Institution: University of Plymouth

Unit of Assessment: UoA1

Title of case study: Improving safety, health outcomes and cost effectiveness in patients with chest pain using Computed Tomographic Cardiac Angiography (CTCA)

Period when the underpinning research was undertaken: 2009-2020

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Dr Carl Roobottom	Honorary Consultant - Radiology	01.09.2099- present

Period when the claimed impact occurred: 01.08.2014-11.11.20

Is this case study continued from a case study submitted in 2014? N

1. Summary of the impact (indicative maximum 100 words)

Cardiovascular disease accounts for 64,000 UK deaths and costs £9 billion per annum. Angiography is central in the management of patients with suspected heart disease. Roobottom has converted Cardiac Tomographic Cardiac Angiography (CTCA) from a research tool to a robust diagnostic test by improving its safety, developing the technique and providing accuracy data. The team's contribution led to NICE recommending CTCA as the primary diagnostic tool for all patients in the UK (340,000 patients per annum) in 2016. The guidelines are supported by all specialist groups and NICE estimate a minimum saving of £16 million p.a. by its preferred utilisation due to the reduced cost of CTCA compared with invasive angiography.

2. Underpinning research (indicative maximum 500 words)

Professor Carl Roobottom and his team have been at the forefront of developing Cardiac Tomographic Cardiac Angiography (CTCA) in the UK for 15 years.

Prior to CTCA: Until the development of CTCA, the only way to anatomically visualise the coronary arteries, and the narrowing's that cause heart attacks, angina and death, was invasive coronary angiography. This is expensive (£1600), requires hospital admission and has a mortality of 1 in 1000 and a morbidity of 5-10%. In contrast, computed tomographic imaging is a safe outpatient procedure costing £200. CT is used to image most parts of the body. However, its application to image the heart had technical challenges to be overcome which have been the primary focus of the Plymouth group.

Technical Challenges: Roobottom's team were the first to apply Electrocardiographic gating techniques to image the thorax and aorta and subsequently the heart in the UK, demonstrating CTCA as a viable alternative to invasive angiography. [3.1]. The team were the first to report clinical utilization of CTCA in the UK, and their ongoing clinical accuracy trials demonstrated that CTCA provided high accuracy [3.2].

Patient safety: One of the major obstacles to the greater use of CTCA was its very high radiation dosage with known risks of causing cancer. Roobottom has worked extensively on CT dose reduction. Partly this was achieved by realising that only certain parts of the cardiac cycle are required for diagnostic images and only giving radiation in those parts of the heart cycle [3.1 & 3.3]**.** He also helped develop new computational reconstruction methods which were more tolerant of image noise and allowed dose reduction [3.4]. CTCA's low dose was a major

consideration for NICE (CG95, 2016) in recommending the use of the technique as a first line investigation for all 340,000 patients per annum with chest pain.

Difficult Patients: Early studies of CTCA showed that it was an excellent test in younger patients, who typically had little calcium within the vessel wall. However, it showed poor accuracy in patients with metal stents in the vessel or high levels of coronary artery calcium. Roobottom demonstrated that new computational methods of image reconstruction could overcome these limitations, even in high-risk groups who tend to have high levels of calcium in their vessels, with accuracy equal to invasive angiography [3.5]. This meant it could be used in all patient groups.
CTCA is also difficult in patients with abnormal heart rhythm. Roobottom demonstrated that the use of a certain part of the heart cycle not only improved accuracy but also allowed dose reduction [3.3].

From anatomy to function: It is sometimes difficult on angiography to know if a narrowing of a coronary vessel is significant enough to cause symptoms. The conventional method of assessing this is by placing a pressure transducer in the coronary artery. This is expensive (£3000) and uncomfortable for patients. Roobottom has helped to develop the role of CT Computational Fractional Flow Reserve, a new non-invasive alternative, with engineering colleagues. This technique uses CTCA as a basis to perform computational fluid dynamics to assess the haemodynamic significance of a narrowing just from the CT data. The published data [3.6] show it to be highly accurate compared to the invasive alternative. This technique is now recommended as a safe and cost-effective alternative to the invasive procedure (NICE MTG32, 2017).

3. References to the research (indicative maximum of six references)

3.1 A comparison of radiation doses between state-of-the-art multislice CT coronary angiography with iterative reconstruction, multislice CT coronary angiography with standard filtered back-projection and invasive diagnostic coronary angiography. Heart 2010;96:922-926. O Gosling, R Loader, P Venables, C Roobottom, N Rowles, N Bellenger, G Morgan-Hughes

3.2 Prognostic and accuracy data of multidetector CT coronary angiography in an established clinical service. Clinical Radiology 2010, Volume 64, Issue 6, Pages 601-607. R. Van Lingen, N. Kakani, A. Veitch, N. Manghat, **C. Roobottom,** G. Morgan-Hughes

3.3 CT coronary angiography in atrial fibrillation: a comparison of radiation dose and diagnostic confidence with retrospective gating versus prospective gating with systolic acquisition. Clayton B, **Roobottom C**, Morgan-Hughes G. The British journal of radiology 2015 Nov;88(1055):20150533. doi: 10.1259/bjr.20150533. Epub 2015 Sep 4•

