Master of Science in Surgical Care Practice

Validity and reliability of radial artery assessment techniques in coronary artery bypass grafting

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A SYSTEMATIC REVIEW

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Contents

List of tables and figures

List of abbreviations

A-V	arterio-venous
CABG	coronary artery bypass graft
CAD	coronary artery disease
CHC	collateral hand circulation
ETS	endoscopic thoracic sympathectomy
GSV	greater saphenous vein
HCP	healthcare professionals
IHD	ischaemic heart disease
LAD	left anterior descending
LITA	left internal thoracic artery
MAT	modified Allen test
MDCT	multidetector computed tomography
MeSH	Medical Subject Headings
PI	perfusion index
PICO	Population/Problem Intervention Comparison Outcome
PPG	photo-plethysmography
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	international prospective register of systematic reviews
RA	radial artery
RAs	radial arteries
RCT	randomised controlled trial
SR	systematic review
WMA	World Medical Association

Abstract

Background: Validity and reliability of radial artery (RA) assessment techniques, during coronary artery bypass grafting (CABG), has been at the heart of debates for the last decades. The correct RA assessment is crucial prior their surgical harvesting to avoid post-operative complications.

Objectives: This research aims to evaluate and compare validity and reliability of the most commonly adopted RA assessment techniques in CABG surgery.

Data sources: A literature search was undertaken, through five electronic databases, to access recent studies relating the assessment of RAs prior their surgical harvesting during CABG.

Review methodology: A systematic review (SR) was conducted to appraise relevant primary research studies published in English language between 2010 and 2020. Data findings were extracted for analysis, quantitative synthesis and conclusions drawn.

Results: Nine studies were included. Modified Allen test (MAT) presenting with reduced validity and/or reliability was revealed by seven studies. Pulse-oximetry and plethysmography, used in combination with the MAT, offer more objective results than an isolated MAT. Ultrasonography provides important insight into the morphological characteristics of RAs.

Conclusion: Outcomes of this SR suggest ultrasonography screening to be superior in RA assessment for both validity and reliability; however high-quality research is required to support these findings.

Keywords: ultrasonography, modified Allen test, pulse-oximetry, plethysmography, radial artery

BACKGROUND, AIMS AND OBJECTIVES

1. Introduction

The optimal conduit selection for coronary artery bypass graft (CABG) surgery has been widely investigated during the development of this surgical procedure. The gold-standard in CABG was identified in the use of the left internal thoracic artery (LITA) grafted onto the left anterior descending (LAD) coronary artery. The seminal study suggesting this surgical approach was produced as long ago as 1986 (Loop, et al., 1986). Nonetheless, in more recent years Cuminetti, et al. (2017) confirmed that this remains. For multivessel CABG other conduits, harvested elsewhere in the body, may be used as potential grafts. Although revascularisation using venous conduits, particularly the greater saphenous vein (GSV), remains a well-established common practice, the literature suggests arterial grafting to be superior for long-term graft patency, clinical outcomes and survival rates (Aldea, et al., 2016; D'Agostino, et al., 2018). Consequently, the radial artery (RA) is considered one of the first graft choices.

With radial arteries (RAs) becoming more frequently adopted during CABG, the assessment of these vessels, prior their surgical harvesting, appears to be of vital importance to avoid post-operative hand ischaemic complications and unnecessary surgical exposure. Nonetheless, validity and reliability of screening techniques, normally adopted for the morphological and functional assessment of RAs, is the object of current debate and their use remains ambiguous and contradictory (Habib, Baetz and Satiani, 2012). There is no protocol or guideline recommending the most effective assessment technique: the choice for the most accurate and consistent screening technique is yet to be determined.

This research aims to evaluate the most commonly adopted RA assessment techniques and compare their reliability and generalisability. Recommendation on the most valid and reliable screening test may be provided, hence the potential to minimise post-operative acute and chronic complications, including: infections, ischaemia and hand impairment in patients undergoing RA harvesting during CABG surgery.

2. Background literature

The World Health Organisation (2018) classified cardiovascular diseases as the leading cause of death worldwide, with ischaemic heart disease (IHD) being the most prevalent. According to the British Heart Foundation (2020) latest reports, IHD caused 9.43 million deaths globally in 2016. This is a cardiac disorder caused by atherosclerosis: a chronic degenerative process of the coronary arteries which results in the coronary artery disease (CAD). Coronary artery bypass graft surgery is considered the best therapeutic strategy against CAD, yet the most common cardiac operation worldwide (Melly, et al., 2018). Coronary artery bypass surgery has undergone significant changes since its first introduction in 1967. Not only have surgical techniques been developed and perfected over the years, but also conduit graft choices have been reconsidered (Squiers and Mack, 2018). Radial arteries for example, were originally seldom used, due to high rates of early graft failure and intimal hyperplasia. However, with the implementation of pharmacological interventions, such as the use of vasodilators to minimise the risk of RA spasm, and improvement in the harvesting techniques, RAs were reconsidered as optimum grafts for coronary revascularisation (Tatoulis and Schwann, 2018). They are one of best possible graft conduits in fact, second only to the internal thoracic arteries (Yadava, et al., 2016). Not only have RA conduits shown superior patency rates than saphenous vein grafts, but they are also considered easy to harvest, due to their anatomical location. Nonetheless,

the function of this vessel, along with the ulnar artery, is extremely important in the blood supply of the hand. Therefore, RA harvest may alter vascular and neurological normal physiology, thus producing devastating results, yet causing considerable morbidity and impairment (Blitz, Osterday and Brodman, 2013). Moreover, peripheral arterial calcification involving RAs is another aspect to consider while planning for the harvesting of these vessels: it may compromise the long-term graft patency, thus impacting on patient's survival after CABG (Watchmaker, Watchmaker and Watchmaker, 2019). All the above emphasises the imperative need for the correct morphological and functional RA assessment prior to proceed with their surgical harvesting.

In recent years, the steady increase in the use of RA grafts, has established the necessity to investigate the best assessment technique, improving surgery outcome and standards of care (Cuminetti, et al., 2017). Nevertheless, in current clinical practice, RA assessment protocol varies, depending on local institutional policy or surgeon's preferences. The assessment technique choice ranges from the pre-operative modified Allen test (MAT), to the intra-operative use of a pulse-oximetry to measure oxygen saturation changes, after invasive occlusion of RA. Other institutions use the squirt test, in which blood flow is visually inspected after invasive occlusion and surgical incision of the distal RA segment (Habib, Baetz and Satiani, 2012). The inconsistency of a universally agreed approach, the adoption of invasive and non-measurable, hence subjective, techniques underline the lack of an evidence-based practice, indicating the urgent need for further research.

The availability of up to date systematic reviews, related to the research topic, was investigated, consulting the international prospective register of systematic reviews (PROSPERO) and Cochrane database. The only study found, focused on the reliability of the MAT and the incidence of acute hand ischaemia after RA puncture. It does not consider the irreversible and major complications secondary to the surgical harvesting of

RAs during CABG, which will form the rationale for this SR. Moreover, it does not reflect on the use of additional assessment techniques other than the MAT.

A scoping review was undertaken to appraise published literature and have a clear understanding of current knowledge relating to the research topic.

Available screening tests have been widely investigated with the aim to determine their validity/reliability. Nonetheless, primary research studies conducted in the last decade, presented with inconsistent results, thus highlighting a controversial approach in the RA assessment. The most commonly discussed techniques within the current literature include: MAT, ultrasonography, pulse-oximetry and digital plethysmography. In addition to the above, other assessment techniques, such as: angiography hand arteriogram, computed tomography angiography, intraoperative pressure measurement, laser speckle contrast analysis and manual or histopathology based morphometry were also documented within the literature. However, these were more sporadically adopted or used in combination with MAT or ultrasonography to determine their validity and reliability.

The Allen test was the first developed screening technique to assess the capacity of the blood supply to the hand, in the event of RA procedures, which would have temporarily or permanently compromised RA blood flow. These procedures include: arterial puncture for blood gas sampling, catheterisation for percutaneous coronary interventions, or harvesting during CABG surgery or formation of a radio-cephalic arteriovenous fistula for haemodialysis access (Zisquit and Nedeff, 2019). In 1952, twenty-three years after its first introduction, the practice on how to perform the Allen test was reviewed by Irving Wright, with the aim to promote more objective results. It was therefore renamed the modified Allen test (Zisquit and Nedeff, 2019).

The modified Allen test, being considered a cost effective and time efficient technique, represents the most common RA screening test (Sivaharini, Babu and Mohanraj, 2018).

Although MAT was identified to be a safe, adequate and simple technique to perform (Ronald, Patel and Dunning, 2005; Yadava, et al., 2015), it was later confirmed to be prone to observer biases, thus emphasising its subjectivity (Altinsoy, et al., 2017). Furthermore, MAT presents with limited sensitivity and specificity, hence showing significant false-negative and false-positive results (Kohonen, et al., 2010; Gokhroo, et al., 2016; Altinsoy, et al., 2017; Zhang, et al., 2020). Therefore, there are some studies suggesting the combined use of MAT with pulse-oximetry or digital plethysmography, in order to overcome common MAT limitations. Specifically, their use aims to determine a more quantifiable and objective result, hence a more accurate RA assessment, yet avoiding more expensive and time consuming techniques (Al-metwalli, 2014; Elwali and Moussavi, 2020).

Conversely, the use of ultrasonography was supported by several trials as it enables the selection of the best quality RA segment. Furthermore, it allows a wider morphological and physiological assessment of RAs, hence the potential to minimise unnecessary surgical exposure and post-operative ischaemic complications (Yadava, et al., 2016; Vukovic, et al., 2017). Ultrasonography was in fact recognised as an accurate method to assess anatomical aspects of RAs, predicting stenosis and structural variation of the vessel, thus facilitating the early detection of intraluminal atherosclerotic plaques. Moreover, it permits the inner diameter measurement of the vessel and the estimation of blood flow within forearm major arteries, thus predicting radial/ulnar dominance and avoiding hand ischaemia (Yadava, et al., 2016). Despite the efficiency in the functional assessment of RAs, ultrasound was considered a time consuming and expensive technique, also requiring examiners' advanced skills. Therefore, ultrsonography use was questionable and not always justified (Yadava, et al., 2015).

The correct pre-operative RA assessment may have a positive impact on both short and long-term surgical outcomes, reducing mortality and morbidity rates after CABG surgery. The identification of the best RA assessment technique may contribute to a higher quality of patient-centred care.

3. Research aims and objectives

Research aims:

- To evaluate and compare screening techniques in assessing radial artery quality for use in coronary revascularisation
- To recommend the most accurate and reliable test within cardiac institutions, reinforcing evidence-based practice

Research objectives:

- To establish the validity and reliability of the MAT, pulse-oximetry, plethysmography and ultrasonography
- To determine if screening test choice has a significant impact on the outcome of surgical treatment

4. The research question

The research question was formulated as following:

Is ultrasonography more accurate and reliable than the modified Allen test, pulse-oximetry and plethysmography, in radial artery assessment for patients undergoing coronary revascularisation?

METHODOLOGY AND PROTOCOL

5. Research design

The literature review, performed in relation to the research topic, revealed contradictory findings from the primary research studies undertaken. A systematic review represents the most efficient methodology to compare the findings of several primary studies, answering the same research question. It enables the reviewer to systematically collect and critically appraise published literature, extract and analyse data to produce a synthesis (Boland, Cherry and Dickson, 2017). A systematic review was therefore considered the most appropriate approach to answer the research question, yet producing evidence-based knowledge and highlight the gaps within the literature, which would eventually require further research. Moreover, an SR methodology allows the appraisal of different study designs and a larger variety of populations, however avoiding concerns on the generalisability determined by sample size when conducting a primary research study. Furthermore, standards of clarity, rigor and replication are not compromised (Kane, Butler and Ng, 2016).

This systematic review includes primary research studies with a quantitative nature. Numerical data will be extracted, interpreted and synthesised from all selected studies, through clear prescriptive steps, and a systematic review, with a quantitative design, will be presented. Research studies with a quantitative methodological philosophy are epistemologically grounded in positivism (Creswell and Creswell, 2018). This is considered an objective and scientific paradigm. It refers to an experimental approach of collecting data; as a consequence, results are not influenced by participants' judgements and experiences (Kivunja and Kuyini, 2017). Collecting and analysing empirical data, a quantitative synthesis is produced, to answer the research question formulated, thus

providing an important insight into the choice of most valid and reliable RA assessment technique, thus impacting clinical practice.

