DIAGNOSTIC CORONARY ANGIOGRAPHY ACCESS IN JOHANNESBURG

Khulasande Liso Sifiso Ntaka, MBChB (UKZN), FCP(SA)

Student number: 2301770

Supervisor: Professor Nqoba Tsabedze, MBBCh, FCP (SA), Cert Cardiology (SA), MMed (Int Med), FESC

Supervisor: Dr Thomas Kalk, MBBCh, FCP (SA), Cert Cardiology (SA)

Supervisor: Dr Dineo Mpanya, MBChB, FCNP (SA), MMed (Nucl. Med), PhD (Wits)

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in fulfillment of the requirements for the degree of Master of Medicine.

Johannesburg, 2023

DECLARATION

Student's contribution to the article and agreement of co-authors

I, Khulasande Liso Sifiso Ntaka, student number 2301770, declare that this research report is my work and that I contributed adequately towards the research findings in the article stated below, which is included in my research report.

Signature of Student: _____ Date: 25/10/2023

Name of Primary Supervisor: Professor Nqoba Tsabedze

Signature of Primary Supervisor: _____ Date: 30 October 2023

Agreement by co-authors: By signing this declaration, the co-authors listed below agree to the use of the article by the student as part of the research report.

Title: Diagnostic coronary angiography access in Johannesburg

Submitted to the Journal of the Society for Cardiovascular Angiography & Interventions

Author	Name	Signature	Date
1	Khulasande Ntaka		25/10/2023
2	Thomas Kalk		31/10/2023
3	Dineo Mpanya		30/10/2023
4	Nqoba Tsabedze		30/10/2023

DEDICATION

To my beautiful wife, Zola.

Thank you for your abundant patience,

Understanding and support.

ACKNOWLEDGEMENTS

Thank you to all my supervisors for your invaluable guidance and patience. Thank you to all the Charlotte Maxeke Johannesburg Academic Hospital staff who assisted me with retrieving all the necessary documents.

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JOURNAL OF THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY & INTERVENTIONS

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DESCRIPTION

JSCAI is a peer-reviewed, international, Gold Open Access journal covering the broad field of cardiovascular diseases. *JSCAI* aims to be a highly credible and well-balanced reference that highlights practical techniques and pathways of care and delivers high impact scientific contributions drawn from clinicians and colleagues in interventional cardiology. *JSCAI* publishes original research, editorials, study designs, reviews, meta-analyses, imaging and case reports, and research letters. The subject matter includes all interventional subspecialities including coronary, peripheral, structural, and congenital heart disease

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INTRODUCTION

JSCAI is a peer-reviewed, international, Gold Open Access journal covering the broad field of cardiovascular diseases. JSCAI aims to be a highly credible and well-balanced reference that highlights practical techniques and pathways of care and delivers high impact scientific contributions drawn from clinicians and colleagues in interventional cardiology. JSCAI publishes original research, editorials, study designs, reviews, meta-analyses, imaging and case reports, and research letters. The subject matter includes all interventional subspecialities including coronary, peripheral, structural, and congenital heart disease.

JSCAI is indexed by DOAJ.

Types of articles

1 **Submission type Word Limit Abstract Style Central Illustration Table/Figure Limit Reference Limit** Original research 4500* Structured Yes — — Study design 3500* Structured Yes — — Comprehensive review 8000* Unstructured Yes — — Meta-analyses 8000* Structured Yes — — Editorials (by invitation) 1000 — No 1 total 10 Imaging and Case Reports 1000 — No 1 total 5 Research letters 1000 — No 1 total 5 Letters to the editor 400 — No 1 total 5 Pearls in hemodynamics 500 — No 1 total 5 *Introduction through conclusion, references, figure legends

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The editors will consider clinically relevant original research articles for publication. Additionally, submissions of innovative first-in-human experiences, experiences describing innovative uses of existing devices in new indications, and case series of these experiences may be considered in select situations.

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Submissions provide brief vignettes of unique or important fundamental hemodynamic teaching points. Drs. Larry Dean and Morton Kern, who edit this section, hope to expand on these concepts with case studies that further amplify the understanding of invasive hemodynamics. Submissions of illustrative case examples are encouraged.

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Letters to the editor in *JSCAI* should focus on a specific research manuscript that has been published in *JSCAI*. Letters must be submitted within 4 weeks of the posted date of the article. The editors will seek a reply from the authors of the original paper and publish the letter and the reply together. *JSCAI* will only consider letters submitted about original research articles and will not accept letters about review articles, editorials, or any other submissions, including guidelines.

Contact details for submission

Editor-in-Chief: Alexandra J. Lansky, MD
Executive Editor: Dominic P. Francese

JSCAI
Yale School of Medicine
Section of Cardiovascular Medicine
New Haven, CT 06510
E-mail: JSCAI@yale.edu

Reporting sex- and gender-based analyses

Reporting guidance

For research involving or pertaining to humans, animals or eukaryotic cells, investigators should integrate sex and gender-based analyses (SGBA) into their research design according to funder/ sponsor requirements and best practices within a field. Authors should address the sex and/or gender dimensions of their research in their article. In cases where they cannot, they should discuss this as a limitation to their research's generalizability. Importantly, authors should explicitly state what definitions of sex and/or gender they are applying to enhance the precision, rigor and reproducibility of their research and to avoid ambiguity or conflation of terms and the constructs to which they refer (see Definitions section below). Authors can refer to the Sex and Gender Equity in Research (SAGER) guidelines and the SAGER guidelines checklist. These offer systematic approaches to the use

and editorial review of sex and gender information in study design, data analysis, outcome reporting and research interpretation - however, please note there is no single, universally agreed-upon set of guidelines for defining sex and gender.

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Divide your article into clearly defined sections. Each subsection is given a brief heading. Each heading should appear on its own separate line. Subsections should be used as much as possible when cross-referencing text: refer to the subsection by heading as opposed to simply 'the text'.

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Results
Results should be clear and concise.

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The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

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Essential title page information

Title. Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible. Titles should be no more than 15 words. ***Author names and affiliations.*** Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. You can add your name between parentheses in your own script behind the English transliteration. Present the authors' affiliation addresses (where the actual work was done), including city, state/province (if applicable), and country, below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate address. ***Word count.*** Word count includes the introduction through conclusion, the references, and figure legends. ***Corresponding author.*** Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. This responsibility includes answering any future queries about Methodology and Materials. **Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.** ***Declaration of Interests.*** All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. ***Present/ permanent address.*** If an author has moved since the work described in the article was done, or was visiting at the time, a 'Present address' (or 'Permanent address') may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

Highlights

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Acknowledgements

Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

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Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

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Bar graphs

To present frequency data (numbers or percentages). Each bar represents a category. The scale on the frequency axis should begin at 0, and the axis should not be broken. If the data plotted are a percentage or rate, error bars may be used to show statistical variability.

Line graph

To demonstrate the relationship between 2 or more quantitative variables, such as changes over time. The dependent variable appears on the vertical axis (y) and the independent variable on the horizontal axis (x); the axes should be continuous, not broken.

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Survival plot

To display the proportion or percentage of individuals (represented on the y-axis) remaining free of or experiencing a specific outcome over time (represented on the x-axis). The curve should be drawn as a step function (not smoothed). The number of individuals followed-up for each time interval (number at risk) should be shown underneath the x-axis.