3.4 Intra-patient comparison of Reduced-dose Model-based Iterative Reconstruction withStandard-dose Adaptive Statistical Iterative Reconstruction in the CT Diagnosis and Follow-up of Urolithiasis Tennant S, Pang CL, Dissanayake P, Vardhanabhuti V, Stuckey C, Gutteridge C, Hyde C, **Roobottom CA**. Eur Radiol. 2017 :4163-4172

3.5 Diagnostic accuracy of high-definition CT coronary angiography in high-risk patients. Iyengar SS, Morgan-Hughes G, Ukoumunne O, Clayton B, Davies EJ, Nikolaou V, Hyde CJ, Shore AC, **Roobottom CA**. Clin Radiol. 2016 Feb;71(2):151-8. doi: 10.1016/j.crad.2015.10.021.

3.6 Estimating the accuracy of a reduced-order model for the calculation of fractional flow reserve (FFR) Boileau E, Pant S, Roobottom CA, Sazonov I, Nithiarasu P. Int J Numer Method Biomed Eng. 2018 Jan;34(1)

4. Details of the impact (indicative maximum 750 words)

Roobottom's main priority as a clinician is to deliver and develop high quality care to the maximum number of patients possible. Cardiovascular disease is the world's biggest killer, 7.4

million UK patients have the disease, with 460 patients dying each day. As a Doctor performing invasive angiography, he appreciated it was painful and risky for his patients. Seeing the potential of CTCA, Roobottom was the first UK clinician to begin clinical research in this area. He developed a close relationship with General Electric (GE) technology, the world's largest manufacturer of CT equipment, to develop the techniques and technology for performing cardiac CT. This technology and reporting software are now incorporated into all CT scanners sold by the company.

Improving patient safety
Ensuring patient safety is multifaceted and involves a safe investigation, accurate application and performance of the investigation. Roobottom's work on radiation reduction and technique has resulted in CTCA being transformed from the highest radiation dose CT technique to one of the lowest.

Radiation
In 2003, CTCA was a very high radiation dose examination. Radiation reduction was vital to improve clinical and patient acceptability by reducing the risk of radiation-induced cancers. Roobottom's research showed that using radiation only during certain parts of the heart cycle could reduce exposure by over half (3.3). Further work utilising new computer image reconstruction techniques, with GE technology, showed that radiation doses could be reduced by a factor of 15 without reducing accuracy [5.1]. Jane Hickey, GE Healthcare said, *"[Roobottom's] input… to GE helped develop both the hardware and software for cardiac imaging. His research was pivotal in demonstrating how to reduce radiation dose and maintain high diagnostic accuracy."* [5.2]. This technique is now utilised in all GE scanners across the world.

Little real-world radiation dose data existed for the majority of cardiovascular CT. Therefore, Roobottom participated in a study to document real-world radiation doses for coronary CTA in the United Kingdom. A dose survey questionnaire was distributed to members of the British Society of Cardiovascular Imaging and other UK cardiac CT units. This national audit demonstrated that CTCA exposes the patient to a very low dose of radiation [5.3].

His work on guidelines and standards and accreditation have ensured national dissemination and adherence of these techniques by incorporating them into national standards and making them part of the accreditation process by the Royal College of Radiologists [5.4].

Application of technique
The performance of CTCA is technically challenging for the operator and requires a high level of expertise. Roobottom recognised that for CTCA to become a non-specialist tool at a global level, more widespread knowledge of how the technique could be deployed was required. In order to facilitate this, he worked with GE to set his centre up as reference site to allow others to visit. GE regularly use his site both for national and international customers to showcase cardiac CT and to provide onsite training for customers. Moreover, he has lectured across the world on their behalf. Jane Hickey, GE Healthcare said*, "Professor Roobottom was the first UK Radiologist to set up a Cardiac CT service in the UK. For over a decade Professor Roobottom has run a cardiac CT course with GE to provide much needed training and accreditation in cardiac CT reporting both in the UK, Africa and the Middle East. Up to 6 courses run per year to ensure that Radiologists and Cardiologists can obtain this vital training."* [5.2] Plymouth has had over 200 visitors from around the world from 2014-19 to learn how to perform CTCA.

In addition, he:

- Published documents on safe practice and equipment requirements through the British Society of Cardiac Imaging (BSCI) (2017) [5.4]

- Set up the current accreditation process used by the BSCI, which is internationally recognised, undertaken by the majority of practitioners in the UK and is a compulsory requirement of medical insurance companies.[5.5]
- Sits on the NICE MTAC (ongoing) to evaluate new technologies being produced.