6. Search strategy

A comprehensive search of all available literature was performed and a scoping review undertaken. A high quality review is in fact performed by appraising all available evidence, relating to the research question (Parahoo, 2014). Therefore, primary and secondary research, abstracts, as well as grey literature and conference proceedings were considered, and available data searched adopting a pragmatic and systematic approach.

Five electronic databases were consulted to retrieve studies, published between 2010 and 2020, considering RA assessment techniques during CABG surgery, including: MEDLINE, PubMed, CINAHL, SCOPUS and Embase. These databases were specifically selected as they provide relevant resources relating to biomedical health sciences, yet pertaining to the research subject. MEDLINE and PubMed are two search platforms offering over twenty-seven million biomedical and life science related records. The CINAHL database provides nursing and allied health literature. SCOPUS is considered the largest platform for peer-reviewed abstract literature linked with technology, medicine and social science fields. Embase is an electronic database covering international biomedical literature (Parahoo, 2014). The full-text of studies unavailable on the mentioned databases was obtained from the British Library, the academic institution library and the reviewer's clinical institution research department.

The selection of keywords in the Medical Subject Headings (MeSH) terms, Boolean search operators (AND, OR) and word truncation (asterisk wildcard) are of fundamental importance to combine and retrieve variants of a word stem (Baumann, 2016). The MeSH terms adopted are reported in table 1.

Table 1: Database searches

Searches	MeSH terms
S1	Doppler *OR* ultrasound *OR* ultrasonograph* *OR* sonograph* *OR* sonogram *OR* Duplex *OR* mapping *OR* vein map*
S2	modified Allen test *OR* Allen test *OR* Allen*
S3	pulse oximet* *OR* oximet*
S4	plethysmograp* *OR* photoplethysmograp* *OR* PPG
S5	radial arter* *OR* forearm arter* *OR* ulnar arter*
S6	CABG *OR* coronary artery bypass graft* *OR* coronary bypass *OR* coronary revascularisation *OR* cardiac surgery *OR* heart surgery

Four combined searches were performed, in every database, including above MeSH terms and following the strategy highlighted in table 2, producing more relevant search results.

Table 2: Database search strategy

1.	**S1** *AND* **S5** *AND* **S6**
2.	**S2** *AND* **S5** *AND* **S6**
3.	**S3** *AND* **S5** *AND* **S6**
4.	**S4** *AND* **S5** *AND* **S6**

This allowed the combination of different key-words, including:

- one RA assessment technique
- forearm arteries
- coronary artery bypass grafting

An overview of the four combined searches is presented in table 3.

Table 3: Combined database searches

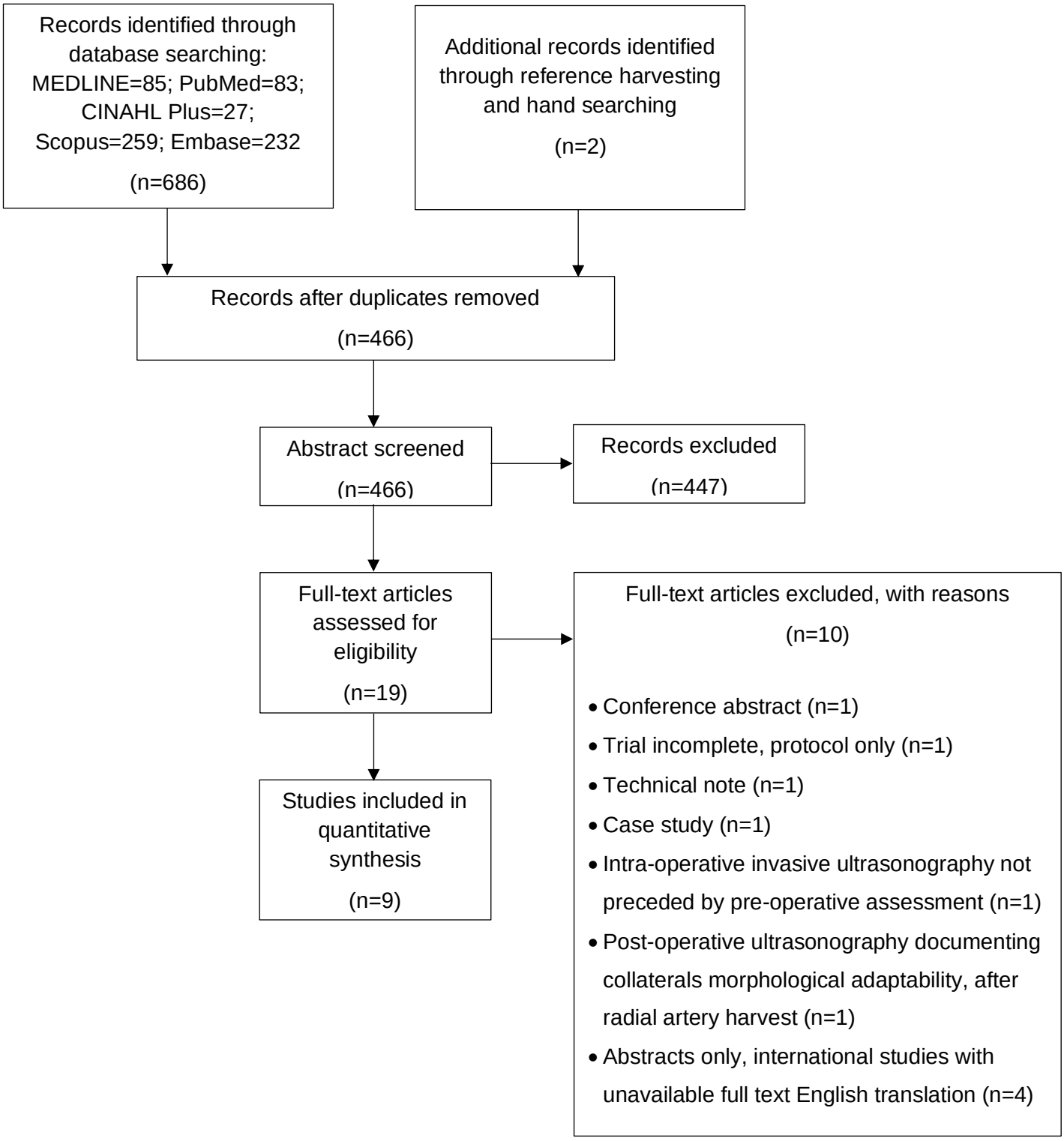
Searches	Screening techniques	Conduit		Surgery	
1.	Doppler **OR** ultrasound **OR** ultrasonograph* **OR** sonograph* **OR** sonogram **OR** Duplex **OR** mapping **OR** vein map*	**AND**	radial arter* **OR** forearm arter* **OR** ulnar arter*	**AND**	CABG **OR** coronary artery bypass graft* **OR** coronary bypass **OR** coronary revascularisation **OR** cardiac surgery **OR** heart surgery
2.	modified Allen test **OR** Allen test **OR** Allen*				
3.	pulse oximet* **OR** oximet*				
4.	plethysmograp* **OR** photoplethysmograp* **OR** PPG				

Results of the database searches are reported in appendix A.

Additional records were identified through reference harvesting and hand searching of relevant specialist journals. Complimentary searches were conducted in Google Scholar and ProQuest, allowing the author to search the grey literature to retrieve any other studies, abstracts, theses and conference proceedings, with the aim to identify further resources answering the research question.

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart (*Figure 1*) was used to retrace the steps of the search process undertaken, yet highlighting the search outcome (Moher, et al., 2015). Initially, 686 articles were retrieved from the database searches, 2 additional articles were identified through reference harvesting and hand searching. Duplicates were removed using RefWorks software, leaving 466 articles. Abstract were screened and full-text reviewed, removing 447 and 10 articles respectively. Nine articles were included in the quantitative synthesis.

Figure 1. PRISMA Flowchart of search process



7. Study selection

Once all available articles were screened, a methodical and impartial study selection was performed. The first phase in the selection process involves the definition of a well-structured review question. Eriksen and Frandsen (2018) recommended the use of the PICO (Population/Problem Intervention Comparison Outcome) framework to formulate a research question. It is in fact a largely adopted tool in reviews with a quantitative design (Fain, 2017). Therefore, the research question of the presented SR was structured by using this model, as reported in table 4.

Table 4: PICO Framework for defining the Research Question

P	I	C	O
Population/Problem	Intervention	Comparison	Outcome
Adult patients undergoing CABG surgery	Pre-operative ultrasound mapping of the RA	Modified Allen test, pulse-oximetry and plethysmography	Accurate and reliable assessment of RAs

Inclusion and exclusion criteria were established and applied, narrowing the search results to those studies that specifically answered the research question, yet excluding less relevant evidence. Bettany-Saltikov (2016) suggests that high quality SRs are obtained by following this prerequisite. A rigorous study selection requires the definition of explicit and clear inclusion and exclusion criteria. These set out the boundaries and define the attributes for a study to be included. The PICO framework facilitates the selection of evidence-based resources (Watt and Eng, 2015). Therefore, the inclusion and exclusion criteria were established following the PICO system and they are presented in table 5 below.

Table 5: Inclusion and Exclusion Criteria

Inclusion criteria	Rationale	Exclusion criteria
• All adult patients requiring pre-operative RA assessment for elective or urgent CABG surgery*	Elective CABG surgery rates peak in the late 70s. Aging population is considered a risk factor of CAD (Royal College of Surgeons, 2012). During emergency situations, the pre-operative RA assessment may be compromised: limited time may be available prior a rapid harvesting procedure is undertaken.	• Children (patients aged under 18) • Emergency CABG
• Pre-operative ultrasound mapping of the RA • Assessment of morphological and functional characteristics of the forearm arteries through Doppler ultrasound	Exposure of RA not preceded by pre-operative assessment may lead to the non-usability of the vessel if RA is defined unsuitable for coronary graft, yet causing surgical consequences for the patient. Documenting post-operative anatomical adaptability of major forearm arteries after RA harvesting is not considered within the objectives of this SR.	• Intra-operative invasive ultrasonography only, determining vessel exposure • Post-operative ultrasonography used to document collateral morphological adaptability after RA harvest
• Allen test or Modified Allen test (MAT) • Pulse-oximetry • Plethysmography	The rationale for this research project is to compare the most conventional and documented assessment techniques within the literature.	• Techniques other than: Doppler ultrasonography, Allen test, MAT, Pulse-oximetry, Plethysmography** • Intra-operative techniques only, determining forearm vessels exposure, not preceded by any pre-operative assessment
• Accurate and reliable assessment of RAs potentially selected as grafts for coronary revascularisation	Radial artery assessment is commonly undertaken prior to several RA procedures. It is largely documented within cardiology (percutaneous coronary intervention) and vascular surgery (arterio-venous (A-V) fistula).	• Assessment of RAs prior: arterial puncture for blood gas analysis, cannulation, angiography or A-V fistula
• All primary research studies published in peer-reviewed journals between 2010 and 2020*** • English language only	The focus will be on most recent and up to date presented trials only.	• Studies written in another language, with English translation not provided • Studies published before 2010

* Primary research studies where participants are assessed for potential future CABG/RA harvest will be appraised and eventually included in the SR.

** Studies where other techniques are used in combination with the above will be appraised and eventually included in the SR.

*** Including randomised controlled trials (RCT), case-control and cohort studies.

Applying inclusion and exclusion criteria to the 19 articles, resulted in 10 being excluded with reasons (appendix B). The remaining 9 articles were selected for the quantitative synthesis.

8. Critical appraisal

The nine remaining primary research studies were critically appraised and their quality assessed. Downes, et al. (2016) emphasised the importance of critical appraisal in the design, analysis and reporting of a research study, prior to implementation in clinical practice. Assessing research quality is an aspect of vital importance, as it enables the reviewer to investigate if a study was conducted applying the appropriate measures to minimise bias, thus increasing the standard. Similarly, the quality of the studies will impact on the quality of the systematic review (Boland, Cherry and Dickson, 2017). Therefore, a rigorous quality assessment is required, as it may influence the systematic review shape, conclusion and outcome. According to Heale and Twycross (2015), appraising rigour in quantitative studies is obtained by measuring validity and reliability, hence assessing the accuracy and the consistency of the results. Moreover, reproducibility and generalisability of the studies are other important parameters, to highlight their trustworthy (Saunders, Lewis and Thornhill, 2019). Generally, articles published in peer-reviewed journal are expected to be robust in their design and conclusions drawn. However, their quality level may vary; therefore, a comprehensive quality appraisal is recommended to evaluate strengths and limitations of the studies.