Box and whisker plot

To show data distribution from 1 or more groups, particularly aggregate/summary data. Each element should be described (the ends of the boxes, the middle line, and the whiskers). Data points that fall beyond the whiskers are typically shown as circles.
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To illustrate summary data, particularly in meta-analyses and systematic reviews. The data are presented both tabularly and graphically. The sources (with years and citations, when relevant) should comprise the first column. Provide indicators of both directions of results at the top or bottom of the plot on either side of the vertical line (eg, favors intervention). Typically, proportionally sized boxes represent the weight of each study, and a diamond shows the overall effect at the bottom of the plot.
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To display quantitative data other than counts or frequencies on a single scaled axis according to categories on a baseline (horizontal or vertical). Point estimates are represented by discrete data markers, preferably with error bars (in both directions) to designate variability.
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To show individual data points plotted according to coordinate values with continuous, quantitative x- and y-axis scales. A curve that is generated mathematically may be fitted to the data to summarize the relationship among the variables.
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References

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List: Number the references in the list in the order in which they appear in the text.
Examples:
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1. Van der Geer J, Hanraads JAJ, Lupton RA. The art of writing a scientific article. *J Sci Commun.* 2010;163:51–59. https://doi.org/10.1016/j.Sc.2010.00372
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2. Van der Geer J, Hanraads JAJ, Lupton RA. The art of writing a scientific article. *Heliyon.* 2018;19:e00205. https://doi.org/10.1016/j.heliyon.2018.e00205
Reference to a book:
3. Strunk W Jr, White EB. *The Elements of Style.* 4th ed. New York, NY: Longman; 2000.
Reference to a chapter in an edited book:
4. Mettam GR, Adams LB. How to prepare an electronic version of your article. In: Jones BS, Smith RZ, eds. *Introduction to the Electronic Age.* New York, NY: E-Publishing Inc; 2009:281–304.
Reference to a website:
5. Cancer Research UK. Cancer statistics reports for the UK. Accessed 13 March 2003. http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/; 2003. .
Reference to a dataset:
[dataset] 6. Oguro M, Imahiro S, Saito S, Nakashizuka T. Mortality data for Japanese oak wilt disease and surrounding forest compositions, Mendeley Data, v1; 2015. https://doi.org/10.17632/xwj98nb39r.1
Reference to software:
7. Coon E, Berndt M, Jan A, Svyatsky D, Atchley A, Kikinzon E, Harp D, Manzini G, Shelef E, Lipnikov K, Garimella R, Xu C, Moulton D, Karra S, Painter S, Jafarov E, Molins S. Advanced Terrestrial Simulator (ATS) v0.88 (Version 0.88). Zenodo; 2020, March 25. https://doi.org/10.5281/zenodo.3727209

Journal abbreviations source
Journal names should be abbreviated according to the List of Title Word Abbreviations.

RESEARCH REPORT

Name of Journal: Journal of the Society For Cardiovascular Angiography & Intervention

Type of paper: Original Research

Title: Diagnostic Coronary Angiography Access In Johannesburg

Authors: Khulasande Liso Sifiso Ntaka [*], Dineo Mpanya, Thomas Kalk, [Nqoba] Tsabedze

Affiliation: Division of Cardiology, Department of Internal Medicine, School of Clinical Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

[*] Corresponding author
Dr Khulasande Liso Ntaka
Division of Cardiology, Department of Internal Medicine, University of the Witwatersrand, Charlotte Maxeke Johannesburg Academic Hospital, 17 Jubilee Road, Parktown, Johannesburg, Gauteng, 2193, South Africa

Email: 2301770@students.wits.ac.za

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Highlights:

- Radial artery access is as safe as femoral artery access.
- Higher crossover rate in the radial artery access group.
- Radial artery access was preferred in 49% of patients.

ABSTRACT

Background: Contemporary interventional cardiology guidelines prefer radial over femoral artery access when performing diagnostic coronary angiograms (DCA). There is a paucity of data on the safety and efficacy of radial and femoral DCA in low-and-middle-income countries.

Methods: We retrospectively reviewed inpatient medical records and DCA reports of patients referred for DCA and evaluated the safety and efficacy of the femoral versus radial artery access route.

Results: There were 653 patients with a mean age of 58.2 ±12.6 years. Radial access was used in 318 (48.7%) patients. The median duration of the DCA was slightly longer with radial access and was 50 minutes (Interquartile range (IQR): 40–60), while the median procedural duration for femoral artery access was 45 minutes (IQR: 35–60) (P = 0.010). The median total radiation dose in the femoral artery access group was 3511 μGym^2 (IQR: 2154–5821), and patients in the radial artery access group were exposed to a median radiation dose of 4011 μGym^2 (IQR: 2298–6411) (P = 0.0661). A total of 639 (97.9%) DCA were performed without crossover, and 99.0% (95% CI: 97.2 – 99.8) of DCA performed via the radial artery did not require crossover to transfemoral access, and 96.1% (95% CI: 93.4 – 97.9) of the DCA done via the femoral artery did not require crossover to transradial access (P = 0.009).

Conclusion: Almost half of all diagnostic angiograms were performed via the radial artery. Both radial and femoral artery access were equally safe and efficacious in patients with coronary artery disease.

KEYWORDS: Diagnostic coronary angiography; vascular access; radial artery access; femoral artery access; vascular complications; radiation exposure; contrast media

ABBREVIATIONS

AKI, Acute kidney injury; CABG, Coronary artery bypass graft; CVD, Cardiovascular disease; CMJAH, Charlotte Maxeke Johannesburg Academic Hospital; DCA, Diagnostic coronary angiography; eGFR, estimated glomerular filtration rate; LMIC, Low and middle-income countries; LVEF, Left ventricular ejection fraction; IFR, Instantaneous wave-free ratio; IQR, Interquartile range; MACE, Major adverse cardiovascular events; MDRD, Modification of Diet in Renal Disease; NSAIDs, nonsteroidal anti-inflammatory drugs; PCI, percutaneous coronary intervention; STEMI, ST segment elevation myocardial infarction.

INTRODUCTION

In 2019, non-communicable diseases accounted for 74% of deaths globally. Cardiovascular diseases (CVD) are the leading cause of death worldwide, of which ischaemic heart disease ranks the highest, followed by cerebrovascular disease and chronic obstructive pulmonary disease.[1] In South Africa, the prevalence of CVD is rising, with 85 525 deaths per annum reported in 2018.(2)

Diagnostic coronary angiography (DCA) is the gold standard in diagnosing coronary artery disease. Despite an increasing prevalence of CVD in low-and-middle-income countries (LMICs), there is a paucity of data on the efficacy and safety of DCA. Ekou et al. conducted a study evaluating the role of primary percutaneous coronary intervention (PCI) in managing ST-elevation myocardial infarction (STEMI) in sub-Saharan Africa. Femoral artery access was the most commonly used vascular access route when performing coronary angiograms in their centre. Also, in their study, femoral access accounted for most non-fatal vascular complications.(3) Similarly, most international studies associate femoral artery access with more vascular complications when compared to radial access. (4, 5)

In the recent decade, a radial-first policy has been adopted internationally by interventional cardiology centres. In some of these countries, it has replaced femoral

artery access as the main vascular access route for percutaneous coronary intervention.(6) This is mainly due to the evident advantages radial artery access has over femoral artery access. These advantages include fewer vascular complications such as haemorrhage, pseudoaneurysms, arteriovenous fistula, arterial dissection, and other major cardiovascular events (MACE).(7, 8) Ease of postprocedural care and shorter hospital stays are other advantages noted.(9, 10) Though there are multiple available international studies on this topic, only a few have been published on the safety and efficacy of DCA's performed in LMICs. Therefore, this study aimed to describe clinical and procedural factors of the transradial versus transfemoral approach for coronary angiography in the Division of Cardiology at the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) in South Africa. We hypothesize that our study will reveal similar findings as the international studies which had a lower vascular complication rate amongst the radial artery access group.

METHODS

We retrospectively reviewed inpatient medical records and diagnostic coronary angiogram reports of consecutive patients referred to the CMJAH between 1 January 2018 and 31 December 2019. The CMJAH is one of the two state-owned facilities in Johannesburg equipped with an intensive care unit, cardiac admission wards, outpatient services, and electrophysiology and catheterisation laboratories. This tertiary academic hospital serves a population of approximately 5.2 million individuals.[(11)] The catheterisation laboratory at the CMJAH is considered a high-volume centre and is an accredited training site for cardiology fellows.

All patients 18 years and older who underwent DCA were included in the study. Patients referred for physiological or haemodynamic studies, such as instantaneous wave-free ratio (IFR), left and right heart catheterisation, or percutaneous coronary interventions (PCI) during the DCA, were excluded. Also, patients with previous coronary artery bypass graft (CABG) surgery were excluded. The rationale for

excluding patients with prior CABG surgery is the prolonged or unpredicted procedural times observed when performing DCA in such patients. The previous history of CABG surgery may also introduce selection bias in the vascular access route chosen by the operator.

We documented demographic data, comorbidities, biochemical laboratory data, concomitant anticoagulant therapy, left ventricular ejection fraction (LVEF), procedural findings and measured the success rate. The success rate was defined as the number of angiograms completed without access crossover. Biochemical data was extracted from the National Health Laboratory Services website. The Modification of Diet in Renal Disease (MDRD) equation was used to calculate the estimated glomerular filtration rate (eGFR).

