

CARDIOVASCULAR MEDICAL DEVICES

Focus areas of cardiovascular medical device research in South Africa

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We investigated the focus of cardiovascular medical device research in South Africa over the 15-year period 2000 - 2014. Information drawn from journal articles was used for the analysis, with attention to articles describing a contribution to the development of a cardiovascular medical device, or a new application of an existing device. The findings suggest that research has focused on diagnostic and monitoring as well as prosthetic cardiovascular medical devices, with specific emphasis on vascular and valvular heart diseases.

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Cardiovascular diseases (CVDs) are the leading cause of death worldwide^[1] and the leading cause of non-communicable disease morbidity and mortality in South Africa (SA).^[2,3] The main drivers of the CVD burden in the country include urbanisation, increased

tobacco use, poor diets associated with high cholesterol, and diabetes, as well as a general lack of physical activity leading to overweight/obesity.^[2,4] CVD mortality in SA is primarily a result of myocardial infarction, stroke, congestive heart failure, cardiomyopathy and diseases related to high blood pressure.^[3] CVD-related morbidity is often a consequence of angina, atherosclerosis, coronary artery disease, cardiomyopathy and rheumatic heart disease (RHD),^[3,5] with RHD being especially prevalent in underprivileged children below the age of 15 years.^[5] It is estimated that between 1997 and 2004, 33 people died per day in SA from myocardial infarction, 37 per day from heart failure and 60 per day from stroke,^[3] while there were approximately 130 myocardial infarction and 240 stroke survivors each day over the same period.

Cardiovascular medical devices are tools that can be employed for the diagnosis, monitoring, surgical intervention, therapy or prosthetic treatment of cardiovascular conditions;^[6] they can potentially impact on CVD morbidity and mortality. In 2007, the World Health Organization implemented the priority medical devices project^[7] with the aim of redirecting resources towards combating high-burden diseases such as CVD by improving medical device access, quality, clinical relevance and use. The 2006 guidelines of the National Department of Health^[2] also encouraged collaboration for more focused medical device development. Previous work^[6] has shown that there has been a general increase in collaboration for cardiovascular medical device development in SA since 2000, as indicated by journal publications. However, the focus of this published activity has not been explored.

Identification of cardiovascular medical device focus areas

We examined the focus of SA cardiovascular medical device research over the period 2000 - 2014. Journal articles discussing CVDs in the

SA context were collected using methods and criteria detailed in previous work.^[6] The journal articles were accessed using PubMed and Web of Science. An article was included in the study if at least one of the authors had an SA affiliation, it had been published between 1 January 2000 and 31 December 2014, and it described a contribution to the development (and not just the clinical use) of a device or a new application of an existing device. A set of 122 articles satisfied these criteria.

Two approaches were used to identify the research focus areas of the journal articles. One approach classified each article based on the CVD, condition or structure addressed by the device. The second involved assigning a category to each article in a similar manner to the Code of Federal Regulations Title 21 of the US Food and Drug Administration,^[8] namely diagnostic, monitoring, therapeutic, surgical or prosthetic device. Diagnostic devices and monitoring devices were combined into a single class, since medical devices that play a diagnostic role are also often used for monitoring purposes. Prosthetic devices included any implantable device intended for correcting CVD conditions, while surgical devices were those intended for CVD surgical interventions. Finally, therapeutic devices were those that assist in the management of CVD.

Diseases and conditions addressed

Fig. 1 shows the types of disease, condition or cardiovascular structure addressed.

Valvular heart diseases were most commonly addressed and accounted for 18% of the articles. Examples include the development of a percutaneous aortic heart valve,^[9] numerical simulation of the behaviour of aortic valves^[10] and the application of finite element methods to improve stent design for a percutaneous heart valve.^[11] Similar in proportion to valvular devices were devices for vascular diseases (17%), addressing conditions related to blood vessels. A large proportion of the devices (12%) were classified as 'nonspecific' as these either addressed several aspects of the cardiovascular system or did not clearly define the disease, structure or condition addressed.

