Cardiac Pacing in Sub-Saharan Africa JACC International

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Brief Title: Cardiac Pacing in Sub-Saharan Africa

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Abstract

Many parts of the developing world, especially Sub-Saharan Africa, completely lack access to cardiac pacing. We initiated a multinational program to implement cardiac pacing in 14 countries in Sub-Saharan Africa (1996-2018), aiming eventually to build self-sustainable capacity in each country. This was based on an "on-site training" approach of performing procedures locally and educating local healthcare teams to work within resource-limited settings, with prospective evaluation of the program. In 64 missions, a total of 542 permanent pacemakers were implanted. In 11 of these countries, the first pacemaker implant in the country was through the mission. Over half of those initially listed as suitable died before the mission(s) arrived. The proportion of implantations that were completely handled by local teams increased from 3% in 1996 to 98% in 2018. These findings demonstrate the feasibility and effectiveness of a proctorship-based approach to the development of local cardiac pacing capabilities in Sub-Saharan African nations.

Condensed Abstract

Many parts of the developing world, especially Sub-Saharan Africa, completely lack access to cardiac pacing. This multinational cardiac pacing program in 14 countries in Sub-Saharan Africa (1996-2018), aimed eventually to build self-sustainable capacity in each country, based on an "on-site training" approach of performing procedures locally and educating local healthcare teams to work within resource-limited settings. The evaluation demonstrates the feasibility and effectiveness of a proctorship-based approach to the development of local cardiac pacing capabilities in Sub-Saharan African nations. Despite this, however, implantation rates remain over 500-fold lower than in industrialized nations; this mandates further efforts towards local capacity development.

Key words: Developing Countries; Pacing; Heart; Sudden Death; Technology; Education; Training

Abbreviations

AV = Atrio-ventricular
IQR = Interquartile range

Introduction

Since it was first performed in 1958, cardiac pacing has expanded exponentially, with now nearly 1,000 implantations annually per million population, in developed countries.(1,2)While the need for cardiac pacing is similar worldwide, developing regions of the world lag significantly behind their developed counterparts in having reasonable (or in some cases, any) access to this potentially life-saving procedure.

Sub-Saharan Africa, one of the poorest parts of the world, is undergoing an epidemiologic transition, with the incidence of deaths related to cardiovascular causes increasing rapidly over time.(3) However, except for South Africa, there has been very little implementation of cardiac pacing (1,4-6). Lack of adequate expertise in the form of skilled physicians is a major limitation to provide cardiac pacing to the population overall, along with scarcity of resources, funding and technology.

Through a dedicated effort over the past two decades (1996-2018), we have carried out a project to develop cardiac pacing in Sub-Saharan Africa, based on training local healthcare teams and adapting to regional constraints. This unique project aimed to establish and build a sustainable local capacity for cardiac pacing.

Methods

Scope of the Program

The main objective of Africa-Pace was to initiate and build sustainable local and regional capacity for cardiac pacing in countries of sub-Saharan Africa, by partnership with local cardiologists and healthcare teams providing clinical services mainly within the framework of public institutions, such as teaching hospitals. The pacing program, initiated in 1996, is part of a broader initiative called *Cardiology and Development*, launched by the European Georges

Pompidou Hospital and the French Institute of Health and Medical Research in Paris. *Cardiology and Development* is a specific Non-Governmental Organizations aiming to link Care-Research-Teaching in emerging countries, especially in Africa and Asia (7-12).

The pacing program was based on a concept of doorstep delivery of technology and on-site training. This comprised both theoretical teaching as well as carrying out planned missions to perform procedures in local hospitals, with the involvement of the local cardiologists/support staff, so that center-specific challenges could be identified and overcome by collaborative effort.

Through this approach, we aimed to: (i) provide services to the patients most in need of cardiac pacing during the initial collaborative missions; (ii) achieve proficiency among participating local cardiologists after missions, and (iii) enhance collaborations between African countries to help make the program sustainable. Furthermore, we additionally hoped to raise awareness among policy makers regarding the urgent need to develop this lifesaving therapy, and to promote education of the healthcare community.