Angiographic data was obtained from the angiography report registry on the Research Electronic Data Capture (REDCap) database, the procedure book in the catheterisation laboratory, filed hard copies of angiogram reports and archived cine images. Variables such as vascular access route, procedural duration, contrast volume, total radiation dose and reported complications were also captured. During the study period, our centre was still in the midst of transitioning from the traditional transfemoral artery access route to the transradial artery access route. Though this adoption was due to the growing evidence favouring radial artery access, the vascular access used by the operator was still mostly based on their discretion. No set standards of operation were in place during that time.

Lignocaine was used as local anaesthetic followed by administering intra-arterial verapamil and nitrocine into the radial artery to prevent spasm. Heparin was also used to prevent vessel occlusion. Radial artery access closure was done using an inflatable radial band, whereas femoral artery closure was achieved with manual compression followed by a compressive bandage.

The procedural time was defined from the time when the patient entered the catheterisation laboratory until after the procedure when the patient exited the catheterisation laboratory. As such, the procedural time also incorporated the time

required to apply the radial artery band which was routinely applied while the patient was still in the catheterisation laboratory. However, manual compression post femoral access was routinely done in the recovery room and was omitted when estimating the procedural time.

The rate of crossover was obtained from the angiogram reports. Supplementary sources were the theatre registry book and archived cine films which as hold record if access crossover occurred. When access had failed, it was to the discretion of the operator to choose which next access route to attempt. The radiation dose was defined as the total amount of radiation in $mGym^2$ emitted in the interventional lab during each procedure.

The safety of each vascular access was measured by comparing the total radiation dose, the total volume of contrast media used, and the prevalence of local vascular complications. Study variables were captured into the Research Electronic Data Capture (REDCap) database. Permission to conduct the study was obtained from the University of the Witwatersrand Human Research Ethics Committee (Clearance certificate number: M2011118) and relevant hospital authorities.

Statistical Analysis

The statistical analysis was conducted using Stata/SE version 17.0 (Stata CORP LLC, Texas). Categorical data is summarised using numbers and percentages. Normally distributed continuous variables are summarised as the mean and standard deviation, while variables with a skewed distribution are summarised using the median and the interquartile range (IQR). The Student's t-test was used to compare means, and the Pearson's Chi-square test was used to compare categorical variables. The Wilcoxon rank-sum test was used to compare the medians. Confidence intervals were set at 95% and a P-value less than 0.05 was considered as a threshold for statistical significance.

RESULTS

Demographic and clinical characteristics

Between 1 January 2018 and 31 December 2019, 1189 DCA were performed (**Figure 1**). After excluding ineligible patients, the final study cohort comprised 653 patients, of which 408 (62.5%) were males. The mean age in the study cohort was 58.2 ± 12.6 years. Hypertension was the most common comorbidity, reported in 299 (45.8%) patients, followed by dyslipidaemia in 157 (24.0%), diabetes mellitus in 146 (22.4%) patients, and chronic kidney disease in 62 (9.5%).

Diagnostic coronary angiography was performed as an elective procedure in 457 (81.6%) patients and as an emergency procedure in 103 (15.8.4%) patients. The remaining 96 patients did not have enough data to discern whether the DCA was scheduled as an elective or an emergency procedure. The femoral artery access route was used in 335 (51.3%) patients. Among the 157 patients with dyslipidaemia, 93 (59.2%) had transfemoral access (P = 0.022), and 18 of the 25 (72.0%) patients with atrial fibrillation had transradial access (P = 0.017). Among the patients with atrial fibrillation, 96% of these patients had an elective DCA.

A total of 55 (8.4%) patients were prescribed warfarin, and 38 (69.0%) of these patients had radial artery access (P = 0.002). The median INR among patients on warfarin was 1.84 (IQR: 1.22–2.45), and 1.07 (IQR: 1.01 – 1.16) among patients who were not on warfarin (p<0.001). There were no bleeding complications among patients on warfarin.

In the entire study cohort, 202 (30.9%) patients were taking oral nonsteroidal anti-inflammatory drugs (NSAIDs), of which 110 (54.5%) had radial artery access (P = 0.049). Among the 653 patients referred for DCA, 80 (12.2%) had underlying valvular heart disease, and 48 (60.0%) of these patients had radial artery access (P = 0.031). The rest of the baseline demographic and clinical characteristics did not differ between patients subjected to femoral and radial artery access during the DCA (**Table 1**).

Procedural Findings

In 2018, 297 DCA were performed, and this number increased to 356 in 2019. In 2018, 112 (37.7%) of all DCA were performed via the radial artery, and this increased to 206 (57.9%) in 2019 ($p<0.001$). The DCA revealed normal epicardial coronary vessels in 229 (50.3%), single vessel disease in 95 (20.9%), double vessel disease in 65 (14.3%) and triple vessel disease in 66 (14.5%). The median duration of the procedure was longer in the radial artery access group when compared to the femoral access group [50 minutes (IQR: 40.0 – 60.0) versus 45 minutes (IQR: 35.0 – 60.0), P = 0.011] (**Figure 2**). The mean contrast volume administered in the radial and femoral artery access group did not differ significantly and was 83.7 ± 36.1 millilitres (ml) and 88.9 ± 37.1 ml, respectively (P = 0.073). In the entire cohort, the median radiation dose was 3726 μGym^2 (IQR: 2181.7 – 6205.0), and it did not differ significantly between the radial and femoral artery access group [4011.0 μGym^2 (2298.0 – 6411.4) versus 3511.0 μGym^2 (2154.0 – 5821.5), P = 0.066] (**Table 2**).

Outcomes

A total of 653 DCA were performed, and 613 (94.2%) were completed without the need to repeat the procedure. Some of the reasons for repeated DCA included failure to advance a guide wire, haemodynamic instability, and onset of chest pain. Failed access was mainly documented during the transfemoral approach, accounting for 24 (61.5%) failed procedures. In this study, 639 (97.9%) DCA were performed without crossover, and 99.0% (95% CI: 97.2 – 99.8) of the DCA performed via the radial artery did not require crossover to femoral access and 96.1% (95% CI: 93.4 – 97.9) of the DCA performed via the femoral artery access route did not require crossover to transradial access, P=0.009. Clinically significant procedure-related complications were uncommon. Vascular spasms were encountered in eight patients subjected to radial artery access. Other documented complications were femoral artery dissection (n=2), haematoma (n=2), aortic dissection (n=1), and femoral artery haemorrhage (n=1).

DISCUSSION

We retrospectively reviewed medical records of 653 patients referred for diagnostic angiography in Johannesburg and assessed the efficacy and safety of radial versus femoral artery access. Transradial access was used by 48.7% of patients. The crossover rate was low and documented in 2.1%, with most patients requiring crossover from femoral to radial artery access (P=0.009). In the Radial Versus Femoral Randomized Investigation in ST-Elevation Acute Coronary Syndrome (RIFLE-STEACS) trial,(4) the crossover rate was 9% in the radial access arm and 3% in the femoral access arm.

In some international studies radial artery access was associated with longer procedural times and higher radiation exposure doses than femoral access.(12, 13) In our study, the longer procedural duration was in the transradial access group, with a median procedural duration of 50 minutes (P = 0.011). The longer procedural duration is probably due to the inherent complexity of catheterising the radial artery with its smaller diameter and higher propensity for spasm.(14)

We did not find statistically significant differences in the total radiation dose emitted or volume of contrast media between patients in the radial and femoral artery access groups. This is a common finding also discovered by Feldkemp et al., who investigated if radial access was protective against contrast-induced nephropathy compared to femoral access.(15) Their study showed that the contrast volume was comparable in each vascular access group (P = 0.438). Surprisingly they concluded that even though the contrast media given was similar in both access arms, radial artery access was associated with significantly fewer acute kidney injuries (AKI), particularly in a subgroup of patients with an acute coronary event.