The nine studies included in this SR were critically appraised through a validated and updated quality assessment tool: the modified Downs and Black checklist (appendix C). This checklist was considered the most appropriate tool, allowing the assessment of both randomised and non-randomised research studies, of healthcare interventions, presenting

with a quantitative methodological approach (Downs and Black, 1998). Validity and reliability of this scale were evaluated to be appropriate by the National Collaborating Centre for Methods and Tools. Overall, this scale obtained a strong methodological rating (National Collaborating Centre for Methods and Tools, 2020). Acknowledged to be applicable to the retrieved studies and not compromising the standards of the review process, the modified Downs and Black checklist was adopted within this SR. Outcome of the critically appraised studies are presented in the results section of this SR (table 8).

9. Ethical appraisal

Activities performed in a clinical environment respect the ethical mandate to promote wellbeing to people receiving care. Healthcare professionals (HCP) abide by their code of ethics and professional conduct, constantly respecting this principle (Nursing and Midwifery Council, 2018). Consequently, primary research studies, conducted on healthcare interventions, must respect the same ethical mandate. Therefore, ethical approval must be obtained by the Research Ethics Committee prior to undertake primary researches (Polit, 2017). A systematic review is considered the highest level of research design in the hierarchy of evidence (Murad, et al., 2016; Thoma, et al., 2019). However, it does not undertake primary research, and therefore, no ethical approval is required. Nonetheless, complying with academic regulations, the Faculty Research Ethics Panel of the university was informed prior to commencing this SR. A stage 1 Research Ethics Application Form (appendix D) was completed and submitted to the faculty along with evidence confirming the successful completion of the Research and Professional Ethics online course (appendix E).

Research on healthcare interventions is regulated by common law, other than by professional regulatory bodies, including the General Medical Council (General Medical

Council, 2000) and the Medical Research Council (Medical Research Council, 2007), and different statutes, such as the Human Rights Act 1998 and the Mental Capacity Act 2005. All the above ensure medical practice meets ethically approved criteria of safeguarding rights of health, safety and wellbeing of patients keen to participate in research studies. Researchers' enthusiasm and the interest of the society must never prevail over the wellbeing, security and interests of participants (Al Tajir, 2018).

Decision making in healthcare research is influenced by the ethical principles of autonomy, beneficence, non-maleficence, justice, fidelity, veracity and confidentiality (Parahoo, 2014). Considering these principles, researchers balance the risk of harm and the potential benefit produced by the research process. Safety of participants must never be compromised and risk of harm maintained at minimal level, regardless of the benefits brought from the research to the community. Similarly, researchers owe the duty to inform participants regarding the aim of the study, what his/her involvement will lead to. Furthermore, risks and benefits of the research must be disclosed. A study respecting these ethical principles is recognised as high quality evidence (Parahoo, 2014).

A further regulation to orientate HCP's practice, in the field of medical research, is represented by the Declaration of Helsinki. This is a statement of ethical principles, produced by the World Medical Association (WMA), providing directives to HCP on how to conduct healthcare research involving human subjects (WMA, 2018). Primary research studies, included in this SR, replicated these principles.

The nine articles included in this SR were critically appraised to establish their ethical quality, other than the rigour adopted in their research process. The ethical appraisal involved the assessment of whether these studies sought ethical approval by a Research Ethics Committee and if voluntary and informed consent was gained by all participants.

All studies clearly respected anonymity, privacy and confidentiality of participants, throughout the research. However, three out of the nine studies did not have documented ethical approval and/or consent statements from participants. One of these studies (Zhang, et al., 2020) had a retrospective nature; hence data were collected from clinical databases. In these circumstances it is rather difficult to gain patient consent. Therefore, Ethics Committees investigate if such research is sufficiently valid to justify the breach of autonomy, yet establishing the absence of any other alternatives to perform the research (Hope, Savulescu and Hendrick, 2008). In this study patient consent was waived, however ethical approval was granted by the Ethics Committee.

Wu, et al. (2019) revealed that reporting of ethical consideration in peer-reviewed international journals is currently developing compared to earlier years, when ethical standards were not clearly defined, and therefore, many clinical trials did not report ethical considerations. However, improvements are required as this tendency is still a matter of concern: as evidence of ethical review are sometimes still omitted (Wu, et al., 2019). This would suggest incomplete reporting from Kohonen, et al. (2010) and Gokhroo, et al. (2016), which however does not mean ethical principles were not respected or ethical approval not granted. Outcomes of the ethical appraisal process are reported in table 6.

Table 6: Ethical approval and participant consent statement

Authors	Year	Ethical approval	Participant consent
Kohonen, et al.	2010	x	x
Al-metwalli	2014	✓	✓
Yadava, et al.	2015	✓	✓
Gokhroo, et al.	2016	x	✓
Yadava, et al.	2016	✓	✓
Altinsoy, et al.	2017	✓	✓
Vukovic, et al.	2017	✓	✓
Elwali and Moussavi	2020	✓	✓
Zhang, et al.	2020	✓	x

✓ Ethical approval/participant consent statement declared

x Ethical approval/participant consent statement not mentioned

10. Data extraction

Data extraction process was performed, following the appraisal of rigour and ethical assessment of the selected studies. It is considered beneficial to undertake quality assessment first, as exclusion of primary studies with poor quality, may avoid unnecessary data extraction (Fleeman and Dundar, 2017).

The aim of the data extraction is to summarise and present relevant data addressing and relating to the research question (Boland, Cherry and Dickson, 2017). A bespoke data table was designed and piloted to facilitate collection of both descriptive and analytical data, to highlight study characteristics and outcomes.

Table 7: Data extraction tool

Study characteristics data extraction form	
Study author	
Year	
Study design	
Population and sample size	
Intervention	
Comparison	
Key results	
Primary conclusion	

Data extraction was conducted by the reviewer independently; however accuracy of the process was monitored by the reviewer's academic supervisor. It is recommended that a cross-check is conducted by two reviewers independently, in order to minimise errors and bias, yet determining more robust results (Büchter, Weise and Pieper, 2020). Similarly, contacting authors for clarification of missing data is another strategy with the potential to improve the quality of the review.

Variables to extract from the studies were identified. Dependent variables were represented by: intra-operative findings (pressure measurement, manual morphometry), post-operative findings (histopathology based morphometry), morphological examination through Doppler ultrasound, forearm/hand arteriogram and computed tomography angiography of upper limbs. Independent variables include the use of ultrasonography, modified Allen test, pulse oximetry or plethysmography during RA assessment.

11. Data analysis

Different methods may be used in a SR to analyse, summarise and present data extracted from primary researches. These include meta-analysis, meta-synthesis and narrative analysis (Siddaway, Wood and Hedges, 2019). Meta-analysis is a statistical method able to derive conclusions with a low margin of error, as suggested by Gurnsey (2017). However, it may only be performed if extracted data is sufficiently similar, thus the combination of primary research appears a sensible process to undertake. According to Denscombe (2012) the use of descriptive statistical analysis, if conducted with rigour and transparency, is a valid strategy to present data and findings of primary studies. Therefore, a meta-analysis is not an essential component of a review, as corroborated by Boland, Cherry and Dickson (2017).

The heterogeneity of studies characteristics, the diversity in their adopted protocols and the inconsistency of research outcomes precluded the combination of extracted data, thus preventing the use of a statistical analysis. The reviewer opted for an alternative analyses method: a narrative synthesis is presented.

RESULTS AND DISCUSSION

12. Results

After applying inclusion and exclusion criteria to the findings of the literature search, nine primary research studies were selected for the final review. These studies were consequently critically appraised through the modified Downs and Black checklist for their quality assessment (appendix C), where results are synthesised in table 8. Study characteristics and outcomes were collected using the piloted data extraction tool. Findings were combined and presented in table 9. Furthermore, ethical considerations, bias and limitations were considered for each study.

The Downs and Black checklist was firstly developed in 1998, with the aim to produce a valid and reliable quality assessment scale to appraise randomised and non-randomised trials (Downs and Black, 1998). A modified version of the checklist was then proposed, which nowadays appears more largely adopted (Hooper, et al., 2008; Trac, et al., 2016). It consists of 27 specific questions, divided in five subscales: Reporting; External validity; Internal validity - bias; Internal validity - confounding; Power. Answers may be: “Yes”, “No”, “Partially” (only for question 5) and “Unable to determine” (only for questions 11-26). The highest possible score for the checklist is 28. Four studies were assessed as Fair quality and five studies were considered Good quality. Quality index for each subscale was measured in all nine studies (*Figure 2a*) and the proportion of studies with high, medium and low quality index for each subscale is presented (*Figure 2b*).

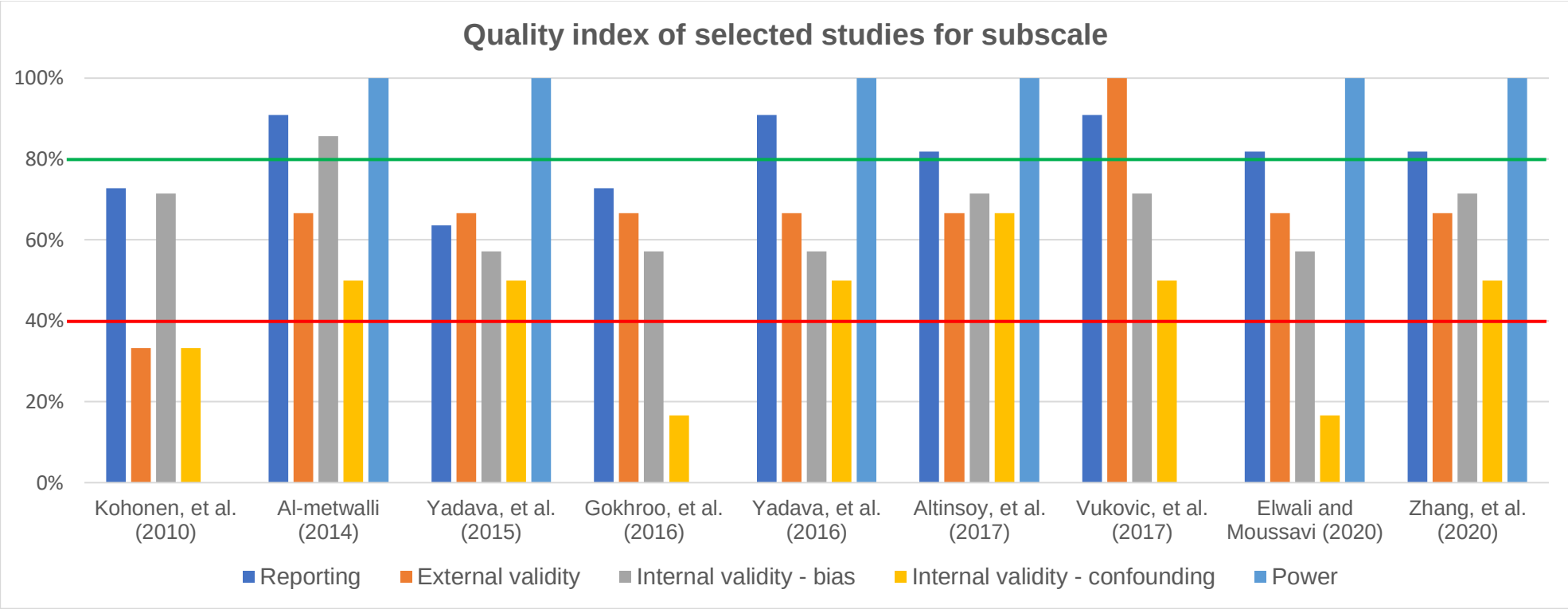
Table 8: Quality levels of selected studies