Preparation for the Missions

Each mission was carried out by agreement and invitation from the Health Ministry of each particular country. Africa-Pace staff, in conjunction with each local team sought necessary approvals from hospital and national authorities to undertake the mission, including customs for devices, visas for visiting staff, and obtaining authorization for visiting physicians to work in the country.

We aimed to develop a local pacemaker team consisting of an engaged and committed cardiologist (who would perform the implantation) and two nurses (who would be trained on-site). If available, a local surgeon was trained as well. Commitment to the program and (likely) permanence of staff at the hospital were key requirements.

Local cardiologists screened patients who might require cardiac pacing and selected those deemed suitable for the planned intervention. A minimum of 15 patients was necessary to plan a mission. The list of patients and indications for implantation were discussed with the local team prior to the mission by conference call. Pre-procedure work-up (chest X-ray, full blood count, electrolytes and creatinine) was performed by the local team, aimed at identifying any contraindications to implantation. Preparation of basic infrastructure, such as x-ray equipment and sterile instruments, was also arranged by the local team.

The Africa-Pace team had two experienced pacemaker implanters, initially from European and subsequently from African countries (to ensure that the program could be sustained long-term), who were also able to adapt and innovate as necessary to overcome challenges in resource-constrained settings. Africa-Pace was responsible for arranging the pacemaker equipment (pulse generators and leads). As funding was very limited, new devices with expiry dates close to the date of the mission were provided by industry, free of charge. At least three missions were planned to one site, aiming for about 10 to 15 implantations during each mission; hence in most cases the local implanter performed about 30 to 40 procedures under supervision before becoming truly independent and doing implantations in the absence of the proctor.

Carrying out the Missions

The first day on site was dedicated to verifying that all requirements were in place for the procedures. The visiting cardiologist met with the local cardiologist at the hospital with the rest of the team. The procedure room as well as all consumables and equipment brought by the visiting team were double-checked. The cardiologist leading the mission reviewed the plan and the expected duties of each member of the team in detail. All medical records were then

discussed and the patients admitted thereafter. Rules of good practices, including sterility and hygiene, were provided to the nurses and other local staff.

The visiting cardiologist performed the first procedure (closely observed and assisted by the local team) and then guided the local cardiologist (trainee) for the remaining procedures. Pacemaker implantation was done under local anesthesia. Intravenous antibiotic coverage was administered at the time of skin incision. During the following second and third missions to each site, the visiting cardiologist was available in the lab and supervised the trainee without scrubbing in, with the aim of enabling the local team to operate independently.

Patients were usually discharged on the 4th post-procedure day if there were no complications. Inspection of the incision site and ruling out pocket complications was emphasized. Only basic training on checking the pacemaker by means of a magnet was provided. Remote support continued, via regular conference calls, once the local team was proficient to do procedures independently, to encourage continued maintenance of good clinical standards. All patients were systematically invited for a routine visit 4 weeks after implant, either at the implant center or a closer medical center for patients living in very remote areas.

Outcomes of the mission were summarized and made public through national and regional media, with a special focus on the new local team. Meetings with policy makers were scheduled in order to gain support for future missions and the expansion of the local cardiology clinic. Traditionally, the visiting physician also gave at least one lecture at the local University on a variety of topics in order to optimize the educational component of each mission.

Data Collection and Statistical Analysis

Data on implanted patients were prospectively obtained during missions according to a pre-specified Case Report Form, and collected by the Paris Cardiovascular Research Center

(French Institute of Health and Medical Research, Paris, France), in collaboration with the implantation center. The data comprised recording of device functionality and any related events/complications. In parallel with the systematic collection of data on first implantations during the 64 missions, further efforts were directed towards following the deployment of pacing nationally in each of the 14 countries involved in the program. This focused especially on the number of implantations in each country in order to provide incidence of implantation per million inhabitants and ascertaining peri-procedure events, if any. All data were collected by the French Institute of Health and Medical Research, at Unit 970, Cardiovascular Epidemiology. Data were analyzed using SAS version 9.3 (SAS Institute, Cary, North Carolina). All tests were 2-tailed, and *P* values of less than 0.05 were considered to indicate statistical significance.