Improving applicability

Improved outcome is dependent on accurate and timely diagnosis for all patients. Roobottom's development of new techniques, including high-definition CT, demonstrated that all patients could be investigated with CTCA with high accuracy. These results were key to persuading NICE to change its recommendations for use of CTCA from just low risk patients (2010) to the first line investigation for all patients, including those at high risk [5.6]

Accuracy is not only dependent on the production of good quality images but also on accurate interpretation. This requires high-quality education. To achieve this, Roobottom has:

- Integrated cross-sectional anatomy teaching for all medical students at the Peninsula Medical School.
- Created the Peninsula Radiology Academy, the only stand-alone facility in the UK dedicated to training in imaging. This is a multi-professional facility which delivers innovative education locally, nationally and internationally with exceptional participation feedback. It was praised by a Health Education England review in 2017 [5.7].
- Set up a cardiac CT training course, running five times per year, which since 2005 has trained 375 doctors. The majority of these are now currently performing CTCA in the UK.

Improving outcomes in acute chest pain

Chest pain accounts for 700,000 Emergency Department (ED) attendances per annum and 40% of hospital admissions. However, 85% of patients are subsequently discharged without a diagnosis. CTCA has a negative predictive value approaching 100%, and logically, if delivered directly to patients in the ED, will save lives and allow massive cost savings (by preventing hospital admission) as well as improving patient satisfaction (by speedier diagnosis). Roobottom led the case for a state-of-the-art CT scanner in ED in his hospital (2019), which is estimated to save the Trust £800k p.a. and halve admissions of patients presenting with chest pains. To define the role of CTCA in acute chest pain, Roobottom was involved in the largest CTCA trial ever as lead Radiologist. This 1750 patient study has categorised which subgroups derive the most benefit from CTCA in acute chest pain [5.8].

Changing national guidelines & practice

Roobottom was the lead clinical expert for NICE in their diagnostic guidance on the use of advanced CT scanners in difficult to examine patients which recommended the increased use of CTCA with the appropriate CT equipment.

In 2015, due to his national reputation, he was appointed as the sole radiological clinical expert on the Clinical Guidelines committee for stable chest pain and he was instrumental in highlighting the accuracy, cost efficiency and prognostic advantages of CTCA. This led NICE [5.5] to recommend it in 2017 as the first line investigation for all patients with stable chest pain (340,000 p.a.). NICE performed an economic evaluation of the impact of this change in England in patients who presented to chest pain clinics. In this relatively small subgroup, they estimated an ongoing £16 million p.a. saving from the switch to CTCA, which has largely occurred. Across all patient groups and applied to a UK, rather than just an English population, the savings will be substantially greater [5.2, 5.5, 5.6, 5.8].

He also sat on the NICE guidelines committee for acute chest pain. This recommended the use of CTCA as the primary second line investigation in patients presenting with acute chest pain [5.6]. Dr Stephen Harden, Registrar Royal College of Radiologists said. *"[Roobottom's] role as the cardiac CT representative on the NICE guidelines committee for stable chest pain has helped produce a paradigm change in the investigation of stable chest pain, putting CT as the first line*

investigation. This will lead to a massive increase in the use of cardiac CT and the UK is leading the world in this regard. NICE has estimated the change will save millions of pounds per year as well as reducing risks to patients." [5.5]

4. Sources to corroborate the impact (indicative maximum of 10 references)

5.1 Prospective intra-individual comparison of standard dose versus reduced-dose thoracic CT using hybrid and pure iterative reconstruction in a follow-up cohort of pulmonary nodules-Effect of detectability of pulmonary nodules with lowering dose based on nodule size, type and body mass index. Vardhanabhuti V, Pang CL, Tenant S, Taylor J, Hyde C**, Roobottom C.** Eur J Radiol. 2017 Jun;91:130-141

5.2 Letter of Support Jane Hickey CT Lead GE Healthcare UK

5.3 A prospective national survey of coronary CT angiography radiation doses in the United Kingdom. Castellano IA, Nicol ED, Bull RK, **Roobottom CA,** Williams MC, Harden SP. J Cardiovasc Comput Tomogr. 2017 Jul - Aug;11(4):268-273. doi: 10.1016/j.jcct.2017.05.002. Epub 2017 May 8

5.4 The safe practice of CT coronary angiography in adult patients in UK imaging departments. Harden S, Bull RK, Bury RW, Castellano EA, Clayton B, Hamilton M, Morgan-Hughes G, Roditi G, **Roobottom CA**, Nicol E. Clinical Radiology 2016;71:722-728

5.5 Letter of support Dr Stephen Harden, Previous President BSCI/BSCCT and Current Registrar Royal College of Radiologists

5.6 The Updated NICE Guidelines 2016 https://www.nice.org.uk/guidance/cg95

5.7 HEE Radiology Academies Review 2018 https://www.hee.nhs.uk/our-work/radiology-academies-review TRLS-D-16-00522

5.8 Rapid Assessment of Potential Ischaemic Heart Disease with CTCA - The RAPID-CTCA trial: A multi-centre parallel group randomised trial to compare early Computerised Tomography Coronary Angiography versus standard care in patients presenting with suspected or confirmed Acute Coronary Syndrome. Alasdair J Gray, Carl Roobottom, Jason E Smith, Steve Goodacre, Katherine Oatey, Robert F Storey, Steff C Lewis, Praveen P, David E Newby. £2.6 million NIHR grant