The mean age in our study was 58 years, and almost half (46%) of patients had hypertension. Dyslipidaemia was prevalent in 24% of our study population, and in 59% of these patients, the DCA was performed via the femoral artery (P=0.022). We speculate that this association stems from the fact that dyslipidaemia carries a well-

established risk to cause more severe coronary artery disease. Perhaps these patients presented with more critical disease and were subjected to femoral artery access in anticipation of potential intervention. Our finding is similar to Alkatiri et al. who reported that the transfemoral approach tends to be the preferred access route in patients with multiple comorbidities.(16) However, there is limited evidence in the literature showing a similar association or pattern of distribution.(4, 17) One of the largest multicenter landmark studies conducted by Romagnoli et al. named, the Radial Versus Femoral Randomized Investigation in ST-Elevation Acute Coronary Syndrome (RIFLE-STEACS) is such a study which found no association of dyslipidaemia to vascular access route. The trial spans from 2009 to 2011, with 1001 patients with acute ST-segment elevation myocardial infarction. There were 500 patients randomised to the radial access group. The prevalence of hypercholesterolaemia was comparable in both access groups (P = 0.223).(4)

In our study, 6% of patients with atrial fibrillation had transfemoral access compared to 2% subjected to transradial access (P = 0.017). These findings are similar to a study by Sherwood et al. investigating outcomes of cardiac catheterisation in patients with atrial fibrillation on anticoagulation therapy in contemporary practice.(18) Similar to their cohort, in our study, 96% of patients with atrial fibrillation had their procedure done electively via the femoral artery with the interruption of oral anticoagulation.(18) In our study, the radial access route was used more than the transfemoral access route in patients prescribed warfarin or NSAID. This supports the evidence that radial access has fewer bleeding complications when compared to transfemoral access.(19)

The radial artery was the preferred access in patients with valvular heart disease who are being worked up for open heart surgery (P=0.031). This was an expected finding, as most of these elective procedures were done as a screening investigation. There was little or no foreseen need for intervention. The operators preferably selected this route for its perceived lower vascular complication risk and shorter hospital stays.(4) Conversely, femoral access is more commonly used in emergencies. First, the patient's clinical presentation may require assistive devices such as an intra-aortic balloon pump which cannot be inserted via radial access. Secondly, the probability of coronary artery

intervention is higher in emergencies; therefore, the operator may need to use a bigger cannula for larger intervention equipment. However, an overwhelming body of evidence suggests that radial artery access in these emergency cases is just as efficient at providing emergency interventions and may have an additional advantage of fewer major adverse cardiovascular events (MACE) and bleeding complications.(19-21) Vascular complications have been the crux of discussion between transradial and transfemoral access. It has been identified that vascular complications, particularly bleeding, are associated with poorer outcomes and higher rates of MACE.(19, 22) In our study, complications were rarely documented. In our cohort, crossover of vascular access route was rarely observed when initial access failed. The rates were much lower than most international studies.(23, 24) This could be explained by the exclusion of patients requiring PCI from our study cohort. Performing an intervention likely introduced another level of complexity into the procedure, hence increasing the risk of access crossover, particularly with radial artery access.(24)

Limitations

This was a single-centre retrospective study with a relatively small sample size. We relied on information documented in medical records. Due to the low rate of complications, the authors could not determine variables associated with the occurrence of complications. Also, long-term sequelae from vascular complications were not assessed. With regards to access route selection, there may have been clinical selection bias as access route was left to the operator's discretion. Despite these limitations, this study sheds some light on the safety and efficacy of DCA and, to some extent, competency when adopting newer interventional techniques in a high-volume centre in Johannesburg.

CONCLUSIONS

The radial artery was the preferred access in 49% of DCA. The efficacy and safety of the transradial and transfemoral access were comparable, although the procedural duration was slightly longer with radial access.

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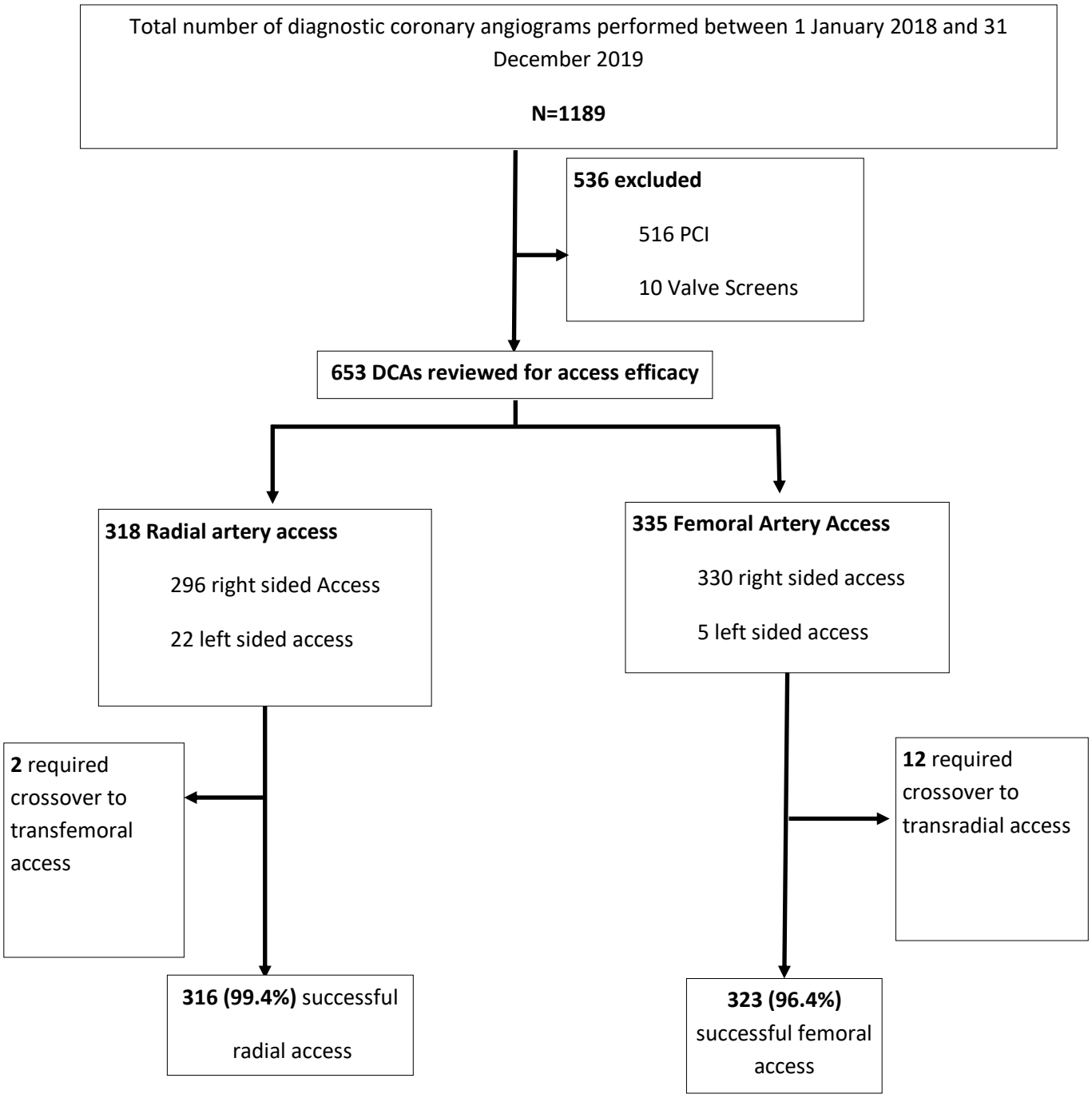

Figure 1 Study Flow Chart. DCA: diagnostic coronary angiography. PCI: percutaneous coronary intervention

Table 1: Baseline demographic and clinical characteristics of the study cohort stratified according to the site of angiography vascular access

