to achieve long-term survival.[3] Within this context, the implementation of clinical practice guidelines, quality assessment, research and education in the field of dialysis access may be considered even more crucial and relevant than in regions with better access to transplantation.

The goal of vascular access is to provide repetitive and reliable access to the circulation, while minimising complications. Practice guidelines from several international vascular access societies endorse the radio-cephalic AV fistula as the first site of peripheral vascular access creation, followed by the brachio-cephalic AV fistula provided the target vessels are suitable.[4-6] Based on superior outcomes, brachio-basilic arterio-venous fistulae (BBAVF) should be considered above AV grafts, as the third option in peripheral vascular access creation.[4-6] Despite these guidelines, AV grafts are at times performed inappropriately early and may, in some instances, decrease the likelihood of future successful BBAVF creation. The perceived complexity of the BBAVF procedure might be the reason why some access surgeons prefer AV graft creation. By reporting on our local experience with the use of BBAVFs, and by reviewing the technical aspects of this procedure as well as the pitfalls, we anticipate wider local acceptance of this procedure for suitable candidates in accordance with international guidelines.

MATERIALS AND METHODS:

The study was approved by the University of Cape Town's Human Research Ethics Committee (Reference number 794/2017) and included a waiver of informed consent as only anonymised registry data was used to perform the study.

Study design

This is a retrospective, descriptive study of 41 consecutive haemodialysis patients who underwent brachio-basilic arterio-venous fistula creation at Groote Schuur Hospital, from 1 January 2014 to 24 April 2020. The patients were identified from a prospectively maintained operative database and reviewed retrospectively. The primary aim of the study was to report on access patency, including primary, assisted-primary and secondary patency at 30 days, 1 year and 3 years. The secondary aims were to report on functional outcomes and complications with the use of this technique. All patients underwent pre-operative ultrasound assessment to assess the quality and size of the target vessels in keeping with the standard of care. BBAVF were only considered in cases where the superficial veins were not suitable for AVF creation and where both the brachial artery and basilic vein diameters exceeded 2.0 mm. All procedures were performed by transplant surgeons using the same surgical technique.

Definition of outcomes

Primary patency was defined as the interval from access creation to the first intervention intended to maintain or re-establish adequate access flow (intervention-free interval). Assisted primary patency was defined as the interval from access creation to first thrombosis (thrombosis-free interval). Secondary patency was defined as the interval from access creation to access abandonment. Patency rates were censored for the following events: transfer to peritoneal dialysis, transplant, lost to follow-up and death. The last date of patency assessment (end-date) was the 24th of April 2020.

Surgical procedure

Both one-stage and two-stage procedures were performed during the study period. The first stage of the two-stage procedure was performed under local anaesthesia through a 2-3cm longitudinal incision in the region of the distal bicipital groove. An end-to-side anastomosis of the basilic vein to the brachial artery was performed. Four weeks after the first stage

procedure, an ultrasonographic assessment of maturation was performed. Once maturation had been confirmed, the second stage procedure was performed under general anaesthesia. A 12-15cm longitudinal incision was made 1cm posterior to the bicipital groove, limiting the proximal extent of the incision as much as possible. The brachial fascia was incised and the arterialised outflow vein was identified and dissected from its bed by ligation and division of all tributaries up to the point of confluence with the brachial veins, while preserving the medial cutaneous nerve branches to the forearm. The mobilised vein was elevated, divided distally and tunnelled laterally with a gentle curve, followed by an end-to-end re-anastomosis. The one-stage procedure followed the same principles described in the second stage of the two-stage procedure, without the need to divide and re-anastomose the basilic vein, as a direct end-to-side anastomosis of the basilic vein to the brachial artery was performed. Patients were evaluated at 72 hours post-procedure for early complications. Thereafter, cannulation readiness was assessed on a weekly basis through physical examination and duplex ultrasound. Once cannulated, patients were assessed periodically for complications. Dialysis catheters were removed once the BBAVFs were cannulated with 2 needles, for 2 consecutive weeks, without incident.

Indications for intervention

Surveillance of the BBAVFs were not performed. Instead, access was monitored for signs of dysfunction and selectively interrogated with duplex ultrasound as an adjunct to physical examination. Interventions (both open and endovascular) were performed for dysfunctional access. Thrombosed BBAVFs were considered for surgical thrombectomy if referred within 72 hours of thrombosis.

Statistical analysis

Quantitative data were collected and appropriately coded to assist data analysis using Stata/SE version 13.1 (StataCorp®, College Station, Texas). Descriptive statistics were used

to summarise patient characteristics, functional outcomes, complications and patency. The distributions of each variable were explored using histograms for continuous variables and tabulations for categorical variables. Continuous variables were summarised by mean ± standard deviation (if normally distributed) or median with interquartile range (IQR) (if skewed distribution). Categorical outcome variables including functional outcomes, complications and patency were expressed as frequencies and percentages per specified time point. The duration of fistula patency and median fistula survival time were estimated using Kaplan-Meier method and illustrated using Kaplan-Meier survival curves. Survival probabilities at 30 days, 1 year and 3 years were presented with 95% confidence intervals.

RESULTS:

Study population:

From 1 January 2014 to 24 April 2020, a total of 41 brachio-basilic arterio-venous fistulae (BBAVFs) were created and followed up in 41 prevalent haemodialysis patients at our facility.