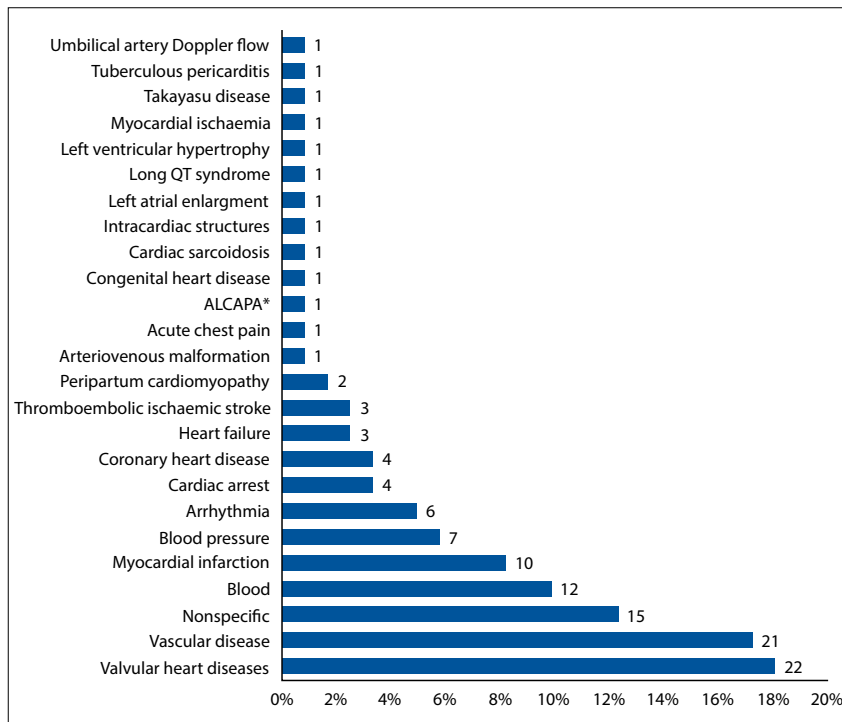


Fig. 1. Diseases, conditions or structures addressed by cardiovascular medical device research in SA between 2000 and 2014. The number of articles is shown next to each bar. The x-axis gives the proportion of articles as a percentage of all relevant search results. (*ALCAPA = anomalous origin of the left coronary artery from the pulmonary artery.)

Myocardial infarction and high blood pressure, which are among the leading contributors to cardiovascular deaths in SA, accounted for 8% and 6% of the articles, respectively, while heart failure and thromboembolic ischaemic stroke each accounted for only 2%. None of the articles captured addressed rheumatic heart disease, which is a prevalent heart condition among children from low-income settings in SA.^[3,5]

Clinical applications

An alternative approach to understanding the focus of cardiovascular medical device research entailed classifying the articles based on their clinical applications. Research on development of cardiovascular devices was more focused on devices intended for diagnosis, monitoring or prosthetic treatment than on therapeutic or surgical devices. Nearly half (48%) of the articles described the development of diagnostic and monitoring devices, and just over one-third (35%) discussed the development of prosthetic devices. Therapeutic and surgical devices jointly accounted for 17% of the articles. Examples of diagnostic and

monitoring devices drawn from published articles include new applications for electrocardiograms, artery waveform analysers and phonocardiograms. These devices addressed vascular and valvular diseases. Prosthetic devices included vein grafts and heart valves, related also to vascular and valvular diseases.

Influence of foreign collaborators

From the 122 articles in this study, 298 authors were affiliated to 51 SA organisations, with an additional 166 authors affiliated to 97 foreign organisations. The affiliations of the first and last authors were determined for each publication, as it was assumed that if either of these authors had an SA affiliation, the research could be considered to be locally driven.

Approximately 89% of the articles had a first and/or last author affiliated with an SA organisation, suggesting that despite foreign organisations outnumbering local organisations, the research focus was still largely dictated by local organisations. In addition, although fewer local organisations

were represented in the publications, approximately three times more local than foreign authors were represented per organisation.

Conclusion

The focus of cardiovascular medical device research in SA has been examined using journal articles published between 2000 and 2014. The findings suggest that diagnostic and monitoring cardiovascular devices as well as prosthetic devices receive more attention in SA than surgical and therapeutic devices. The main structures addressed are heart valves and blood vessels. This is consistent with a high incidence of atherosclerosis, which is one of the major causes of cardiovascular morbidity in SA.

The majority of the articles examined were led by authors with SA affiliations, confirming strong local capacity in cardiovascular medical device research.

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