Authors	Year	Measurements taken					Grade of quality of the trial through Modified Downs and Black
		Ultrasonography	Allen test / MAT	Pulse-oximetry	Plethysmography	Other	
Kohonen, et al.	2010	✓	✓		✓	Intraoperative pressure measurement	Fair (16/28)
Al-metwalli	2014	✓	✓	✓			Good (22/28)
Yadava, et al.	2015	✓	✓			Histopathological examination	Fair (17/28)
Gokhroo, et al.	2016		✓			Angiography arteriogram	Fair (15/28)
Yadava, et al.	2016	✓				Manual morphometry; histopathology based morphometry	Good (20/28)
Altinsoy, et al.	2017		✓			Multidetector computed tomography angiography	Good (21/28)
Vukovic, et al.	2017	✓	✓	✓			Good (21/28)
Elwali and Moussavi	2020		✓		✓		Fair (17/28)
Zhang, et al.	2020	✓	✓				Good (20/28)

Modified Downs and Black score ranges were attributed as previously documented (Hooper, et al., 2008; Trac, et al., 2016):

- Excellent (26-28)
- Good (20-25)
- Fair (15-19)
- Poor (≤14)

Figure 2a. Quality index for subscale

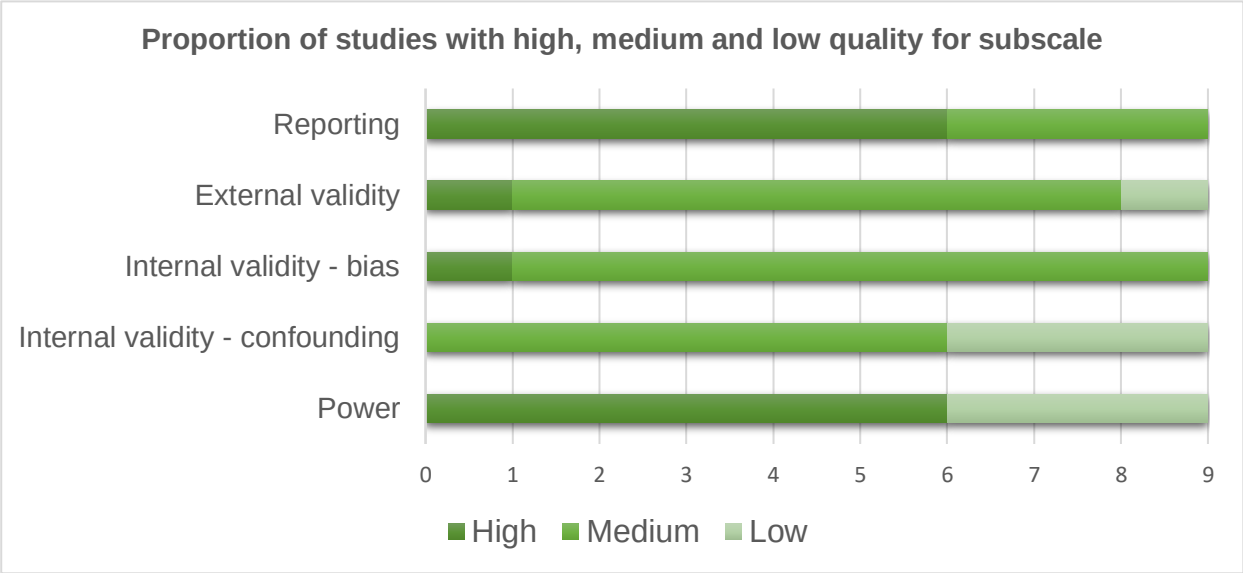


Power subscale ranges 0-1: it is not shown on the histogram if statistical significance ($p<0.05$) was not reached from the study.

The quality index for each subscale was measured, and studies were considered of:

- HIGH quality index for subscale (if score ≥80%)
- MEDIUM quality index for subscale (if 40%<score<80%)
- LOW quality index for subscale (if score ≤40%).

Figure 2b. Quality index proportions



All studies present with a research protocol linked with the research question of this review and overall, their quality was satisfactory.

A summary of trial characteristics and outcomes is reproduced in table 9 below.

The nine primary research studies, all single centre trials, were undertaken between 2002 and 2019, with their publications dated from 2010 to 2020. Eight studies adopted a prospective methodology and presented the following study designs: four observational studies; one cohort study; one randomised trial; one randomised controlled trial; one pilot study. Only one study adopted a retrospective cohort data analysis from a previously conducted observational trial. Sample size of the studies ranges from 11 to 536 participants, whose characteristics are presented in table 10.

Table 9: Summary of selected studies

Study author	Year	Study design	Population and sample size	Intervention	Comparison	Key results	Primary conclusion
Kohonen, et al.	2010	Prospective cohort study	Adult patients undergoing elective CABG surgery (N=90)	Allen test, Doppler ultrasonography and plethysmography of second and fourth digit performed pre-operatively.	Pressure measurement taken intra-operatively at the distal end during proximal occlusion of RA.	Ten patients presented with a positive Allen test. In five of these patients intra-operative pressure measurement demonstrated harvestable RA. Doppler signal was not audible in 24 patients during RA compression, suggesting non usability of RA.	Allen test may present with false positive results. Intraoperative pressure measurement is suggested when no metric screening tests are available.
Al-metwalli	2014	Prospective randomised controlled trial	Adult operating room's staff undergoing RA assessment for potential future CABG and RA harvest (N=42)	Modified Allen test, pulse-oximetry and perfusion index test performed on both hands (84 hands assessed).	Doppler ultrasonography examination.	MAT presented with positive results, hence showing abnormal CHC, in 16 hands. Doppler ultrasonography diagnosed abnormal CHC in 3 hands. Pulse-oximetry method indicated abnormal CHC in 4 hands.	Using Doppler ultrasound as a reference test, PI (combination of MAT and pulse-oximetry) is a valid objective test for diagnosis of abnormal CHC with high sensitivity, specificity and accepted PPV (75.5%).
Yadava, et al.	2015	Prospective observational study	Adult patients undergoing elective CABG surgery, with RA being one of the graft conduits (N=100)	Modified Allen test and Doppler ultrasonography performed pre-operatively.	Post-operative histopathological examination of proximal and distal RA segments.	Doppler ultrasound presented with false-positive (3%) and false-negative (2%) rates, for calcification and atherosclerosis investigation of RA, as confirmed by histopathological examination.	Routine ultrasonography examination of RA is not justified prior to RA harvest. Allen test can be safely used prior to RA harvest as for easier reproducibility and interpretation of their results.
Gokhroo, et al.	2016	Prospective observational study	Patients undergoing RA assessment for potential future CABG and RA harvest (N=302)	Modified Allen test.	Forearm and hand arteriograms obtained through angiography examination.	MAT presented with negative results in all patients, thus suggesting harvestable RA. Angiography examination identified 30-40% of patients presenting with atherosclerotic changes, therefore considered highly susceptible for digital ischaemia in the event of RA harvest.	Isolated MAT is not sufficient for documenting CHC, prior to any RA radical procedure. It should be supplemented by other tests.

Yadava, et al.	2016	Prospective observational study	Adult patients undergoing elective CABG surgery, with RA being one of the graft conduits (N=100)	Doppler ultrasonography performed pre-operatively.	Intra-operative manual morphometry and post-operative histopathology based morphometry.	Bland-Altman analysis showed a good correlation between Doppler ultrasonography, morphometry and histopathology for intimal and medial thicknesses, with a 95% limit of agreement.	Ultrasound is an accurate technique to evaluate wall thickness and inner diameter of RAs.
Altinsoy, et al.	2017	Prospective randomised trial	Adult patients undergoing total arterial CABG surgery (N=55)	Allen test and modified Allen test pre-operatively on both hands (110 examinations performed).	Multidetector computed tomography angiography of upper limbs.	RA occlusive disease confirmed in six patients, through MDCT angiography, not measurable with positive Allen test or MAT results.	Allen test presents with false negative results; MAT is a subjective test.
Vukovic, et al.	2017	Prospective observational study	Patients candidates for CABG, with RA being one of the graft conduits (N=536)	Ultrasonography investigation assessing ulnar peak systolic flow velocity with compression of RA, Allen test and pulse-oximetry performed pre-operatively.	Ultrasonography examination assessing morphological characteristics at proximal, middle and distal segments of the RA.	Positive Allen test / abnormal pulse oximetry results were identified in 9 patients. Ultrasonography showed the presence of diffuse morphological abnormalities (inner diameter <2mm, atherosclerosis, calcifications, severe hyperplasia) in 71 patients.	Ultrasound provides complete morphological RA assessment with selection of the best segment.
Elwali and Moussavi	2020	Prospective pilot study	Adult participants undergoing RA assessment for potential future CABG and RA harvest (N=11)	Modified Allen test.	Photo-plethysmography measurement of the thumb and little fingers.	PPG showed congruent results with anatomy of blood circulation. MAT presented with negative result (harvestable RA) in all participants. PPG revealed elevated risk of accessing RA in 8 participants.	PPG may provide indications on the hand blood circulation and recommendation on the use of RA grafts in CABG.
Zhang, et al.	2020	Retrospective cohort study	Patients undergoing forearm arteries assessment for potential future CABG and RA harvest (N=164)	Ultrasonography examination of RA and UA and modified Allen test performed prior ETS.	Ultrasonography examination of RA and UA and modified Allen test performed after ETS.	ETS resulted in dilating RAs, as confirmed by ultrasound examination. Patients presenting with positive MAT prior ETS, revealed a transition to a negative result after ETS.	MAT may present with false negative results after ETS.

CABG – coronary artery bypass graft; CHC – collateral hand circulation; ETS – endoscopic thoracic sympathectomy; MAT – Modified Allen test; MDCT – multidetector computed tomography PI – perfusion index; PPG – Photo-plethysmography; PPV – positive predictive value; RA – radial artery; UA – ulnar artery.

Table 10: Population characteristics

Study author	Year	Sample size	Gender	Mean age ± SD (range)	Coronary risk factors						
					DM	Smoking	HTN	Dyslipidaemia	PVD	Stroke	KD
Kohonen, et al.	2010	N=90	74 M 16 F	62.4 ± 7.6 (44-75)	24 (26%)	39 (43%)	59%	88%	ND	ND	ND
Al-metwalli	2014	N=42	22 M 20 F	35.2 (23-44)	ND	ND	ND	ND	ND	ND	ND
Yadava, et al.	2015	N=100	ND	61.4 (44-80)	54	33	69	10	6	3	ND
Gokhroo, et al.	2016	N=302	189 M (62.6%)	58.59 ± 11.3	87 (28.8%)	135 (44.7%)	154 (50.9%)	154 (50.9%)	ND	ND	41 (13.6%)
Yadava, et al.	2016	N=100	79 M 21 F	61.45	54	33	69	10	6	3	ND
Altinsoy, et al.	2017	N=55	42 M (76.3%) 13 F (23.7%)	53.7 ± 8.3 (27-70)	45 (81.8%)	44 (80%)	28 (50.9%)	31 (56.3%)	8 (14.5%)	ND	4 (7.2%)
Vukovic, et al.	2017	N=536	464 M (86.6%)	59.4 ± 6.9	120 (22.4%)	386 (72%)	437 (81.6%)	324 (60.4%)	103 (19.2%)	ND	ND
Elwali and Moussavi	2020	N=11	7 M 4 F	26.5 ± 2.6	ND	ND	ND	ND	ND	ND	ND
Zhang, et al.	2020	N=164	74 M 90 F	24.987 ± 9.722 (M) 27.844 ± 10.564 (F)	1 M (1.4% M) 2 F (2.2% F)	19 M (25.7% M) 5 F (5.6% F)	4 M (5.4% M) 2 F (2.2% F)	1 M (1.4% M) 1 F (1.1% F)	1 M (1.4% M) 22 F (24.4% F)	ND	ND

DM – diabetes mellitus; F – female participants; HTN – hypertension; KD – kidney diseases; M – male participants; ND – not declared; PVD – peripheral vascular disease; SD – standard deviation.

In five studies (Kohonen, et al., 2010; Yadava, et al., 2015; Yadava, et al., 2016; Altinsoy, et al., 2017; Vukovic, et al., 2017) participants were adults patients undergoing elective CABG surgery, with their RAs being assessed as potential graft conduits for coronary revascularisation treatment. In the remaining four studies (Al-metwalli, 2014; Gokhroo, et al., 2016; Elwali and Moussavi, 2020; Zhang, et al., 2020) participants were adult individuals, undergoing RA assessment, in the event of future CABG and RA harvest procedure. Baseline demographic characteristics, including gender and mean age of participants, were specified in the majority of the studies, except for one study (Yadava, et al., 2015) in which gender of participants was not disclosed. Seven studies also reported detailed information regarding prevalence of major coronary risk factors among their study population.