	All patients (n=653)	Transradial access (n=318) 48.7%	Transfemoral access (n=335) 51.3%	P-value
Clinical Parameters				
Age, years (SD)	58.2±12.7	58.7±12.5	57.7±12.7	0.3231
Males (%)	408(62.6)	198(62.3)	210(62.9)	0.872
Ethnicity (%)				0.221
Black African	245 (37.6)	127(39.9)	118(35.3)	
Mixed Ancestry	58 (8.9)	33(10.4)	25(7.5)	
Indian	104 (16)	45 (14.2)	59 (17.7)	
Caucasian	245 (37.6)	113 (35.5)	132 (39.5)	
Hypertension	299(45.8)	141(44.3)	158(47.2)	0.469
Diabetes Mellitus	146(22.4)	68(21.4)	78(23.3)	0.560
HIV	27(4.1)	12(3.8)	15(4.5)	0.652
Dyslipidaemia	157(24)	64(20.1)	93(27.8)	0.022
Smoker	131(20.1)	60(18.9)	71(21.2)	0.458
ExSmoker	77(11.8)	40(12.6)	37(11.0)	0.544
CKD	62(9.5)	26(8.2)	36(10.8)	0.263
Atrial Fibrillation	25(3.8)	7(2.1)	18(5.7)	0.017
Previous CAD	83(12.7)	40(12.6)	43(12.8)	0.921
No comorbidities	60(9.2)	29(9.1)	31(9.3)	0.953
Warfarin	55(8.4)	38(12)	17(5.1)	0.002
NSAID	202(30.9)	110(34.6)	92(27.5)	0.049
Systolic BP	127.4 ± 26.4	126.4 ± 27	128.5 ± 25.9	0.4262
Diastolic BP	75 ± 14.5	76 ± 14	74 ± 15	0.1472
eGFR	68.3 ± 26.7	68.1 ± 24.1	68.5 ± 29	0.8455
Haemoglobin	13.9 ± 2.2	14 ± 2.2	13.7 ± 2.1	0.1330
Platelets	261.7 ± 92.8	260.1 ± 88.5	263.1 ± 96.7	0.6779

INR, Median [IQR]	1.08 (1.01-1.2)	1.09 (1.0-1.2)	1.07 (1.02-1.16)	0.2755
Left Ventricular EF	46.7 ± 15.7	46.9 ± 16.0	46.4 ± 15.5	0.7775

BP= blood pressure; CAD= coronary artery disease; CKD= chronic kidney disease; eGFR= estimate glomerular filtration rate; HIV= human immunodeficiency virus; INR = International normalised ratio; EF = ejection fraction; IQR = interquartile range; NSAID = Nonsteroidal anti-inflammatory drug; SD = standard deviation.

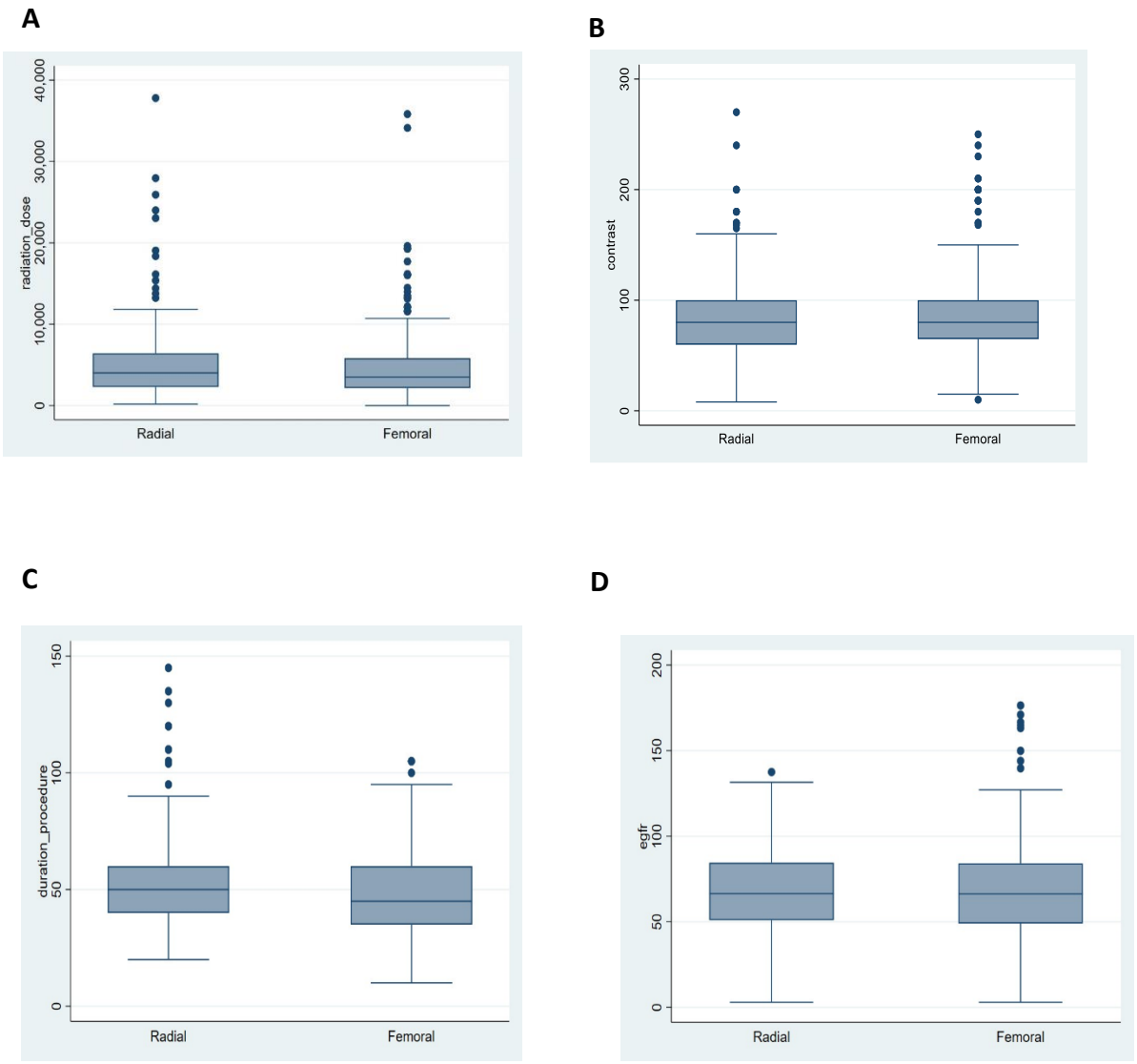

Figure 2 Procedural factors grouped according to vascular access (**A**) radiation dose (µGym^2), (**B**) contrast volume (ml), (**C**) duration of procedure (minutes) and (**D**) estimated glomerular filtration rate (ml/min/1.72 m^2)

Table 2: Procedural factors for diagnostic coronary angiography stratified according to access route

Variable	Total (N=653)	Transradial (N=318) 48.7%	Transfemoral (N=335) 51.3%	P-value
Indications for DCA				
Known CAD	99(15.2)	44 (13.9)	55 (16.4)	0.358
Suspected CAD	484 (74.1)	225 (70.8)	259 (77.3)	0.056
Valvular disease	80 (12.3)	48 (15.1)	32 (9.6)	0.031
Perioperative	9 (1.4)	7 (2.2)	2 (0.6)	0.079
Duration of procedure, min	46 (40-60)	50 (40-60)	45 (35.0- 60)	0.011
Urgency				0.010
Elective	457 (81.6)	231(87.2)	226(76.6)	
Emergency	103 (18.4)	34 (12.8)	69 (23.4)	
Total radiation dose, μGym^2	3726 (2181–6205)	4011 (2298-6411)	3511 (2154-5822)	0.066
Total contrast dose, ml	86.4 ± 36.7	83.8 ± 36.1	89 ± 37.2	0.073
Diseased vessels on angiography				
Normal angiogram	229 (50.3)	118(55.1)	111(46.1)	0.053
Single vessel disease	95 (20.9)	40 (18.7)	55 (22.8)	0.279
Double vessel disease	65 (14.3)	26 (12.1)	39 (16.2)	0.220
Triple vessel disease	66 (14.5)	30 (14.0)	36 (14.9)	0.781

SD = standard deviation; μGym^2 =micro Grays per metre squared; IQR= interquartile range; ml = millilitres; min=minutes

APPENDIX 1 : Study Protocol

DIAGNOSTIC CORONARY ANGIOGRAPHY ACCESS IN JOHANNESBURG

Research Protocol

Student

Khulasande Liso Sifiso Ntaka (MBChB)

Student No. 2301770

Supervisors

Nqoba Tsabedze

MBBCh (Wits), FCP (SA), Cert Cardiology (SA), MMed (Int Med) (Wits) FESC

Academic & Clinical Head – Division of Cardiology

Department of Internal Medicine

Thomas Kalk

MBBCh (Wits), FCP (SA), Cert Cardiology (SA)