Demographic data:

The median age of the patients was 45 years (IQR 32-54). Twenty females and 21 males were included in the study. (Table 1)

Baseline characteristics:

The following baseline characteristics were reported at the time of BBAVF creation. The median cumulative days on haemodialysis was calculated as 1 343 (IQR 828-2 920). The median cumulative days with dialysis catheter was calculated as 704 (IQR 348-1 460). All BBAVF procedures were performed in prevalent haemodialysis patients and as such, no pre-emptive BBAVFs were performed. Two patients had not undergone previous attempt at peripheral AV access, with 137 previous attempts made in the remaining 39 patients. Nineteen of the 41 patients (46.3%) had a previous attempt at brachio-axillary AV graft

creation. A pre-existing (failed) ipsilateral brachio-axillary AVG was present in 12 of 41 patients (29.3%) that ultimately underwent BBAVF creation. Of the 41 BBAVFs that were performed, 24 (58.5%) were performed as a one-stage procedure and 17 (41.5%) as a two-stage procedure. Of the 17 first-stage procedures performed, all 17 reached maturity and could either be transposed (n=14) or elevated (n=3) during the second-stage procedure. All first-stage procedures were performed under local anaesthesia, while all other (second-stage and one-stage) procedures were performed under general anaesthesia. (Table 1)

Table 1: Demographic and baseline characteristics of 41 patients that underwent BBAVF.

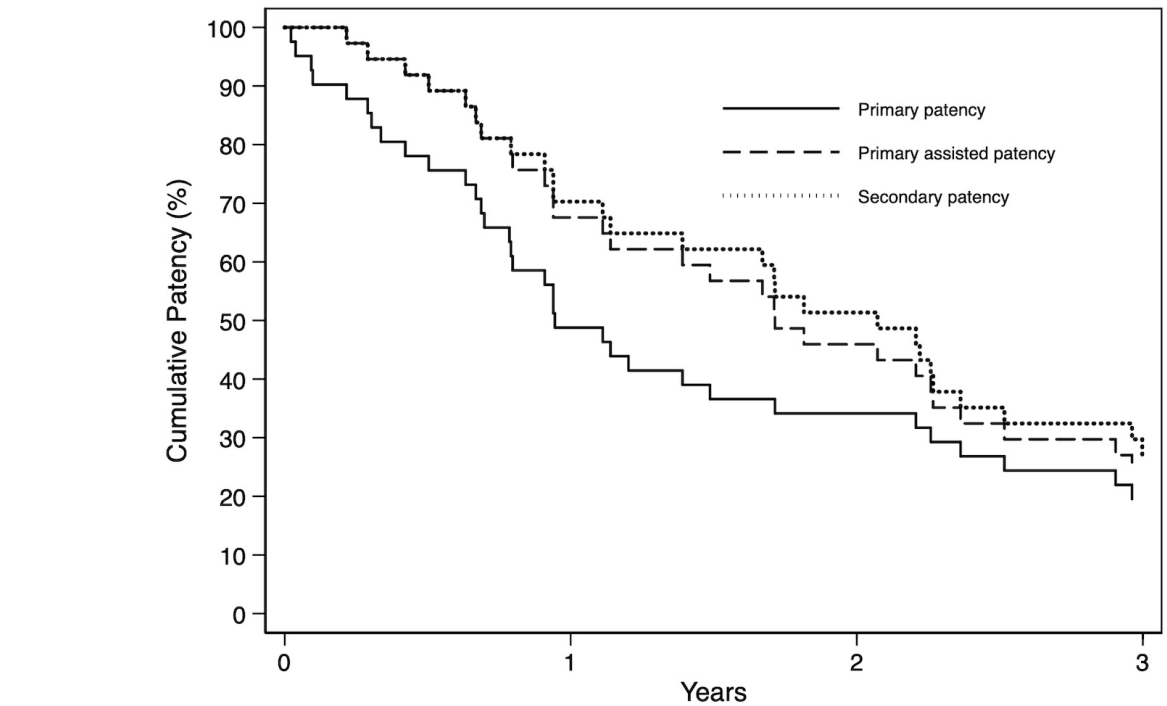
Median age (IQR) in years	45 (32-54)
Male: Female	21:20
Median cumulative haemodialysis days (IQR)	1 343 (828 – 2 920)
Median cumulative haemodialysis catheter days (IQR)	704 (348 – 1 460)
Previous attempts at peripheral AV access 6 5 4 3 2 1 0	 n = 2 (4.9%) n = 7 (17.1%) n = 9 (22%) n = 13 (31.7%) n = 7 (17.1%) n = 1 (2.4%) n = 2 (4.9%)
Previous ipsilateral attempt at BA-AVG	n = 12 (29.3%)
One-stage procedure Two-stage procedure	n = 24 (58.5%) n = 17 (41.5%)

Primary outcome

Patency rates:

The primary patency rates at 30 days, 1-and 3-years were 95.1% (95% CI 81.9-98.8), 48.8% (95% CI 32.9-62.9) and 19.5% (95% CI 9.2-32.7) respectively. Assisted-primary patency rates at 30 days, 1 year and 3 years were 100%, 67.7% (95% CI 50.0-80.1) and 24.3% (95% CI 12.1-38.8) respectively. Secondary patency rates at 30 days, 1 year and 3 years were 100%, 70.3% (95% CI 52.8-82.3) and 27% (95% CI 14.1-41.8) respectively.