Different RA assessment techniques were compared in the studies. Modified Allen test and ultrasonography resulted in the most commonly discussed, being investigated in eight and six trials respectively. Pulse-oximetry and plethysmography were also examined in two studies each. Moreover, six other assessment techniques were documented within five of the nine trials, however, with the aim to establish validity and reliability of the four previously mentioned screening techniques. These further tests include: intraoperative pressure measurement, histopathological examination, angiography arteriogram of forearm arteries, manual morphometry, histopathology based morphometry and multidetector computed tomography angiography.

The study from Yadava, et al. (2016) evaluated the morphological characteristics of RAs with three assessment techniques: pre-operative Doppler ultrasonography, intra-operative manual morphometry and post-operative histopathology based morphometry. A correlation was established among morphometric findings of tunica intima and tunica media thicknesses. The study revealed the accuracy of Doppler ultrasonography, validated

against histopathology examination, for providing reliable data on wall thickness and luminal diameter measures. Nonetheless, confounding factors were encountered, first among all, the histopathological confirmation of Doppler findings are only available for the distal and proximal segments of RAs. Moreover, this is the first study validating Doppler against histopathological examination of RAs during CABG surgery, and therefore results are not confirmed by other research. Nonetheless, a correlation between the two examinations, while assessing RA wall thickness, was performed within the context of haemodialysis patients for the formation of A-V fistula (Kim, et al., 2004).

Similarly, the study performed by Vukovic, et al. (2017) confirmed the findings from Yadava, et al. (2016), identifying ultrasound as an accurate technique in providing pre-operative quality assessment of RAs. It enables the examiner to select disease-free sections of RAs, thus promoting the surgical harvesting of best morphological segments of the vessel, thus improving CABG outcomes. Although this research adopted the same design as Yadava, et al. (2016), conducting a prospective observational study, the review question was addressed on a significantly larger population (N=536). Nonetheless, this trial did not conduct angiographic or morphometric follow-up examinations to prove the hypothesis that RAs with better morphological characteristics result in superior long-term graft patency. As a consequence, predictive value of the examination is not confirmed, neither the statistical significance documented.

Conversely, in 2015 Yadava and his team presented a study with discordant results. Comparing MAT with ultrasonography and histopathological examination of RAs extremities, the researchers analysed the predictive value, sensitivity and specificity of ultrasonography. They suggested that the use of ultrasonography was not justified prior to RA harvest, with the MAT recognised as a technique easy to perform, interpret and reproduce, yet emphasising that it is a safe isolated screening technique. In this study only

one reviewer was involved in the ultrasonography assessment of RAs, while it is not declared who performed the MAT, thus weakening the validity of the methodology adopted. Furthermore, the authors propose that the use of ultrasound should be limited to those patients presenting with positive MAT, which would suggest a non-harvestable RA, in order to exclude false-positive results. However, in this study ultrasonography was only implemented on patients presenting with negative MAT, thus preventing from revealing false-positive results. Another finding worth highlighting is that they advise ultrasound RA assessment not necessary in all cases, especially in countries with limited resources. This does not justify that people living in developing countries should receive inferior care.

In earlier years, Kohonen, et al. (2010) compared, through a prospective cohort study, the pre-operative Allen test and ultrasonography findings, with plethysmography of the second and fourth digits and invasive intra-operative blood pressure measurement. The authors revealed contradictory findings between Allen test and ultrasonography, highlighting the reduced specificity of the Allen test, which presents with significant false-positive results. Therefore, Kohonen, et al. (2010) suggest the use of intraoperative pressure measurement when Allen test is positive and no other objective metric techniques are available. Nonetheless, statistical significance was not reached to confirm this hypothesis. Another limitation of the study is represented by the relatively limited sample size (N=90). Follow up assessment was considered; however, this was conducted only in 19 patients. Moreover, a low quality index was measured for the external validity and internal validity-confounding subscales of the modified Downs and Black checklist (*Figure 2a*).

More recently, Gokhroo, et al. (2016) conducted a prospective observational study, relating MAT results to the forearm and hand angiography arteriograms, obtained from their study population (N=302). They recommended that the use of isolated MAT is not justifiable for documenting collateral hand circulation, prior to any RA radical procedures,

including surgical harvesting. This trial presented with the second larger study population, and detailed information was also provided for the operator performing the procedures and the examiners analysing their results. However, no evidence of statistical significance or predictive value of results was documented. Additionally, a low quality index for internal validity-confounding subscale was calculated (*Figure 2a*).

The study from Altinsoy, et al. (2017) adopted a similar research protocol, comparing, in a prospective randomised trial, the Allen test and the MAT with the multidetector computed tomography (MDCT) angiography of upper limbs. The study determined the presence of RA occlusive disease, secondary to calcification, in six patients, confirmed at the MDCT angiography, however not detectable from an abnormal Allen test/MAT result. Therefore, validity and effectiveness of these screening tests were revealed to be limited and their use questionable. Nevertheless, computed tomography angiography was only performed in patients presenting with negative, hence normal Allen/MAT, thus preventing from considering false-positive results, yet limiting the use of arterial grafting. Although the study establishes the subjectivity and reduced sensitivity of Allen test and MAT, specificity of those screening techniques was not considered, highlighting a limitation of the study.

Among all reviewed research, the only trial presenting with a retrospective design is the cohort study recently conducted by Zhang, et al. (2020). This research was performed by reviewing the medical records of 164 patients who underwent endoscopic thoracic sympathectomy (ETS) treatment. The study aimed to compare the results obtained from Doppler ultrasonography and MAT, completed before and after ETS, to provide insight into RA status, in the event of future CABG and RA surgical harvesting. Endoscopic thoracic sympathectomy resulted in dilating RAs, determining a transition to a negative MAT result in patients who presented with positive MAT prior to ETS. This may potentially lead to false-negative MAT results, as concluded by the researchers. The main limitation of the

study is represented by the adopted retrospective design, which limits researchers' control on the exposure to confounders (Polit and Beck, 2017). Moreover, monitoring of long-term changes in RAs diameter was omitted, thus precluding the possibility to evaluate the temporary/permanent variation of MAT results.

Al-metwalli (2014) presented a prospective randomised controlled trial (RCT), evaluating sensitivity and specificity of Doppler ultrasonography, MAT and pulse-oximetry in assessing collateral hand circulation (CHC). The results highlighted the reduced specificity of MAT, when findings are compared with Doppler ultrasonography. However, the author suggested the use of a perfusion index (PI) test, obtained through the combination of MAT and pulse-oximetry, identified as an accurate objective test with high sensitivity, specificity and positive predictive value. These findings, validating the safe use of pulse-oximetry during RA harvesting, are supported by a previously conducted study (Johnson, et al., 1998). Nevertheless, this trial presented with some limitations. Firstly, participants in this research were all healthy volunteers, whom RA characteristics may be well distinctive and respond differently than the vessel of ill patients requiring CABG and RA surgical procedures. Therefore, despite the high quality evidence of an RCT (Murad, et al., 2016; Thoma, et al., 2019), a more representative study population is required to give more convincing statistical results in the safety of adopting PI. Additionally, with PI being a dynamic parameter, consideration of internal and external stress factors would have been beneficial.

Another strategy to overcome MAT limitations was recently proposed by Elwali and Moussavi (2020). They indicated the use of photo-plethysmography in combination with MAT to provide information on the CHC and recommendation on the safe use of RA grafts. Despite the attentive consideration of different variables, this research has an extremely small sample size (N=11): the smallest among all nine studies. Furthermore, participants'

coronary risk factors were not documented, neither morphometric RA characteristics assessed. All of the above limitations resulted in limiting the generalisability and validity of the trial, which also presents with a low quality index for internal validity-confounding subscale (*Figure 2a*).

Across the nine studies, different conclusions were drawn.

- **Validity of ultrasonography**

  Two studies highlight the validity of ultrasonography in RA assessment (Yadava, et al., 2016; Vukovic, et al., 2017). Accuracy of ultrasound, in evaluating wall thickness and luminal diameter of RAs, was validated by intra-operative physical measurement (Yadava, et al., 2016). Ultrasonography allows detection of calcification and atherosclerotic plaques, providing an accurate and reliable assessment of RA morphology, avoiding the harvesting of diseased RA sections (Vukovic, et al., 2017).

- **Efficiency of MAT**

  One study identifies the MAT as an efficient and safe isolated test, remarking on the non-justifiable routine use of ultrasound (Yadava, et al., 2015).

- **Sensitivity, specificity and subjectivity of MAT**

  The validity and reliability of the MAT are being questioned by four studies. Using the MAT, approximatively 1 in 9 patients resulted in having a false negative MAT (Altinsoy, et al., 2017), increasing to 1 in 3 patients according to Gokhroo, et al. (2016) (poor sensitivity) (Gokhroo, et al., 2016; Altinsoy, et al., 2017; Zhang, et al., 2020). Similarly, approximatively 6% of patients reported a false positive MAT (poor specificity) (Kohonen, et al., 2010). Furthermore, Altinsoy, et al. (2017) reveal that the MAT is a subjective (operator/patient dependent) test.

- **More objective alternatives to the MAT**

  Two further studies suggest a more objective alternative to the MAT, represented by the combination of this with pulse-oximetry (Al-metwalli, 2014) or plethysmography (Elwali and Moussavi, 2020). One study reported a higher sensitivity (100%) and specificity (98.8%) than the isolated MAT (Al-metwalli, 2014).

A correlation between findings and quality level of the studies is synthesised and presented in table 11.

Table 11: Outcomes of the studies

Authors	Quality of the study through modified Downs and Black	Statistical significance
Two studies indicate the superiority of ultrasonography in RA assessment		
Yadava, et al. (2016)	Good	✓
Vukovic, et al. (2017)	Good	
One study identifies the efficiency of MAT		
Yadava, et al. (2015)	Fair	✓
Four studies highlight the limitations of MAT		
Kohonen, et al. (2010)	Fair	
Gokhroo, et al. (2016)	Fair	
Altinsoy, et al. (2017)	Good	✓
Zhang, et al. (2020)	Good	✓
Two studies suggest a more objective alternative to the MAT		
Al-metwalli (2014) (MAT+PO)	Good	✓
Elwali and Moussavi (2020) (MAT+PG)	Fair	✓

✓ - statistically significant study (CI 95%, $p<0.05$); MAT – modified Allen test; PG – plethysmography; PO – pulse-oximetry; RA – radial artery.

The overall finding of the quantitative synthesis, based on the outcomes and the quality assessment of the nine studies, demonstrates a reduced validity and reliability of the MAT. The view of using pulse-oximetry and plethysmography to overcome the limitations of

MAT, and obtain a more objective RA assessment is limited and would require further investigations. Ultrasonography technique obtained a consensus of a better screening test for the morphological assessment of RAs (see background literature).

13. Discussion

A detailed pre-operative vessel examination is extremely important in avoiding unnecessary surgical exploration of RAs, yet minimising ischaemic complication risks in those patients not suitable to undergo their harvesting procedure (Dick, et al., 2011; Altinsoy, et al., 2017). Furthermore, an effective and comprehensive RA quality assessment plays a fundamental role in the prevention of harvesting diseased RA sections, which may cause graft failure and cardiac events after CABG (Chowdhury, et al., 2004; Hosono, et al., 2019). Since Starnes, et al. (1999) acknowledged the limitations of the most commonly adopted MAT, and revealed the risks carried out by its use, different research studies have been conducted to investigate the most valid and reliable RA assessment technique. However, their results demonstrated conflicting evidence, as revealed by this review. Ultrasonography was recognised as a good screening technique, to assess morphological characteristics and anatomical variations in the RA course (Yadava, et al., 2016; Vukovic, et al., 2017). Conversely, the MAT results in a more cost-effective and time efficient test to evaluate CHC prior RA procedures (Yadava, et al., 2015), however it presents with some limitations (Kohonen, et al., 2010; Gokroo, et al., 2016; Altinsoy, et al., 2017; Zhang, et al., 2020). These are overcome by adopting pulse-oximetry or plethysmography to obtain more objective results (Al-metwalli, 2014; Elwali and Moussavi, 2020).