Senior Consultant – Division of Cardiology

Department of Internal Medicine

Dineo Mpanya

MBChB(UCT), FCNP(SA), MMed (Wits) PhD

Nuclear Physician - Consultant, PhD Research Fellow – Division of Cardiology

Department of Internal Medicine

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ABBREVIATIONS

CAD	Coronary artery disease
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
DCA	Diagnostic coronary angiography
DNA	deoxyribose nucleic acid
Gy	Gray
PCI	percutaneous coronary interventions
Sv	Sievert

1. INTRODUCTION

Diagnostic Coronary Angiography (DCA) is the visualisation of the coronary vessels radiographically with the assistance of intracoronary contrast media. This procedure illustrates better the coronary vessels and any suspected coronary vascular abnormalities(1). In addition to identifying and localising coronary lesions, DCA can be performed in conjunction with percutaneous coronary interventions (PCI) such as balloon angioplasty and stent insertion. The most common indication for DCA is suspected or known coronary artery disease (CAD). This includes diseases such as stable or unstable angina, acute myocardial infarction, and post-revascularisation ischaemia. Diagnostic coronary angiograms are also performed on patients with valvular heart disease and cardiomyopathies, where an ischaemic aetiology needs to be excluded(1). Patients who present with unexplained cardiac failure, cardiac defects, and those being worked up for corrective heart surgery after the age of forty, all have sound indications for performing a DCA.

There are two common access approaches used when performing DCA, the transfemoral and the transradial approach, with the transfemoral approach being the traditional route. There are other less common access methods described for patients with challenging radial and femoral vascular access. The brachial access is one such method which is unfavourable due to its increased risks of neurological complications. The axillary artery approach is another access method that is rarely used by experienced interventionalists(2).

Transradial access approach is relatively new compared to the transfemoral approach. It was first described in 1989 in Campeau(3). Many studies have since been done to compare the

advantages and disadvantages of the two access approaches(4-7). There is growing evidence showing that the transradial access is safe and efficient when performing DCA, and perhaps even more so than the transfemoral approach(7).

Cardiac catheterisation is performed in an angiography suite with multiple monitoring equipment for assessing the patients' cardiac function throughout the procedure. A radiographic machine is also used by the interventionalist to identify the patients' real-time vascular anatomy throughout the procedure. This procedure is also aided by the use of intracoronary contrast media, which renders the coronary vessels radiopaque during the cine film run. Healthcare staff involved in performing this procedure are, therefore, also exposed to radiation during DCA.

In South Africa, there is a lack of research comparing the efficacy and safety of these two vascular access techniques. The purpose of this study is to investigate the safety and success rates of transradial and transfemoral vascular access when performing DCA.

2. BACKGROUND / LITERATURE REVIEW

Cardiovascular disease (CVD) is a major healthcare burden in South Africa and worldwide(8). In South Africa, one in six deaths was attributed to CVD in 2014(9). The rapid rise in CVD risk factors is the most significant underlying contributor to the increase in the prevalence of CVD in South Africa(8, 10). Some of the non-modifiable risk factors include age, male gender, and family history. The well-recognised modifiable risk factors are hypertension, dyslipidaemia, smoking, diabetes mellitus, and obesity.

In most cases, coronary artery disease (CAD) is a consequence of atherosclerosis of the coronary arteries(11, 12). Atherosclerosis is a disease of medium and large-sized arteries where there is an accumulation of lipids, proinflammatory cells that transform into foam cells,

and cellular debris within the arterial intimal layer(13). This eventually leads to plaque formation. The luminal area decreases, restricting blood flow and causing ischaemia in the myocardium. The plaque may become unstable and rupture, leading to thrombus formation and occlusion of the coronary artery, thus causing myocardial infarction(11).

Research into the best management of coronary artery diseases in relation to the time of presentation and nature of the arterial disease is still ongoing(14,15). At present, there are two main approaches in managing these patients, pharmacological and non-pharmacological. Pharmacological management entails the use of thrombolytic therapy (streptokinase /tissue Plasmin Activator (t-PA)), antiplatelet therapy (aspirin/ clopidogrel), lipids management (statins), and other forms of therapy, all aimed at improving perfusion. The non-pharmacological approaches include interventional cardiology and open-heart surgery.

Diagnostic coronary angiography, which is a specialised form of coronary investigation, is the most common initial procedure undertaken when investigating patients suspected to have CAD. Diagnostic coronary angiography is the gold standard in the management of acute myocardial infarction. If a stenosed vessel is visualised, intervention may be taken during the same procedure by inserting devices that restore the calibre of the vessel, hence improving blood flow.

2.1 Transfemoral Vascular Access

Transfemoral vascular access is the most practised method of cardiac angiography. Though it is no longer the preferred access route as in the past, it is still the favoured access site when performing complex interventional angiography procedures requiring multiple and/or large bore types of equipment and catheters(16). The femoral artery has a larger vessel calibre, which

accommodates larger French size catheters and also provides ease of maneuverability (16). Some patients may need access via both femoral artery and vein as in valvular heart disease assessment as well as right and left heart catheterisation. Current best-practice methods for vessel puncture advise on the routine use of ultrasonography and fluoroscopy where available(17, 18). However, based on the International Femoral Access Practices Survey (i-FACTS) study, only 11% of interventionalist use fluoroscopy, and the majority rely on palpation alone(19). There are well-documented complications that arise when using palpation alone, namely bleeding complications, pseudoaneurysms, arteriovenous fistula, dissections with or without limb ischemia. Other significant complications include infections as well as thrombosis and/or embolism(17).

Until the 1950s, the Sones' technique was used to cannulate the femoral artery. Dr Mason Sone introduced this technique. Sone's technique involves dissecting through the skin and underlying tissue until the femoral artery is visualised, followed by introducing a catheter into the vessel. This has now changed and replaced by the widely used modified Seldinger technique.

The use of ultrasonography and fluoroscopy is advised to limit repeated punctures(19). In this approach, a 21 gauge or 18 gauge needle is introduced into the artery percutaneously, and a catheter guidewire is threaded through the needle. The needle is then removed, and a sheath or catheter is railed over the guidewire. The femoral artery is located in the femoral triangle with the borders made by the inguinal ligament superiorly, sartorius muscle laterally and the adductor longus muscle medially. Cannulation is made at the base of the triangle just below the inguinal ligament, above the bifurcation of the femoral artery. Caution must be taken not to use the inguinal skin crease as a landmark as this is below the femoral bifurcation in 70% of patients(17).

Minor and major complications associated with this procedure have been described. The minor complications are stable haematoma, minor bleeding, and ecchymosis. The major complications include arterial dissection, limb ischemia, retroperitoneal haemorrhage, pseudoaneurysm, AV fistula, infection, major bleeding and thromboembolic phenomena(17). These complications have been associated with percutaneous coronary interventional procedures as opposed to a diagnostic coronary angiogram. This is likely due to the use of larger sheath sizes and the need for anticoagulation. Supporting this, Chandrasekar B et al. found that coronary angiography complications were 3.6% and 15.1% in those who went for diagnostic and therapeutic procedures, respectively(17, 20).

2.2 Transradial Vascular Access

There is growing expertise and training availability in refining the necessary skills required when performing transradial angiography(21). The radial artery is superficial and much smaller in diameter than the femoral artery. This makes it easier to compress to achieve haemostasis.

Studies have revealed that this approach has many significant benefits over the traditional transfemoral approach(3, 22, 23). These studies showed that patients have significantly lower bleeding complications, shorter duration of hospitalisation with early mobilisation, and better cost containment(24). However, this method has disadvantages. Due to the vessel being of small calibre, only smaller sized catheters may be used, limiting working space and flexibility. Therefore, there is a greater need for more developed fine motor skills when using the transradial approach, much more required than with the transfemoral approach(3). Another challenge is that the vascular route to the heart has several branches and tortuous paths, which increases the risk for arterial spasm. This may lead to higher conversion rates to transfemoral catheterisation (25). Transradial access angiography is associated with longer procedural

times, often as a result of difficulty in getting access. Longer procedural time translates to prolonged radiation exposure time for both the patient and the catheterisation staff(26).