Figure 1: Kaplan-Meier analysis of BBAVF patency rates at 1, 2 and 3 years.



Number at risk				
Primary patency	41	20	14	8
Assisted patency	41	25	17	9
Secondary patency	41	26	19	10

Secondary outcomes

Early (30 day) complications:

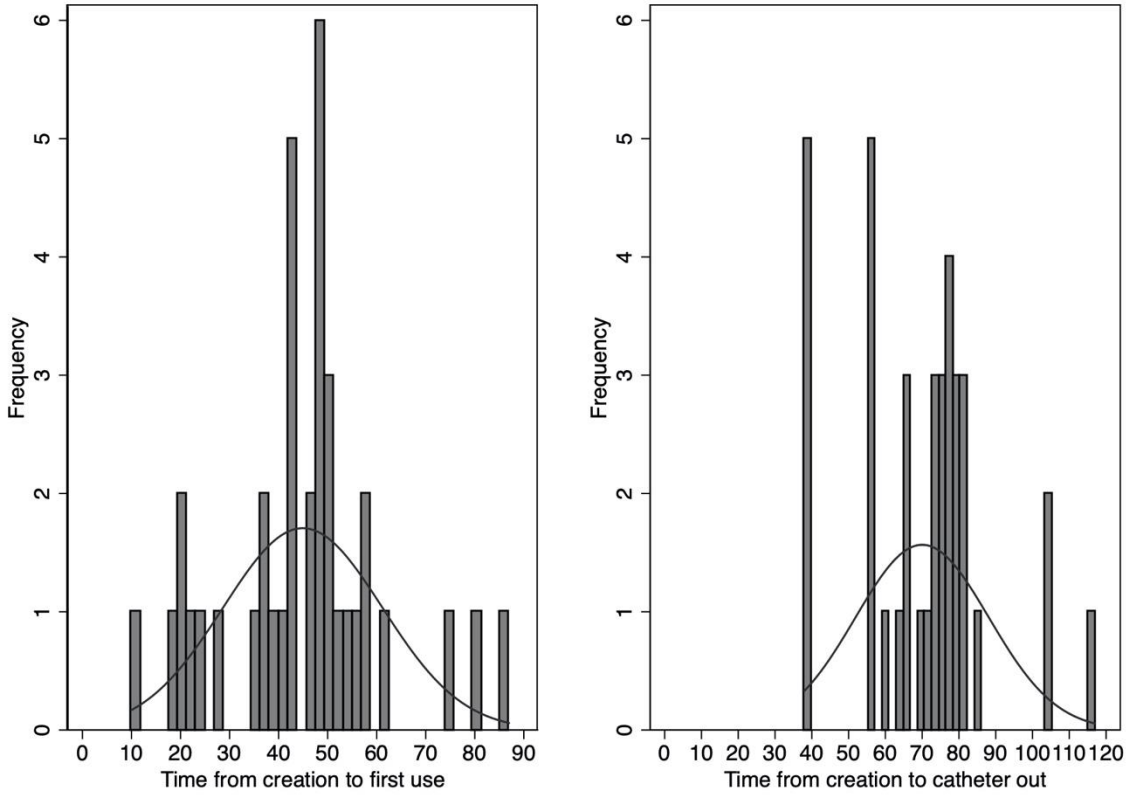
Of the 41 patients that underwent BBAVF creation, 4 (9.8%) presented with minor complications within 30 days. One patient developed minor wound dehiscence that ultimately healed without the need for surgical intervention, possibly due to an element of unrecognised pre-existing central vein stenosis. One patient presented with a wound seroma that resolved spontaneously over time and two patients presented with a sensory neuropraxia of the medial forearm (most likely due to a traction injury to the medial cutaneous nerve to the forearm) that recovered completely by 6 weeks.

Functional outcome:

In 4 of the 41 patients, the BBAVF failed to reach maturation. In the remaining 37 patients, the interval (in days) from creation to first use was documented, as well as the interval from first use to catheter removal. The median interval from creation to use was calculated to be 46 days (IQR 38-51). The median interval from first use to catheter removal was calculated as 25 days (IQR 18-29). The median interval from BBAVF creation to catheter removal, was 73 days (IQR 57-79).

Figure 2: Histograms depicting time (in days) from AVF creation to first use (a) and catheter removal (b).

(a) (b)



DISCUSSION

The clinical scenario where superficial (radio-cephalic, ulnar-basilic and brachio-cephalic) AV fistula sites have been exhausted or where the target vessels have been assessed as unsuitable for AV access creation is not uncommon, particularly in those who have spent years (and often decades) on haemodialysis. Several AV access options have been described to facilitate haemodialysis in this specific subset of patients, potentially negating or delaying the need for tunnelled haemodialysis catheters (THCs) and the complications associated with their use. Clinical practice guidelines from several international vascular access societies have endorsed the use of transposed brachio-basilic AV fistulas above AV grafts (including forearm loop and brachio-axillary grafts) due to superior outcome.[4-6] However, the recently updated NKF-KDOQI guidelines have emphasised the importance of establishing a patient-centred ESKD Life-Plan and have called on clinicians to individualise the selection of access options according to the patient's needs (including life goals and preferences) as well as

dialysis access eligibility (including current medical condition, functional state and life expectancy).[4] Therefore, it may be appropriate for selected patients to be offered a THC as definitive access (life expectancy less than a year, expected living donor transplant within 3 months) and for others to be offered an AV graft (elderly, life expectancy less than 2 years, patient preference). However, for the majority of patients with no superficial AVF option, a transposed brachio-basilic AVF should be considered.