This systematic review compared the findings of nine studies, addressing the review question, after inclusion and exclusion criteria were applied to the search results. One prospective randomised trial and one RCT were identified, however methods of

randomisation were not stated in either of the two studies. In two studies (Al-metwalli, 2014; Elwali and Moussavi, 2020) participants' young age and absence of coronary risk factors revealed the questionable validity and generalisability of their methodology adopted. Similarly, the insufficient documentation of who performed the RA assessment techniques was found in three studies (Kohonen, et al., 2010; Yadava, et al., 2015; Altinsoy, et al., 2017), leading to reduced validity of their methodology. All articles were published in peer-reviewed journals. However, the majority of the trials presented with a small sample size (N≤100), except for one study (Vukovic, et al., 2017) recruiting 536 patients. However, this research was conducted over a longer period of time (12 years: 2004-2016) when compared to other trials.

Findings of the review were impacted by quality of the studies: ultrasound was considered a more effective technique in higher quality studies, and therefore they received major consideration when generating the main outcome of this SR.

Although ultrasonography was evaluated as the best screening technique, in current clinical practice it is not commonly used as considered a more costly and time consuming technique, requiring examiners' advanced skills. In contrast, MAT is widely used due to historical practice and convenience (Habib, Baetz and Satiani, 2012; Sivaharini, Babu and Mohanraj, 2018). Seven of the nine studies evaluating the validity and reliability of MAT, reported negative outcomes in comparison to other screening techniques. This finding is consistent with previously conducted research, highlighting the reduced sensitivity and specificity of the MAT and the subjectivity of its results (Starnes, et al., 1999; Agrifoglio, et al., 2005; Asif and Sarkar, 2008; Vukovic, et al., 2008). An attempt was made to obtain more objective results through the combination of the MAT with pulse-oximetry or digital plethysmography, yet avoiding time consuming and expensive techniques (Al-metwalli, 2014; Elwali and Moussavi, 2020). Although the Al-metwalli (2014) study showed

promising results and was of good quality, significant confounding variables were identified in both primary studies. The main confounder was the recruitment of healthy volunteers, as they may possess different characteristics from patients who require coronary revascularisation. However, results are promising and will hopefully inspire further research in this area.

An early literature review by Habib, Baetz and Satiani (2012) and more recently the study by Chakravarthy, et al. (2020) focused on the specific field of cardiac surgery and presented consistent findings in supporting the use of ultrasonography in RA assessment, thus revealing benefits to patients undergoing CABG. This SR was designed with the aim of determining validity and reliability of the most commonly adopted RA screening techniques, thus promoting evidence-based practice in the correct RA assessment for patients requiring coronary revascularisation.

14. Limitations

The review process was performed by a single individual, with limited experience in research and data analysis: this may generate bias, thus resulting in the main limitation of this SR. A study should be carried out by a co-ordinated specialist research team, in order to minimise bias and subjectivity of results (Polit and Beck, 2017). Only one RCT, relevant to the research question, was included in the SR. This may potentially reduce the statistical power of the review, as the credibility of its results largely depends on the quality of the studies. Moreover, all trials were single-centre studies, limiting the generalisability of their findings. Finally, only English articles published between 2010 and 2020 were considered. Restraints of language and time frame may not only exclude relevant international or earlier studies, but also introduce selection bias.

CONCLUSION

15. Conclusions and implications for practice

Limited studies related to the RA assessment within the context of cardiac surgery were identified, notwithstanding the extensive literature search undertaken. To overcome selection bias, caused by database searches, screening of reference lists from all selected studies was conducted, leading to the inclusion of any additional records. A quantitative synthesis was produced by incorporating all relevant evidence from the current available literature.

All reviewed studies emphasise the importance of an accurate and reliable RA assessment, to prevent harvesting unsuitable vessels which would compromise long-term outcomes after CABG surgery.

Modified Allen test and ultrasonography resulted in the most commonly investigated screening techniques, with the MAT being considered the standard examination in current clinical practice prior to RA harvest. Nonetheless, this SR revealed the reduced validity and reliability of this technique as a general consensus in most of the studies. The use of pulse-oximetry and plethysmography, in combination with the MAT, was documented in two articles and established to be more objective alternatives to the isolated MAT in the RA assessment. Ultrasonography has shown to be superior in the evaluation of morphological characteristics of RAs, including detection of physiological variations and pathological aspects (atherosclerosis and calcification) of the vessel. Ultrasonography provides objective and consistent results in the pre-operative insight of RAs, enabling selection of RA segments with favourable morphological features. However, these findings are yet to be confirmed by high quality evidence, such as RCTs. The systematic review

suggests ultrasonography to be the most accurate and reliable RA assessment technique among the screening tests compared. Nonetheless, confirmation of ultrasound superiority by an RCT represents an essential prerequisite to recommend its routine use in CABG surgery. Conversely, the MAT should no longer be recommended prior to RA harvest, as it presents with limited diagnostic validity and reliability. The need for a large RCT, comparing all four RA assessment techniques, is required to support the findings of this review.

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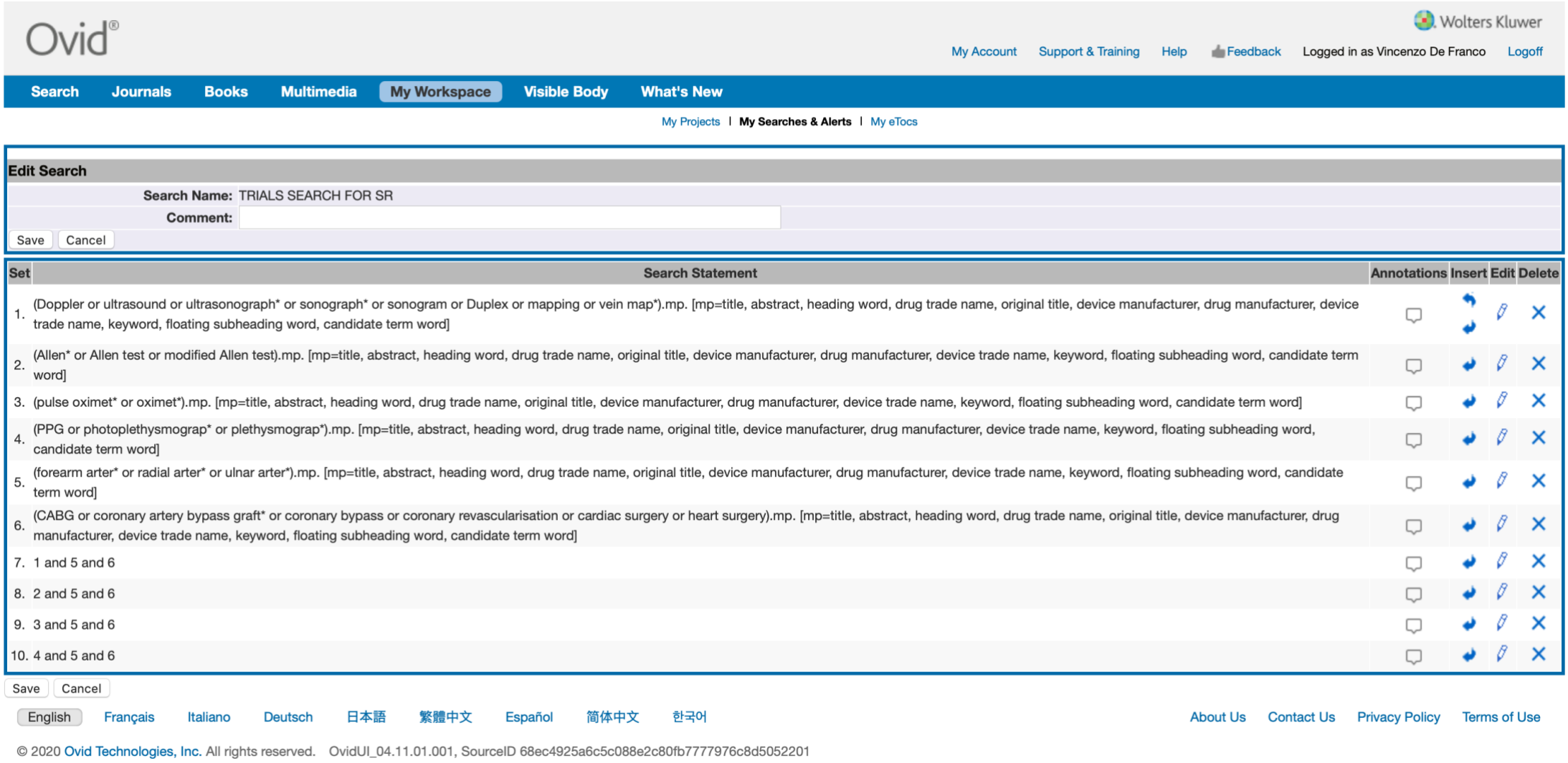
Appendices

Appendix A

Results of the systematic literature search, with number of articles per database

Records published between 2010 and 2020; Abstract available; English language only							
Electronic databases	Interface	Combined database searches				Total studies per database	After removing duplicates
		S1+S5+S6	S2+S5+S6	S3+S5+S6	S4+S5+S6		
MEDLINE	EBSCOhost	58	17	7	3	85	72
PubMed	NCBI	73	7	1	2	83	77
CINAHL	EBSCOhost	20	5	1	1	27	23
Scopus	Elsevier	70	92	47	50	259	176
Embase	Ovid	151	45	27	9	232	192
Total studies per combined search		372	166	83	65	**686**	**466**

Screen shot of search history



Appendix B: Articles excluded with reasons

References	Reason for exclusion
Kamenskaya, O.V., Bulatetskaya, L.M., Klinkova, A.S., Chernyavsky, A.M., Alsov, S.A. and Khvan, D.S., 2011. Assessment of the hand collateral blood flow by the laserdoppler flowmetry method in smoking patients with coronary artery disease prior to the coronary artery bypass grafting. *Interactive Cardiovascular and Thoracic Surgery*, [e-journal] 12(1). http://dx.doi.org/10.1510/icvts.	Conference abstract. This paper presents a previous trial where hand collateral blood flow (CBF) was assessed through Doppler ultrasound, demonstrating reduction in CBF in smokers.
Carranza, C.L., Ballegaard, M., Werner, M.U., Hasbak, P., Kjær, A., Kofoed, K.F., Lindschou, J., Jakobsen, J.C., Gluud, C., Olsen, P.S. and Steinbrüchel, D.A., 2014. Endoscopic versus open radial artery harvest and mammario-radial versus aorto-radial grafting in patients undergoing coronary artery bypass surgery: protocol for the 2 × 2 factorial designed randomised NEO trial. *Trials*, [e-journal] 135(15), pp.1-18. DOI: 10.1186/1745-6215-15-135.	Trial incomplete, protocol only for a future research study. It aims to describe the pre-operative RA assessment through MAT prior CABG and RA harvest. Post-operative surgical complications (hand function, neurological defects, muscular function) will be appraised.
Habib, J., Baetz, L. and Satiani, B., 2012. Assessment of collateral circulation to the hand prior to radial artery harvest. *Vascular Medicine*, [e-journal] 17(5), pp.352-361. DOI: 10.1177/1358863X12451514.	Technical note. This paper describes the use of ultrasonography, MAT, pulse-oximetry and plethysmography in the RA evaluation, and their application in CABG surgery.
Baetz, L. and Satiani, B., 2011. Palmar Arch Identification During Evaluation for Radial Artery Harvest. *Vascular and Endovascular Surgery*, [e-journal] 45(3), pp.255-257. DOI: 10.1177/1538574411399159.	Case study. This study documents the validity of ultrasonography and demonstrates that reliability of Allen test is in dispute.
Sajjad, M.Y., Ugurlucan, M., Otaibi, A.L. and Canver, C.C., 2010. Predictive Value of Intraoperative In Situ Radial Artery Conduit Flow Assessment Prior to Harvesting during Coronary Artery Bypass Surgery. *The Thoracic and Cardiovascular Surgeon*, [e-journal] 58(8), pp.455-458. DOI: 10.1055/s-0030-1249943.	Trial conducting intra-operative invasive RA assessment only (through ultrasonography), not preceded by any pre-operative assessment. Unnecessary surgical exposure of RAs may occur.