Patients who undergo DCA should ideally be considered for radial angiography, if possible(3). Anatomically, the hand is supplied by two major arteries, the ulna artery and the radial artery. These arteries then join in the hand to form the superficial and deep palmar arches. The radial artery takes a more superficial route distal to the hand, making it easier to locate and compress. In the past, it was standard practice to establish good collateral blood supply by performing the Allen Test(27). However, this has shown not to be clinically relevant(27, 28). The Barbeau test is another test that assesses the hand for dual circulation by use of plethysmography, similar to the Allen test; there has been no correlation between these tests and subsequent hand or digital ischaemia(29). Once contraindications have been excluded, the target point of insertion for the radial sheath is 2-3 cm above the wrist crease, while the wrist is in the hyper-flexed position(3). Complications post cannulation include bleeding, radial artery spasm, as well as radial artery occlusion(22). Radial artery occlusion has been found in cases where a large bore sheath was used, larger than the artery's diameter with inadequate anticoagulation and different compression techniques. This occlusion can be avoided by using nitroglycerine before the removal of the sheath. (3, 30)

The well-known radial versus femoral access (RIVAL) trial published in 2011 was a multicentre trial involving 7021 patients from 32 countries. Amongst those patients, 3507 were randomly selected for radial access and 3514 for femoral access. The primary outcome was a composite of death, myocardial infarction, stroke and non-coronary artery bypass graft (CABG) surgery related major bleeding at 30 days. The study reported that 3.7% of the primary outcome occurred in the radial access group, and 4.0% in the femoral access group. This showed that both vascular access routes are safe and effective for diagnostic purposes and intervention. However, at 30 days, 1.19% of the radial group developed a large haematoma, compared to

3.01% in the femoral access group. Seven patients in the radial access group, compared with 23 in the femoral access group, developed pseudoaneurysms that needed closure. This revealed that though both groups were safe, radial access was safer, as evidenced by fewer local vascular complications. Similar findings were also seen in another Radial versus Femoral clinical trial authored by Valgimigli and colleagues(7), who found an overall reduction in major bleeding events. However, unlike in the RIVAL trial, they found a significant reduction in all-cause mortality with the transradial access. The rate of cardiac mortality, stroke and myocardial infarction were nevertheless not significantly different between the two groups.

With this knowledge, further studies have been done to look at the success rate and safety of radial access angiography. In China, a prospective study was done evaluating 2845 patients in a single interventional facility from August 2012 to July 2013. The mean age of the patients was 64 ±7.5 years. There were 57.2% males and 42.8% females. The study participants were patients undergoing diagnostic coronary angiography (49.8%) and PCI (50.2%). Patients with cardiogenic shock, on haemodialysis, and those with an abnormal Allen test were excluded. The study revealed a 97.6% success rate in the angiography group and a 96.3% in the PCI group, thus concluding that transradial access is a sensible and safe choice for both diagnostic and interventional angiography(31). Another recent prospective study done in Slemani Cardiac Hospital looked at a single interventionalists experience with radial access angiography over 2 years. The number of patients who participated in the study is 1561. A total of 1 005 patients were referred for DCA, and 679 were subsequently treated with PCI. The total transradial DCA success rate was 95.6%, and the radial PCI procedural success rate was 96.5%. The radial artery crossover rate was reported to be 4.4%, with the key aetiological causes being radial artery spasm, a tortuous aorta and brachiocephalic artery, a radial loop and a failed radial puncture. The trial also revealed that transradial access is safe and reliable. Furthermore, it also showed that dual artery circulation before the procedure might not be necessary(28).

2.3 Radiation Exposure

Fluoroscopy & cineangiography are essential for coronary angiography. Cineangiography is a procedure that uses continuous X-rays to track the transit of contrast media through a coronary vessel(32). Fluoroscopy is a radiological imaging technique that uses X-rays to capture real-time images of anatomical structures. During the procedure, x-ray beams are continuously transmitted from a fluoroscope, and the moving images are captured on a monitor. Fluoroscopy dates back to November 1895, when X-rays were discovered by a German mechanical engineer, Wilhelm Roentgen. He observed a barium platinocyanide screen emitting fluorescent light due to it being exposed to what is now known as X-rays. They were called X-rays due to their unknown nature at the time. The news about this discovery rapidly spread, and soon after that, X-rays were used for clinical purposes. X-rays are high energy electromagnetic that release ionising radiation, capable of disrupting chemical bonds, including breaking the molecular structure of the deoxyribose nucleic acid (DNA). X-rays can also cast an image of tissue structures beneath the surface(33). Patients who therefore undergo coronary angiography are exposed to varying doses of radiation from X-rays. To quantify this exposure, the International System of Units (SI) is used. Since 1977, the International Commission on Radiological Protection (ICRP) adopted the SI unit over the Common units, which is no longer commonly used. The absorbed radiation dose is measured in Gray (Gy). The effective dose is measured in Sieverts (Sv). This is a calculated ionised radiation quantity measuring the risk of causing clinically significant tissue damage(34).

The health concern related to radiation exposure is that ionising radiation can cause irreparable tissue damage, which may lead to medical conditions like acute radiation syndrome and cancer after long term exposure(34). This is why the ICRP introduced the As Low As Reasonably

Achievable (ALARA) Principle, which assists in balancing the health benefit to risk ratio in medical radiography(34). The three principles are time, distance and shielding. Time refers to limiting the time spent next to a radioactive source. Distance refers to maximising the distances between the radioactive source and the operator and the patient. Shielding refers to using radioprotective equipment during procedures. The South African Health Products Regulatory Authority has further quantified acceptable radiation doses allowed for the healthcare workers and the patient. In one year, 20mSv are allowed as the maximum effective dose for the healthcare worker and 1mSv for patients(35). This is in line with the ICRP guidelines(34). Literature has shown that transradial access is associated with more radiation exposure to the operator and patient(6). Other studies refute this finding and deem transradial access equally safe as transfemoral angiography(36, 37).

As cited in the literature above, there are advantages and disadvantages when performing coronary angiography via transradial or transfemoral access. Though the above study findings share a similar conclusion, there are also significant data differences in both efficacy and safety between the different centres.

3. AIM

This study aims to compare the efficacy and safety of transradial access to transfemoral access coronary angiography at the Charlotte Maxeke Johannesburg Academic Hospital.

4. OBJECTIVES

a) To assess the efficacy of transradial angiography. This will be determined by the success rate of completed transradial angiography cases without cross over to transfemoral access.

b) To assess the safety of transradial angiography compared to transfemoral access. This will be determined by the total dose of radiation used, the total volume of contrast media used as well as the prevalence of local vascular complications between the two access routes.

c) To describe the demographics and clinical characteristics of patients undergoing DCA and their clinical indications.

d) To determine the procedure duration in patients subjected to transradial and transfemoral angiography

e) To assess for predictors of peri-procedural complications

5. METHODS

5.1 Study Design

Retrospective record review.

5.2 Study Population and Sampling

The study population will comprise of patients who had a DCA performed at the Division of Cardiology at the CMJAH between January 2018 to December 2019. Both elective and urgent cases will be included.

5.3 Inclusion criteria

Age 18 years and older

5.4 Exclusion criteria

a) Patients undergoing percutaneous coronary intervention

b) Previous coronary artery bypass graft surgery

c) Patients referred for haemodynamic studies

5.5 Study Site

The study will be conducted at CMJAH, Division of Cardiology.

5.6 Sample Size

A minimum of 100 consecutive patient records will be reviewed. Coronary angiogram reports, catheterisation laboratory procedure book, and the Electronic Health Record System (EHR) will be reviewed.

5.7 Data Collection

The collected data will consist of demographics, comorbidities, procedural factors as well as complications. The data collection sheet is attached as Appendix A. Comorbidities are routinely collected while clerking patients and documented in the angiogram reports and the EHR system. Study data collected will be captured and stored in the password-protected Research Electronic Data Capture (REDCap) tool hosted at the University of the Witwatersrand. The rationale for including patient identifiers such as the date of birth and the hospital number is to ensure that duplicate entries are removed when cleaning data, and for verification of outliers. The patient identifiers will be removed after data cleaning.