The transposed BBAVF procedure was first described in 1976 as an alternative to translocated autologous vein grafts, prosthetic grafts and heterografts for the purpose of haemodialysis access.[7] As opposed to the superficial veins, the basilic veins are positioned deep to the fascia and are protected from damage due to repeated venepuncture, making it desirable as a haemodialysis conduit. In most patients, the basilic vein is a large and compliant vessel that enables the creation of a technically simple end-to-side anastomosis with the brachial artery. In addition, only one anastomosis is necessary as the anatomic continuity of its venous outflow with the axillary vein is maintained and therefore, a potential area of venous anastomotic stenosis is avoided.

Due to its deep position and relatively close proximity to the neuro-vascular bundle, the basilic vein needs to be transposed to ensure safe and repetitive cannulation. Transposition may be performed as a one-stage or two-stage procedure. The most recent meta-analysis on the topic included 3 randomised control trials (including 126 patients) and reported that failure of two-stage BBAVFs (3/47, 6.4%) were less likely to occur than one-stage BBAVFs (16/79, 20.3%; risk ratio 0.27; P=0.02).[8] Complication rates were similar (risk ratio 0.80; P=0.54), but on sensitivity analysis these were less likely to occur with two-stage BBAVFs (37%) than with one-stage BBAVFs (69%, risk ratio 0.57; P=0.03). Two-stage BBAVFs were less likely to lose their functional secondary patency (21.3%) compared to one-stage BBVFs (31.6%, risk ratio 0.61; P=0.11). This non-significant trend became significant on

sensitivity analysis (risk ratio 0.36; P=0.02). In summary, there is evidence to suggest that two-stage BBAVFs may achieve higher maturation rates compared to one-stage BBAVFs, but the evidence for a difference in long-term secondary patency is less robust, calling for further research.[8] Most access surgeons would opt for a two-stage procedure when dealing with a small diameter (<3mm) basilic vein. A two-stage approach will identify fistulae that were destined to fail, while avoiding the extensive incision associated with one-stage procedures. Nevertheless, any advantage of the two-stage procedure needs to be balanced against the 3-6 week (inter-stage) delay as well as the extra cost and inconvenience of a second trip to theatre.

Transposed BBAVFs, much like other autologous AVFs, are prone to the development of stenosis. The segment of transposed basilic vein, just before its confluence with the brachial vein, is considered a high-risk segment for stenosis, also referred to as the swing segment. In this region, the basilic vein transitions from a superficial and lateral location inside the tunnel to its deeper and more medial native position. Turbulent blood flow as a result of the curvature of the vessel at this point, results in altered shear stress within the segment and the development of stenosis within the swing segment.[9] These lesions need to be identified and treated when causing access dysfunction as they pose a major threat to access circuit patency.

Several variations in surgical technique have been described in the literature, including transposition, elevation and superficialisation of the basilic vein. Currently, no level 1 evidence exist to promote one technique above another. However, in our unit, we try to limit the proximal extent of the incision to allow for easier dissection during open revision of swing segment stenosis or subsequent brachio-axillary AVG creation. The incision is made approximately 1cm posterior to the bicipital groove to avoid scar tissue overlying the AVF

when a simple elevation / superficialisation technique is performed. The confluence of the basilic and brachial vein is preserved where possible and a gradual transition from tunnel to native position is ensured by performing a relatively conservative transposition or simple elevation of the basilic vein.

In patients with no further superficial AVF option available, the creation of a prosthetic AV graft has some advantages over BBAVFs. Generally speaking, they are technically easier to create, especially in obese patients and can be punctured earlier than BBAVFs. Some authors have promoted the use of forearm prosthetic loop grafts above BBAVFs, as maturation of the basilic vein (when used as the outflow vein) may facilitate secondary BBAVF creation after graft failure.[10] However, when AV grafts become dysfunctional or fail, it is often due to severe neo-intimal hyperplasia at the graft-vein interface. Therefore, maintenance or salvage procedures (open surgical and endovascular) aimed at addressing these stenoses may encroach on the basilic vein and compromise future ipsilateral BBAVF creation. Graft-vein interface stenoses are notoriously resistant to percutaneous transluminal angioplasty alone and stent-graft deployment is needed to achieve acceptable lesion patency, potentially resulting in the loss of the ipsilateral BBAVF option in cases where AV grafts were performed inappropriately early.