Schena, S., Crabtree, T.D., Baker, K.A., Curci, J., Ralph, J.D. and Hendrick, B.B., 2010. Absence of deterioration of vascular function of the donor limb at late follow-up after radial artery harvesting. *The Journal of Thoracic and Cardiovascular Surgery*, [e-journal] 142(2), pp.298-301. https://doi.org/10.1016/j.jtcvs.2010.10.003.	Post-operative ultrasonography assessment in patients who underwent previous CABG. Ultrasound documented UA remodelling and morphological adaptability following RA harvest.
Işık, M., Yüksek, T., Dereli, Y., Görmüş, N., Durgut, K. and Koç, O., 2015. Evaluation of post-operative flow and diameter changes in brachial and ulnar arteries in coronary artery bypass surgery patients in which the radial artery is used as graft. *Turk Kardiyol Dern Ars*, [e-journal] 43(7), pp.630-636. DOI: 10.5543/tkda.2015.62679.	Abstract available in English language, full text in Turkish only, confirmed by an expert librarian. Trial studying, through ultrasonography, post-operative UA diameter and blood flow changes after previous RA harvesting.
Sato, M., Suenaga, E., Koga, S. and Kawasaki, H., 2010. Significance of preoperative ultrasound evaluation of the forearm arteries prior to coronary artery bypass grafting. *Kyobu Geka*, [e-journal] 63(12), pp.1015-1018.	Abstract available in English language, full text in Japanese only, confirmed by an expert librarian. This study conducts RAs assessment through MAT and Doppler ultrasound.
Shen, L.Z., Chen, X.J., Chen, X., Xu, M., Wang, L.M. and Jiang, Y.S., 2010. The morphometry and eNOS expression of radial artery in elderly patients with coronary atherosclerotic heart disease. *Chinese Journal of Surgery*, [e-journal] 48(11), pp.825-829.	Abstract available in English language, full text in Chinese only, confirmed by an expert librarian. Pre-operative ultrasonography and MAT performed for the RA assessment prior RA harvest. Findings are compared with post-operative histopathology investigations.
Zou, L., Chen, X.J., Xu, M., Chen, W., Wang, L.M., Huang, F.H. and Chen, X., 2012. Comparative study on the ultrastructure of radial artery in elderly patients underwent coronary artery bypass grafting with diabetes mellitus. *Chinese Journal of Surgery*, [e-journal] 49(12), pp.1109-1113.	Abstract available in English language, full text in Chinese only, confirmed by an expert librarian. This trial evaluates the impact of age and diabetes on RAs. Ultrasonography and MAT are used to assess quality and function of RAs.

Appendix C: Modified Downs and Black checklist

Modified Downs and Black checklist			
Reporting	Q1	Is the hypothesis/aim/objective of the study clearly described?	
	Q2	Are the main outcomes to be measured clearly described in the Introduction or Methods section?	
	Q3	Are the characteristics of the patients included in the study clearly described?	
	Q4	Are the interventions of interest clearly described?	
	Q5	Are the distributions of principal confounders in each group of subjects to be compared clearly described?	
	Q6	Are the main findings of the study clearly described?	
	Q7	Does the study provide estimates of the random variability in the data for the main outcomes?	
	Q8	Have all important adverse events that may be a consequence of the intervention been reported?	
	Q9	Have the characteristics of patients lost to follow-up been described?	
	Q10	Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	
External validity	Q11	Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	
	Q12	Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	
	Q13	Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?	
Internal validity – bias	Q14	Was an attempt made to blind study subjects to the intervention they have received?	
	Q15	Was an attempt made to blind those measuring the main outcomes of the intervention?	
	Q16	If any of the results of the study were based on “data dredging”, was this made clear?	

	Q17	In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?	
	Q18	Were the statistical tests used to assess the main outcomes appropriate?	
	Q19	Was compliance with the intervention/s reliable?	
	Q20	Were the main outcome measures used accurate (valid and reliable)?	
Internal validity - confounding	Q21	Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?	
	Q22	Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?	
	Q23	Were study subjects randomised to intervention groups?	
	Q24	Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	
	Q25	Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	
	Q26	Were losses of patients to follow-up taken into account?	
Power	Q27	Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?	
Y(yes)= 1 [Q5 only Y= 2]; P(partially)= 1 [only for Q5]; N(no)= 0; UTD(unable to determine)= 0 [used for Q11-26 only]			**Total (__ /28)**

Modified Downs and Black checklist		Studies included in the review								
		Kohonen, et al. (2010)	Al-metwalli (2014)	Yadava, et al. (2015)	Gokhroo, et al. (2016)	Yadava, et al. (2016)	Altinsoy, et al. (2017)	Vukovic, et al. (2017)	Elwali and Moussavi (2020)	Zhang, et al. (2020)
Reporting	Q1	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Q2	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Q3	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Q4	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Q5	N	Y	P	N	Y	P	Y	P	N
	Q6	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Q7	Y	Y	N	Y	Y	Y	Y	Y	Y
	Q8	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Q9	N	N	N	N	N	N	N	N	Y
	Q10	Y	Y	N	Y	Y	Y	Y	Y	Y
External validity	Q11	UTD	UTD	UTD	UTD	UTD	UTD	Y	UTD	Y
	Q12	UTD	Y	Y	Y	Y	Y	Y	Y	UTD
	Q13	Y	Y	Y	Y	Y	Y	Y	Y	Y
Internal validity – bias	Q14	N	Y	N	N	N	Y	N	N	N
	Q15	UTD	Y	N	UTD	N	UTD	Y	N	N
	Q16	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Q17	Y	N	UTD	UTD	UTD	N	N	N	Y
	Q18	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Q19	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Q20	Y	Y	Y	Y	Y	Y	Y	Y	Y

Internal validity - confounding	Q21	Y	Y	Y	Y	Y	Y	Y	UTD	Y
	Q22	Y	UTD	Y	UTD	Y	UTD	Y	UTD	Y
	Q23	N	Y	N	N	N	Y	N	N	N
	Q24	N	Y	N	N	N	Y	N	N	N
	Q25	N	N	Y	N	Y	Y	Y	Y	N
	Q26	N	N	N	N	N	N	N	N	Y
Power	Q27	N	Y	Y	N	Y	Y	N	Y	Y
Total (__ / 28)		**16**	**22**	**17**	**15**	**20**	**21**	**21**	**17**	**20**

Appendix D: stage 1 Research Ethics Application Form

| CONFIDENTIAL

Stage 1 Research Ethics Application Form

Section 1: Details of the Researcher and their Research

N.B. If you are conducting research that involves 'animals (dead or alive) and significant habitats', please use the Stage 1 Research Ethics Application Form involving Animals and Habitats (www.aru.ac.uk/researchethics).

Applicants carrying out research with children or vulnerable adults may also need to carry out an online Safeguarding course and submit the pass certificate with their ethics application. Please refer to the Question Specific Advice for the Stage 1 Research Ethics Application Form at the above weblink.

Researcher details	
First name	Vincenzo
Family name	De Franco
School/Faculty	FHEMS School of Allied Health
Email address	vincenzo.de-franco@student.anglia.ac.uk
Name of Institution where you study or work	Anglia Ruskin University
Are you: *Please tick*	☐ Undergraduate (UG) Student ☐ Postgraduate Taught (PGT) Student ☐ Postgraduate Research (PGR) Student ☐ Member of ARU Staff ☐ Member of ARU staff carrying out Masters/Doctorate research
Students (including staff proposing research on a course/programme)	
Your SID	1825146
Your course/programme title	MSc Surgical Care Practice
Name of your First Supervisor (for PGR) or Supervisor (for UG and PGT)	Dan Robbins
Research details	
Title of your research project *N.B. For UG/PGT students, this is not the title of your research module*	Reliability of pre-operative radial artery assessment in patients undergoing coronary artery bypass graft surgery – a systematic review.

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Name and institutional affiliation of any research collaborators	Royal Papworth Hospital NHS Foundation Trust
Date of application	05/06/2020
Start date of proposed research	As soon as possible
Brief Project Summary (up to 700 words) Please summarise your research in non-specialist language. Please describe where relevant: *Methodology (please describe what you plan to do as opposed to providing a background in your chosen methodology)* *Theoretical approaches* *Research questions* *Details of participant population (recruitment, inclusion and exclusion criteria*	Undertaking a systematic review (SR) to define the most accurate screening technique in assessing radial artery (RA) quality, for their use during coronary revascularisation surgery. This SR aims to establish the reliability of screening techniques commonly used in the clinical practice: modified Allen test, pulse oximetry, plethysmography and Doppler ultrasound. Furthermore, it aims to determine if screening test choice has a significant impact on the outcome of surgical treatment. Through the rigorous review of existing literature and appraising trials previously performed, the author aims to answer the following research question: "Is Doppler ultrasound more reliable than a modified Allen test, a pulse oximetry and a plethysmography, in radial artery assessment for patients undergoing coronary revascularisation?" The SR will determine the most reliable technique used to assess RA. Quantitative data produced from primary research studies, comparing the above screening techniques, will be appraised. Therefore, the SR is based on a quantitative methodological philosophy. Detailed inclusion and exclusion criteria will be applied with the aim of narrowing the search results to a specific topic and discarding primary studies which do not answer the formulated research question. Specifically, studies will only be selected if referring to the following participant population: adult patients undergoing elective or urgent coronary artery bypass graft surgery. Primary studies will be critically appraised through the assessment of their quality and ethical aspects. Therefore, validity, reliability and generalisability of the studies will be considered. Similarly, the author will assess whether ethical approval was sought and if consent was gained by the participants involved in the research. No primary studies will be included in the SR, regardless of the validity, reliability and generalisability of their contents, if ethical approval was not clearly stated in the research or if the consenting process of participants was not declared. The purpose of this rigorous selection of studies is to ensure a high quality SR. The author intends to explore options for the improvement of existing practice from the available published literature. Moreover, this research study will demonstrate the author's ability to meet the learning outcomes for the module MOD004633.

Please explain the potential value of your research to society and/or the economy and its potential to improve knowledge and understanding.	The research study aims to explore and discuss the rationale of the screening techniques adopted for the morphological and functional RA assessment, with the potential to improve clinical outcome for patients. A more organised and standardised approach means better surgical outcomes and a reduced length of hospital stay. This will assist in solving critical bed shortage issues, ensure smoother running of waiting lists and reduce financial expenses for the NHS. This study will enhance the knowledge and skills of both surgical care practitioners and surgical trainees for the clinical examinations by them performed.

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Section 2: Research Ethics Checklist (Refer to Section 3 for an explanation of the colour coding.)

N.B. If you are conducting research that involves 'animals and significant habitats', please use the Stage 1 Research Ethics Application Form involving Animals and Habitats (www.aru.ac.uk/researchethics).

You must provide a response to ALL questions. Please refer to the Question Specific Advice for completing the Stage 1 Research Ethics Application Form for guidance.

	Will your research (delete as appropriate):			
1	Involve human participants?		YES	NO
2	Utilise data that is not publically available?		YES	NO
3	Create a risk that individuals and/or organisations could be identified in the outputs?		YES	NO
4	Involve participants whose responses could be influenced by your relationship with them or by any perceived, or real, conflicts of interest?		YES	NO
5	Involve the co-operation of a 'gatekeeper' to gain access to participants?		YES	NO
6	Offer financial or other forms of incentives to participants?		YES	NO
7	Involve the possibility that any incidental health issues relating to participants could be identified?		YES	NO
8	Involve the discussion of topics that participants may find distressing?		YES	NO
9	Take place outside of the country where you work and/or are enrolled to study?		YES	NO
10	Cause a negative impact on the environment (over and above that of normal daily activity)?		YES	NO
11	Involve genetic modification of human tissue, or use of genetically modified organisms classified as Class One activities?[1].		YES	NO
12	Involve genetic modification of human tissue, or use of genetically modified organisms above Class One activities?[2].		YES	NO
13	Collect, use or store any human tissue or DNA (including but not limited to, serum, plasma, organs, saliva, urine, hair and nails)?[3]		YES	NO
14	Involve medical research with humans, including clinical trials or medical devices?		YES	NO
15	Involve the administration of drugs, placebos or other substances (e.g. food, vitamins) to humans?		YES	NO
16	Cause (or have the potential to cause) pain, physical or psychological harm or negative consequences to humans?		YES	NO

[1] Email FST-Biologicalsafety.GMO@aru.ac.uk for further information.

[2] As above.

[3] For any research involving human material you must contact ARU-HBMC@aru.ac.uk for further guidance on how to proceed.