6 DATA MANAGEMENT AND ANALYSIS

Statistical analysis will be performed using STATA version 15 (STATA CORP, Texas). Data will be expressed as means and standard deviations when normally distributed and as medians with inter-quartile ranges when non-normally distributed. Data that is categorical will be expressed as numbers and percentages. The cohort will be separated into two groups, those who had transfemoral access and those who had transradial access. Student's t-test will be used to test for intergroup (Transfemoral vs. transradial access) differences with the Chi-square test being used to test for intergroup proportion differences. Univariable and multivariable logistic regression will be used to determine the predictors of peri-procedural complications. All tests will be two-sided with a p-value less than 0.05 considered as statistically significant.

7 ETHICS

Ethics approval will be requested from the University of the Witwatersrand Human Research Ethics (Medical) Committee. Permission to conduct the study will be requested from the Chief Executive Officer at the CMJAH, and the Heads of Cardiology and Internal Medicine. Individual patient information will not be published and the patient's identity will be protected throughout the study.

8 TIMING

	Aug	Sept	Oct	Nov-Dec	Jan-Feb 2021	Mar	Apr
Literature review							
Preparing Protocol							
Protocol							
Assessment							
Ethics Application							
Collecting Data							
Data analysis							
Writing up – thesis							
Writing up-paper							

9 FUNDING

Printing costs will be covered by the Principal investigator.

10POTENTIAL LIMITATIONS

Due to the retrospective nature of the study, data may be missing from the patient records.

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APPENDIX 2 : Data Collection Sheet

Confidential

Demographics

Record ID	_____
Hospital Number	_____
Date of Birth	_____
Gender	◯ Male ◯ Female
Ethnicity	◯ African ◯ Caucasian ◯ Coloured ◯ Indian

Clinical

Comorbidities	☐ Diabetes Mellitus ☐ Hypertension ☐ Dyslipidaemia ☐ Smoker ☐ Ex-Smoker ☐ Kidney Disease ☐ Peripheral Vascular Disease ☐ Human Immunodeficiency Virus ☐ Atrial fibrillation
Medication	☐ Warfarin ☐ NSAID's
Weight (kg)	_____ (kg)
Height (m)	_____
Body mass index	_____
Systolic BP	_____
Diastolic BP	_____
Haemoglobin	_____
Platelet count	_____
International normalized ratio (INR)	_____
Estimated Glomerular Filtration Rate	_____
Left ventricular ejection fraction (LVEF)	_____

Procedural

Access Route	☐ Transfemoral - Right ☐ Transfemoral - Left ☐ Transradial - Right ☐ Transradial - Left
Urgency	○ Elective ○ Emergency
Indication	☐ Known coronary artery disease ☐ Suspected coronary artery disease ☐ Valvular heart disease ☐ Peri-operative evaluation before and after non-cardiac surgery
Was an intra-arterial bolus given?	○ Yes ○ No
Type of intra-arterial bolus	☐ Nitrocine (glyceryl trinitrate) ☐ Verapamil ☐ Unfractionated Heparin (intravenous)
Specify Nitrocine (glyceryl trinitrate) total dose	_____
Specify verapamil total dose	_____
Specify heparin total dose	_____
Sheath size (French size)	_____
Start Date and Time	_____
End Time	_____
Duration of Procedure	_____
Total Radiation Dose	_____
Total Contrast (ml)	_____
Distribution of disease on angiogram	○ No vessel occlusion ○ Single vessel ○ Double vessel ○ Triple vessel

Age at the time of the angiogram _____

Complications & Outcomes

Vascular complications

- ☐ Dissection
- ☐ Radial artery occlusion/loss of radial pulse
- ☐ Haematoma
- ☐ Aneurysm
- ☐ Spasm
- ☐ Haemorrhage
- ☐ AV Fistula

Other _____

Mortality

- ○ Yes
- ○ No

Conversion of Access

- ○ Yes
- ○ No

Site used for conversion of access

	Left	Right
Radial	☐	☐
Femoral	☐	☐

Successful DCA

- ○ Yes
- ○ No

Primary operator

☐ AE ☐ AP ☐ AM ☐ DS ☐ DM ☐ DK ☐ FS ☐ HD ☐ KC ☐ MM ☐ NL
☐ NT ☐ TK ☐ UA

`

APPENDIX 3: Ethics Certificate

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr Khulasande Liso Sifiso Ntaka

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M2011118

NAME: (Principal Investigator)	Dr Khulasande Liso Sifiso Ntaka
DEPARTMENT:	Clinical Medicine Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	Diagnostic coronary angiography access in Johannesburg
DATE CONSIDERED:	27/11/2020
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr N. Tsabedze, Dr T. Kalk and Dr D. Mpanya
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	01/12/2020

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions.Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore be due in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date

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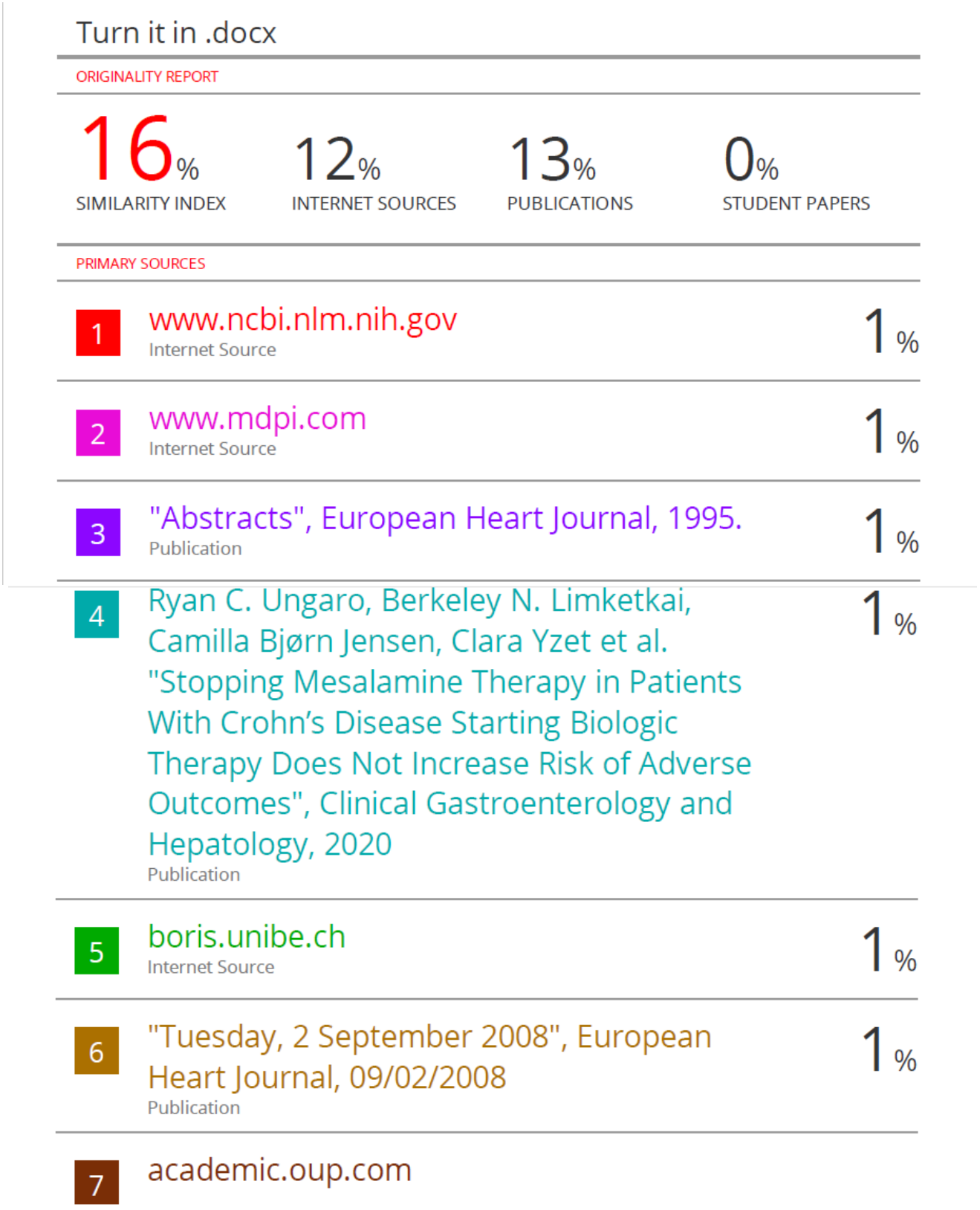

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