BBAVFs have several advantages over AV grafts, including a lower risk of infection and thrombosis. A meta-analysis comparing 1-year primary and secondary failure rates of BBAVFs versus prosthetic AV grafts (OR = 0.67 CI 0.41–1.09 and OR = 0.88 CI 0.69–1.12, respectively) indicated no difference in the outcome between the two groups.[11] However, there was a higher re-intervention rate for AV grafts (0.54 per BBAVF versus 1.32 per graft). In a subgroup analysis including two studies, forearm grafts had a 3-fold increased risk of

failure at 1 year compared to BBAVFs (OR = 0.3, $p < 0.0004$). A direct cost-comparison between AVGs and BBAVFs has not yet been performed. However, in a North American cohort, the average access-related monthly cost associated with AVGs were significantly higher than that of AVFs (USD 2 656 and USD 1699 respectively).[12]

In our series, the primary patency rates at 30 days, 1 year and 3 years were 95.1%, 48.8 and 19.5% respectively. Assisted-primary patency rates at 30 days, 1 year and 3 years were 100%, 67.7% and 24.3% respectively. Secondary patency rates at 30 days, 1 year and 3 years were 100%, 70.3% and 27% respectively. Notably, the 3-year patency rates achieved were relatively modest, possibly due to the low number of procedures performed to maintain (9 procedures) or re-establish (3 procedures) adequate access flow. Fistula performance were monitored by nephrology nurses and nephrologists working in the dialysis units and were referred for revision in case of dysfunction or thrombosis. However, surgeon availability, failure to timeously refer dysfunctional BBAVFs, late referral of thrombosed BBAVFs and suboptimal access to elective / emergency theatre and interventional suite were some of the factors that contributed to the relatively low re-intervention rate in the author's opinion. The importance of vigilant access monitoring has been emphasised in the literature, as up to 70% of BBAVFs may need an intervention by 18 months to maintain patency.[8]

When considering the above patency rates, one has to be cognisant of the fact that, despite a relatively low median age of 45 years, many of the patients had been receiving haemodialysis for a long time, with the median cumulative haemodialysis days at the time of BBAVF creation calculated at 1 343 (IQR 828-2 920). In addition, the median cumulative dialysis catheter days were calculated at 704 (IQR 348-1 460). Both dialysis vintage and dialysis

catheter days have been reported to increase primary failure rate and decrease AV access patency rates.[13]

The BBAVF procedure had not been frequently performed in our unit prior to the study period, with brachio-axillary AV grafts preferred in patients with no superficial AVF option. Consequently, 19 of the 41 patients (46.3%) had a previous attempt at brachio-axillary AV graft creation. A pre-existing (failed) ipsilateral brachio-axillary AVG was present in 12 of 41 patients that ultimately underwent BBAVF creation. Importantly, none of the grafts had undergone revision surgery or interventional procedures at the graft-vein interface. Axillary vein occlusion or high-grade stenosis were excluded with pre-operative duplex ultrasound in all 12 patients prior to BBAVF creation. In this subgroup, 6 BBAVFs were performed as a one-stage procedure, of which 2 failed to mature. Six were performed as a two-stage procedure, with all 6 reaching maturation.

Overall, 24 BBAVFs (58.5%) were performed as a one-stage procedure and 17 (41.5%) as a two-stage procedure. Maturation failure occurred in 4 of the 41 patients (9.8%), all of which were performed as one-stage procedures. Therefore, the maturation failure rate with the one-stage procedure in our series was 16.7%, as opposed to 0% with the two-stage procedure. However, 24 of the first 27 BBAVFs in our series were performed as one-stage procedures and the impact of a learning curve may, in part, contribute to the disproportionately high rate of maturation failure observed with the one-stage procedure in our study.

The study reports on a real-world experience with the use of BBAVFs in a resource constrained environment and provides long-term patency data. We acknowledge that the sample size is small thus results should be interpreted with caution. Despite the retrospective and single centre nature of the study, we believe that the study supports the safety and

feasibility of BBAVF creation and use in accordance with international clinical practice guidelines.

CONCLUSION:

This study indicates that BBAVFs can successfully be performed in a resource constraint environment by surgeons with limited prior experience with the technique. However, careful monitoring, well-established referral pathways for dysfunctional fistulae and access to surgical or endovascular revision seem to be key factors in ensuring long-term patency.

REFERENCES:

1. Stanifer JW, Jing B, Tolan S, et al. The epidemiology of chronic kidney disease in sub-Saharan Africa: a systematic review and meta-analysis [published correction appears in Lancet Glob Health. 2014 May;2(5):266]. Lancet Glob Health. 2014;2(3):e174-e181. https://doi:10.1016/S2214-109X(14)70002-6
2. Purnell TS, Auguste P, Crews DC, et al. Comparison of life participation activities among adults treated by hemodialysis, peritoneal dialysis, and kidney transplantation: a systematic review. Am J Kidney Dis. 2013;62(5):953-973. https://doi:10.1053/j.ajkd.2013.03.022
3. http://www.transplant-observatory.org/export-database/
4. Lok CE, Huber TS, Lee T, et al. KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. Am J Kidney Dis. 2020;75(4)(suppl 2):S1-S164. https://www.ajkd.org/article/S0272-6386(19)31137-0/pdf
5. Maurizio Gallieni, Markus Hollenbeck, Nicholas Inston, et al. Clinical practice guideline on peri- and postoperative care of arteriovenous fistulas and grafts for

haemodialysis in adults. Nephrology Dialysis Transplantation 2019; 34(suppl_2): ii1-ii42. https://doi:10.1093/ndt/gfz072