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17	Involve the collection of data without the consent of participants, or other forms of deception?		YES	NO
18	Involve interventions with people aged 16 years of age and under?		YES	NO
19	Relate to military sites, personnel, equipment, or the defence industry?		YES	NO
20	Risk damage/disturbance to culturally, spiritually or historically significant artefacts/places, or human remains?		YES	NO
21	Contain research methodologies you, or members of your team, require training to carry out?		YES	NO
22	Involve access to, or use (including internet use) of, material covered by the Counter Terrorism and Security Act (2015), or the Terrorism Act (2006), or which could be classified as security sensitive?[4]		YES	NO
23	Risk being construed as encouraging terrorism or inviting support for proscribed organisations and/or contain extremist views that risk drawing people into terrorism or are shared by extremist groups		YES	NO
24	Involve you or participants in a) activities which may be illegal and/or b) the observation, handling or storage (including export) of information or material which may be regarded as illegal?		YES	NO
25	Does your research involve the NHS (require Health Research Authority and/or NHS REC and NHS R&D Office cost and capacity checks)?		YES	NO
26	Require ethical approval from any recognised external agencies (Social Care, Ministry of Justice, Ministry of Defence)?		YES	NO
27	Involve individuals aged 16 years of age and over who lack 'capacity to consent' and therefore fall under the Mental Capacity Act (2005)?		YES	NO
28	Involve processing special category data[5] and/or intend to recruit 100 or over participants? (only answer if your research involves the EEA – see Section 5 for further information).		YES	NO
29	Pose any ethical issue not covered elsewhere in this checklist (excluding issues relating to animals and significant habitats which are dealt with in a separate form)?		YES	NO

Please note that the Faculty Research Ethics Panel (FREP) will refer to the Office of the Secretary and Clerk any application where, in the view of the Chair, the proposed research poses a risk of a legal or security related nature to Anglia Ruskin University. The Chair will seek guidance from the Secretary and Clerk before the FREP decides if the proposed research can be granted ethical approval and/or the nature of any special arrangements which need to be put in place.

[4] The Counter Terrorism and Security Act (2015) and Terrorism Act (2006) outlaws web posting of material that encourages or endorses terrorist acts, even terrorist acts that have occurred in the past. Sections of the Terrorism Act also create a risk of prosecution for those who transmit material of this nature, including transmitting the material electronically. The storage of such material on a computer can, if discovered, prompt a police investigation. Visits to websites related to terrorism and the downloading of material issued by terrorist groups (even from open-access sites) may be subject to monitoring by the police. Storage of this material for research purposes may also be subject to monitoring by the police. Therefore, research relating to terrorism, or any other research that could be classified as security-sensitive (for example, Ministry of Defence commissioned work on military equipment, IT encryption design for public bodies or businesses) needs special treatment. If you have any doubts about whether your research could be classified as security-sensitive, please speak to your FREP Chair.

[5] Special category data is defined as personal data which reveals racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a person, and data concerning health or data concerning a person's sex life or sexual orientation.

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Section 3: Approval process

All student applications must be sent to your Supervisor for checking.
Your Supervisor must then forward the application to the SREP/FREP (as appropriate)

FREP = Faculty Research Ethics Panel
SREP = School Research Ethics Panel

NO answered to all questions **Risk category Green**	Complete Section 6 of this form and then send it to your SREP. **You do not require ethical approval from a committee.** **You can start your research immediately.**
YES to any of Questions 1-11 and/or 29 but NO to all other questions **Risk category Yellow**	Complete Section 4 -6 of this form and submit it, and the Participant Information Sheet (PIS) and Participant Consent Form (PCF), to your SREP. Your faculty may require further documents. **You need to wait for ethical approval before you start your research.**
YES to **any** of Questions 12-24 **Risk Category Red**	Complete Section 5 and 6 of this form and complete the Stage 2 Approval form. Submit both, and any other documents required, to your FREP. **If you answered YES to Question 23 you must also complete and submit for consideration by the committee the Stage 3 Approval form.** **You need to wait for ethical approval before you start your research.**
YES to **any** of Questions 25-27 **Risk Category Purple**	You need external approval(s) which, if granted, may be regarded as equivalent to approval from an Anglia Ruskin ethics committee. Refer to the Question Specific Advice for the Stage 1 Research Ethics Application Form and Code of Practice for Applying for Ethical Approval for further information **You need to wait for ethical and/or governance approval before you start your research.**
Yes to Question 28 **Risk Category Blue**	You must also complete the Special Category Data Questions and submit these with your application (see Section 5).

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Section 4: Project details

Management of Ethical Risk
For each of Questions 1-11 and Question 29, where you have responded 'Yes', please explain for the panel how you justify and will manage the ethical risk created. Your research is in the Yellow risk category.

Section 5: Data Protection

If your research involves personal data and will be in the European Economic Area (EEA), involve transferring data in or out of the EEA (the EEA includes EU member states and also Iceland, Liechtenstein and Norway) or accessing ARU servers within the UK.

1. You must complete the Research Checklist for Data Protection and confirm that you have done this in Section 6.

   https://web.anglia.ac.uk/anet/staff/sec_clerk/Data%20Protection/guidance/research.phtml

2. If you have said 'yes' to Question 28, you must also complete the Further Data Protection Questions and follow further instructions if applicable. You need to submit this document with your ethics application.
   https://web.anglia.ac.uk/anet/staff/sec_clerk/Data%20Protection/guidance/research2.phtml

3. If your research will not involve the EEA, you need to confirm in Section 6 that you will comply with the data legislation relating to the country you are carrying research out in or transferring data in or out of.

Section 6: Confirmation/Declaration statements

	Confirmation Statements (delete as appropriate)	
1	I have completed the relevant training in research ethics.[6]	Yes No Not applicable
2	I have consulted the Research Ethics Policy and the relevant sections of the Code of Practice for Applying for Ethical Approval, available at www.**aru.ac.uk/researchethics.**	Yes No
3	I have completed a Risk Assessment (Health and Safety) and had it approved by the appropriate person.[7]	Yes No Not applicable

[6] Where required, UG or PGT students must submit confirmation with this form that they have passed the on-line ethics training. Some courses have exemption from this requirement. Please check with your supervisor.
[7] For research conducted at ARU including University Centre Peterborough and College of West Anglia, go to **https://web.anglia.ac.uk/anet/staff/sec_clerk/** for the relevant guidance. Students at other institutions must follow local processes.

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4	Either I have reviewed the Research Checklist for Data Protection and comply with its requirements. If I needed to complete the Further Data Protection Questions, I obtained advice from our Data Protection Officer if any of my responses were 'no' and submit the correspondence with this ethics application. Or for research that does not involve the EEA, I will comply with any data protection legislation of the country or countries that my research will involve.	Yes No Not applicable
5	For research funded externally where the funding was acquired via Anglia Ruskin, I have completed a Project Risk Assessment.[8]	Yes No Not applicable
6	I have attached my confirmation of passing a Safeguarding course.	Yes No Not applicable
7	If my research project involves a contract between Anglia Ruskin University and an external party, I have had the contract approved by the Secretary and Clerks Office[9]	Yes No Not applicable

Applicant Declaration
By sending this form from my Anglia Ruskin e-mail account, I confirm that I will undertake the research as detailed here. I understand that I must abide by the terms of my ethical approval and that I may not amend the research without further ethical approval. I also confirm that the research will comply with all Anglia Ruskin ethical guidance, all relevant legislation and any relevant professional or funding body ethical guidance.

Supervisor/First Supervisor Declaration
By sending this form from my Anglia e-mail account, I confirm the statements in the Applicant Declaration and that I will supervise the research as detailed in the application.

Thank you for completing the Stage 1 Research Ethics Application Form.

Please submit it as follows:

Staff Researchers: Send form directly to the relevant committee.

Student Researchers (including staff carrying out research in a student capacity): Send form to Supervisor/First Supervisor.

Supervisor/First Supervisor: Check application and forward to the relevant committee.

For FREP/SREP details please visit the Ethics website: https://web.anglia.ac.uk/anet/rido/ethics/about/frep.phtml On this page you will also find links to each Faculty's website where more information on SREPS can be found.

Date

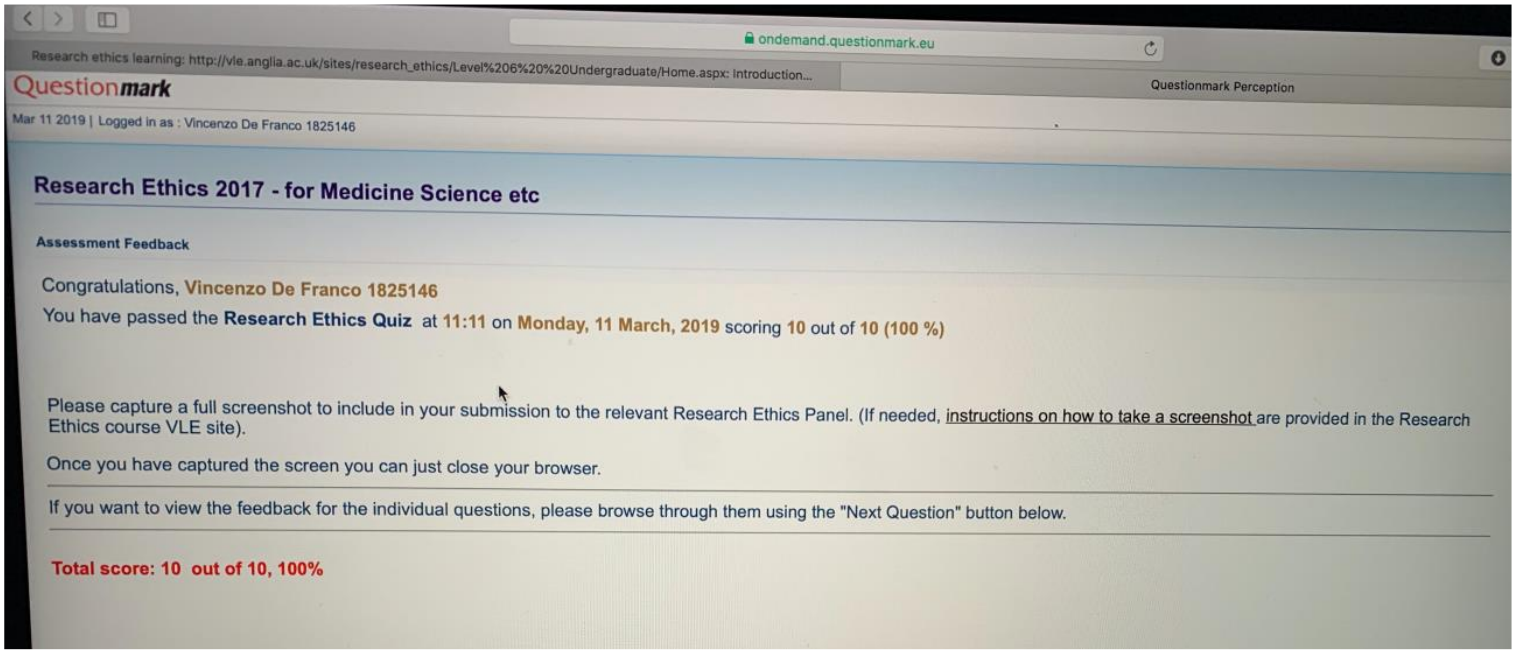
16 September 2019

Version 4.9

[8] For details go to web.anglia.ac.uk/anet/rdcs/compliance/faqs.phtml

[9] For details go to http://web.anglia.ac.uk/anet/staff/sec_clerk/

Appendix E: Research and Professional Ethics online course



Appendix F: Major Project Supervisors Log

Major Project Supervisors Log. MOD004633

To be maintained by supervisor and submitted by student at final submission.

Student Name Vincenzo De Franco	Project title Validity and reliability of radial artery assessment techniques in coronary artery bypass grafting – a systematic review.

ACTIVITY	DATE/COMMENT
Initial proposal Agreed	02/06/2020
Stage 1 ethics proposal submitted to FREP and confirm evidence of student completion of ethics training	08/06/2020
Confirmation of External ethics approval (eg NRES) if applicable	NA
R & D approval if applicable	NA
Approval of research protocol	12/08/2020
Discussion of literature review	17/09/2020
Discussion of methodology	17/09/2020
Discussion of results	11/01/2021
Discussion of Implications for practice.	11/01/2021

Supervisor signature Dan Robbins	Date of completion of Log. 14/01/2021