6. Jürg Schmidli, Matthias K. Widmer, Carlo Basile, et al. Editor's Choice – Vascular Access: 2018 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). European Journal of Vascular and Endovascular Surgery, Volume 55, Issue 6, 2018, Pages 757-818, ISSN 1078-5884, https://doi.org/10.1016/j.ejvs.2018.02.001
7. Dagher FJ, Gelber RL, Ramos EJ, et al. Basilic vein to brachial artery fistula: a new access for chronic hemodialysis. *South Med J*. 1976;69(11):1438-1440. https://doi:10.1097/00007611-197611000-00013
8. Kakkos SK, Kouri AK, Tsolakis IA, Haddad GK, Lampropoulos GC, Karnabatidis D. Surgical and endovascular revision of brachio-basilic vein fistula. J Vasc Access. 2016 Mar;17 Suppl 1:S6-11. https//:doi: 10.5301/jva.5000516.
9. Lee Y, Song D, Kim MJ, et al. Upper Arm Basilic Vein Transposition for Hemodialysis: A Single Center Study for 300 Cases. Vasc Specialist Int. 2016 Jun;32(2):51-6. https//:doi: 10.5758/vsi.2016.32.2.51.
10. Chue KM, Thant KZ, Luo HD, Soh YH, Ho P. Comprehensive Comparison of the Performance of Autogenous Brachial-Basilic Transposition Arteriovenous Fistula and Prosthetic Forearm Loop Arteriovenous Graft in a Multiethnic Asian Hemodialysis Population. Biomed Res Int. 2016;2016:8693278. htpps//:doi: 10.1155/2016/8693278.
11. Lazarides MK, Georgiadis GS, Papasideris CP, et al. Transposed brachial-basilic arteriovenous fistulas versus prosthetic upper limb grafts: a meta-analysis. Eur J Vasc Endovasc Surg. 2008 Nov;36(5):597-601. https//:doi: 10.1016/j.ejvs.2008.07.008

12. Nordyke RJ, Reichert H, Bylsma L, et al. Costs Attributable to Arteriovenous Fistula and Arteriovenous Graft Placements in Hemodialysis Patients with Medicare coverage. Am J Nephrol 2019;50:320-328. https//:doi: 10.1159/000502507
13. Woodside KJ, Bell S, Mukhopadhyay P, et al. Arteriovenous Fistula Maturation in Prevalent Hemodialysis Patients in the United States: A National Study. Am J Kidney Dis. 2018 Jun;71(6):793-801. https//:doi: 10.1053/j.ajkd.2017.11.020

Part C: ADDENDA

TARGET JOURNAL INFORMATION AND INSTRUCTIONS TO AUTHORS:

The **Cardiovascular Journal of Africa** is pleased to consider original articles, reviews, discussions on topical issues, case studies, meeting reports and other contributions relevant to the understanding, treatment and care of vascular disease.

Original articles and reviews are sent for independent peer-review. Material is accepted for publication on the understanding that it has not been published elsewhere. Authors will be asked to confirm this in writing and transfer copyright to the Journal.

Guidelines for Authors and Readers of the CVJA

The Cardiovascular Journal of Africa (CVJA), which incorporates the Cardiovascular Journal of South Africa, is particularly concerned with publication of scientific articles related to Cardiac and Vascular conditions and situations, concerning adults and children, in Sub Saharan Africa. But will accept articles from all parts of the world.

ARTICLE SUBMISSION

All submissions should be written in a clear and succinct manner, following the style of the Journal. Title page should include a descriptive title; authors' surname and forename, address of each author and full address, telephone, fax and e-mail contacts for the corresponding author. In text: tables and figures are either inserted as part of sentence, for example Table 1, or in parentheses, for example (Fig. 1). Each table should carry a descriptive heading.

All images MUST be at or above intended display size, with the following image resolutions: Line Art 800 dpi, Combination (Line Art + Halftone) 600 dpi, Halftone 300 dpi Image files also must be cropped as close to the actual image as possible.

References numbered in the order of appearance in the text, according to Vancouver style. For articles: Author AB, Author C, Author M. The title of the article. Abbreviated journal title 1999; 14: 172–183. For book chapters: Author AB, Author CD. The title of the chapter. In: Editor A, Editor BC, ed. Title of the book, 2nd edn. Location: Publisher, 1999: 133 –139. DOI Numbers / PMID (Pubmed ID / PMC ID) must be added to all references to facilitate tagging for PubMed Central.

Original articles: Title page as above. Abstract (150 words) a short inclusive statement suitable for direct electronic abstracting, identifying the purpose of the study, key methods, the main results and the main conclusion. Keywords: maximum of six keywords for indexing. Introduction: concise description of background, sufficient for the non-specialist to appreciate the context of the work. Clear statement of the purpose of the study. Methods: a brief description of study design, procedures, analytical techniques and statistical evaluation. Results: a clear account of the study findings using quantitative language where possible and cross-referenced to tables

and figures. Discussion: an interpretation of the study placed within the context of current knowledge, leading to specific conclusions where possible. Acknowledgements. References, figures and tables as above.

Submitted manuscripts must be supplied with a covering letter with any additional information that may be helpful to the editor, such as the type or format of article that the manuscript represents. If the manuscript has been submitted previously to another journal, it is helpful to include the previous editor's and reviewers' comments with the submitted manuscript, along with the authors' responses to those comments. Copies of any permission to reproduce published material, to use illustrations or report information about identifiable people, or to name people for their contributions must accompany the manuscript.

Material submitted for publication in the Cardiovascular Journal of Africa is accepted on condition that it has not been published elsewhere. The management reserves the copyright of the articles published. Aspects of cardiovascular medicine related to Sub-Saharan Africa will be encouraged.

RESEARCH PROTOCOL:

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA · UNIVERSITEIT VAN KAAPSTAD

Department of Surgery Research Committee
Fast Track Protocol Pro forma

Protocol Title:

Early results with the use of brachio-basilic arterio-venous fistulae for haemodialysis: A descriptive study

Principal Investigator:

Name	Surname	email
Kenward	Chibuye	kewadolar@yahoo.com

Co-Investigators:

Name	Surname	email
Tinus	Du Toit	dutoitjm@yahoo.com

Introduction (300-800 Words):

In South Africa, approximately 2 500 patients with End-Stage Renal Disease are awaiting renal transplantation. Unfortunately, South Africa has one of the lowest deceased organ donor rates in the world (1.4 donors per million population). Living donor renal transplantation at our institution, has not been able to bridge the gap between organ supply and demand. Renal Replacement Therapy (RRT) in the form of chronic dialysis, is the only hope of long-term survival for these patients, who commonly spend between 3 and 6 years on the program before being transplanted. However, chronic haemodialysis is associated with a cumulative mortality rate of 3-5% per year, predominantly as a result of vascular access complications. Therefore, optimal vascular access management, according to international guidelines, is essential in ameliorating the mortality rate associated with chronic haemodialysis.

The goal of vascular access is to provide repetitive and reliable access to the circulation, while minimizing complications. Several access options have been described in the literature. Compared to arterio-venous access (including fistulas and grafts), chronic vascular access catheters have been consistently associated with worse complication and patient survival rates. The Kidney Disease Outcomes Quality Initiatives (K/DOQI) guidelines on vascular access recommend that catheters should be used in less than 10% of prevalent haemodialysis patients who do not have a contra-indication to arterio-venous access formation. Arterio-venous fistulae (a deliberate, surgically created connection between native artery and vein) are recommended above arterio-venous grafts, as mature fistulae result in lower morbidity, mortality, need for intervention as well as superior long-term patency compared to grafts.

Both Canadian and American guidelines prefer the radiocephalic AV fistula as the first choice for peripheral vascular access creation, followed by the brachiocephalic fistula. These are referred to as simple fistulae, as the native vessels are left undisturbed in their normal anatomical position. According to the guidelines, based on superior outcomes, brachio-basilic arterio-venous fistulae (BB-AVFs) should be considered above arterio-venous graft, as the third option in peripheral vascular access creation. Despite these guidelines, arterio-venous grafts are commonly performed inappropriately early, decreasing the likelihood of future successful BB-AVF creation.

Outcomes of peripheral vascular access are predominantly described in terms of patency

rates. Primary patency is defined as the interval from access creation to the first intervention intended to maintain or re-establish blood flow / reaching a censored event. Assisted primary patency refers to the interval from access creation to thrombosis (including interventions) / reaching a censored event. Secondary patency refers to the interval from access creation to abandonment of access (including interventions). By including a "functionality" modifier into the above definitions at the time of the first dialysis session, the clinical usefulness of access can be determined (functional patency).

Current literature clearly supports the creation of BB-AVFs over arterio-venous grafts. The best evidence currently available takes the form of a randomized multicenter study (n=105) comparing outcomes from BB-AVFs versus arterio-venous grafts. Significantly better primary and assisted-primary patency were observed in the BB-AVF group, with fewer interventions needed to maintain / re-establish patency. However, the perceived complexity of the BB-AVF procedure might be the reason why some surgeons still prefer arterio-venous grafts formation as the third peripheral vascular access option. By reporting on our local experience with the use of BB-AVFs, and by reviewing the technical aspects of this procedure, we anticipate wider local acceptance of this procedure, in accordance with international guidelines.

Research Question/ Primary Aim:

To report on access patency, including:

- Primary patency (calculated at 30 days, 1 year and 3 years)
- Assisted-primary patency (calculated at 30 days, 1 year and 3 years)
- Secondary patency (calculated at 30 days, 1 year and 3 years)

Secondary Aims:

To report on functional outcomes with the use of this technique, including:

- Time to cannulation
- Time to haemodialysis catheter-free dialysis
- Dialysis adequacy (Kt/v and URR) in those BB-AVFs that are still functional

To report on complications, including

- Immediate (within 72 hours)
- Early (within 30 days)
- Late (after 30 days)

Study Design:

This is a descriptive study of patency, functional outcomes and complications in haemodialysis patients at Groote Schuur Hospital who underwent a brachio-basilic arterio-venous fistula (including one and two stage) procedure

Source of Data

i.e. Patient Folder review or Registry database (if a registry please provide HREC number)

Retrospective patient folder review

Dates of data collection:

Please be specific, i.e. 1 Jan 2016 to 31 Dec 2016

1 January 2014 to 31 December 2017

Justification for chosen timeline:

Please provide a reason for dates of data collection
i.e. Start date was when database was implemented, numbers needed to fulfil sample size calculation or previously reported studies have used this timeframe.

We first started performing this procedure with regularity from January 2014. Patency data (our primary objective) in the literature is reported at 1, 3 and 5 years.

Inclusion Criteria:

All haemodialysis patients at Groote Schuur Hospital who underwent a brachio-basilic arterio-venous fistula (including one and two stage) procedure during the study period.

Exclusion Criteria:

These should not be the opposite of the inclusion criteria, but exclusions from the inclusion criteria

Nil

Statistical Analysis:

This should also be completed for a descriptive audit.
I.e. Data will be described in means and standard deviations for normally distributed data and medians and confidence intervals for non-parametric data

Descriptive statistics will be used to summarise sample characteristics, patency, outcomes and complications. The distributions of each variable will be explored using histograms for continuous variables and tabulations for categorical variables. Continuous variables will be summarized by mean ± standard deviation (if normally distributed) or median with interquartile range (IQR) (if skewed distribution). Categorical outcome variables including patency, functional outcomes and complications, will be expressed as frequencies and percentages per specified time point. The duration of fistula patency and median fistula survival time will be estimated using Kaplan-Meier method and illustrated using Kaplan-Meier survival curves. Survival probabilities at 30 days, 1 year and 3 years will be presented with 95% confidence intervals.

Sample Size analysis / Power calculation:
This is required when Primary aim compares two or more groups

A sample size justification is not considered applicable for this study since it is primarily descriptive and is not hypothesis-driven.

Privacy and confidentiality:

Project Timeline:

This project will be enrolled as a MMed degree through the Division of General Surgery. Department of Surgery Research Committee – Fast track Research proposal submission by the end of October 2017. Human Research Ethics Committee application once DRC approval has been obtained – expected by the end of November 2017. The retrospective data collection phase should not take longer than 6 months. Expected time of Publication – September 2018.

Budget:

If Applicable

Nil

Dissemination of data:

i.e. Conference presentation, Publication, Degree

This study will be submitted for the degree: MMed through the Division of General Surgery. The results from this study will be presented at: - General Surgical colleagues at our Division of General Surgery Academic meeting - The VASSA Congress 2019 Journal publication: Target journal - South African Journal of Surgery.

UNIVERSITY OF CAPE TOWN

Department of Surgery
Departmental Research Committee
Dr Timothy Pennel
D24 Office, Groote Schuur Hospital
Observatory 7925
South Africa
Tel (021) 404 3430
Email tim.pennel@uct.ac.za

12 Oct 2017

Dr. K Chibuye

Department of Surgery
University of Cape Town

Dear Dr. Chibuye

RE: Project 2017/112

PROJECT TITLE: Early Results With The Use Of Brachio-Basilic Arterio-Venous Fistulae For Haemodialysis – A Descriptive Study

The above protocol has been reviewed by the Department of Surgery Research Committee. I am pleased to inform you that the committee approved the scientific merit of the study, and endorse the protocol for submission to the relevant ethics committee.

Although this letter serves as confirmation that the above protocol has successfully passed through the surgical DRC, respective ethics committees still require DRC chair signature before submission.

Please use the above project number in all future correspondence,

Yours sincerely

Signature Removed

DR TIMOTHY PENNEL
CHAIRMAN: RESEARCH COMMITTEE

DATA CAPTURE INSTRUMENTS:

Demographic info
Age (years) at time of index BBAVF procedure
Gender

Vascular access history: baseline characteristics at BB-AVF creation
Haemodialysis days at the time of first BBAVF creation
Cumulative haemodialysis catheter days at the time of first BBAVF creation
Number of previous attempts at peripheral vascular access at time of index BBAVF creation (specify sites) – specifically, ipsilateral BA-AVG creations

Indication for BBAVF
Simple sites exhausted
Duplex features prohibiting AVF at simple site

Technical / operative aspects
GA / Locoregional
One / Two stage procedure
If two: Superficialized / Transposed
Time to second procedure (inter-stage period) in days

Patency rates and functional outcome measures
Day of BB-AVFcreation
Day first used for haemodialysis (*Time to cann*ulation)
Day of haemodialysis catheter removal (*Time to haemodialysis catheter free dialysis*)
Day of first intervention (censored for transfer to PD / transplant / loss to follow-up / death) (*Primary patency*)
Day of first thrombosis (censored for transfer to PD / transplant / loss to follow-up / death) (*Assisted primary patency*)
Day of access abandonment (*Secondary patency*)
End-date 04-06-2018 (date of last assessment)

Complications
Early (within 72 hours)
Intermediate (prior to 30 days)
Late (after 30 days)

Thrombotic
Non-thrombotic
Wound complication (sepsis/seroma/haematoma)
Steal syndrome
Acute limb ischaemia
High output cardiac failure
Aneurysm (specify anastomotic or needling segment)

HREC APPROVAL LETTER:

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 404 7682
Email: nosi.tsama@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

16 November 2017

HREC REF: 794/2017

Dr JM Du Toit
General Surgery
Transplant Unit

Dear Dr Du Toit

PROJECT TITLE: EARLY RESULTS WITH THE USE OF BRACHIO-BASILIC ARTERIO-VENOUS FISTULAE FOR HEMODIALYSIS- A DESCRIPTIVE STUDY-(MMeD candidate-Dr K Chibuye)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th November 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student Dr K Chibuye will be involved in this study.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 794/2017