Results

Setting and Participants

Three missions were undertaken every year, eventually targeting 14 countries between 1996 and 2018, for a total of 64 missions. In 11 of these countries, cardiac pacing programs were initiated for the first time (first pacemaker implant in the country was through the mission) **(Figure 1**, dark yellow). Median duration per mission was 7 days (IQR: 3-10). Out of the 1,077 patients initially listed, 542 (50.3%) were eventually implanted. The majority of the remaining patients had died suddenly while waiting for pacemaker implantation, prior to mission arrival. The median waiting time between diagnosis and intervention was 18.4 (IQR: 3.2-26.4) months.

The mean age was 63±9 years (from 14 to 92 years) and 336 (62%) were male (Table 1). The mean heart rate on the day of implantation was 37±8 bpm. The majority of patients were diagnosed with paroxysmal or permanent complete AV block (94%), with the others having sinus node dysfunction. All, except 15 patients (3%), were symptomatic, mainly with

dizziness/syncope (44%) and shortness of breath (53%), with 108 (20%) having experienced more than one symptom. Hypertension (304, 64%), rheumatic heart disease (67, 14%), and coronary artery disease (78, 16%) accounted for the majority of the associated cardiac pathologies.

Pacemaker Implantations

A single chamber (ventricular) pacemaker was most often used (482 patients, 89%). In 2017-2018, four cardiac resynchronization therapy pacemakers were also implanted during the missions by visiting experts. Only one implantable cardioverter defibrillator has been implanted during the missions.

Successful pacing was eventually achieved in all cases. There was no peri-procedural mortality. During the procedure, however, cardiac arrest occurred in approximately 20%, requiring temporary chest compression. This was usually due to third degree AV block without escape rhythm, particularly in patients with end-stage conduction disease. Threshold testing was not commonly performed due to the lack of testing cables or the perceived risk of infection from improperly sterilized cables.

No deaths occurred during implantation or during the in-hospital stay. Peri-operative complications occurred in 33 patients (6%), including lead dislodgment and local hematoma, requiring reintervention in 19 patients (3%). Other complications included pocket infection in 2% and pericardial effusion in 0.5%.

Capacity Building

Overall, this program resulted in a significant increase in local implantation rates over time from 0.04 (95% CI 0.02-0.06) to 0.65 (95% CI 0.54-0.75) per million inhabitants per year for the 1996-2000 and the 2011-2018 periods respectively ($P<0.0001$). Figure 2 depicts the

progressive increase in the number of implantations performed over the years, across the 11 of these countries where cardiac pacing programs were initiated for the first time.

The most advanced center in 1996 was the Heart Institute in Abidjan (Ivory Coast), but civil war considerably delayed its progression, whereas the best progression was achieved in Dakar (Senegal). Importantly, as seen in the figure, the number of implantations performed by the visiting team remained the same over the years, while there was a rapid increase in independently performed implantations by local staff. The proportion of the implantations that were completely handled by local teams moved up from 3% in 1996 to 98% in 2018. Senegal, Ivory Coast, Mauritania, Burkina Faso, Gabon and Cameroon have successfully established their own completely autonomous pacing programs. Other countries including Niger, Mozambique, Mali, Benin and Togo have achieved partial proficiency and are expected to establish their own programs within the coming years. Congo Brazzaville joined this group recently, with the first mission performed in 2012.[13] Finally, a specific program was recently started in Democratic Republic of Congo (Kinshasa), as well as a first mission performed in February 2014 in Guinea just before the outbreak of Ebola which stopped the program; this is to be resumed shortly.[14] The most recent mission took place in Burundi in May 2019.

Discussion

We have described the results of a novel and scalable initiative to make cardiac pacing achievable and sustainable in Sub-Saharan Africa. Over the past two decades, this project has successfully performed pacemaker implants in 14 African countries, making cardiac pacing available for the first time in most of these countries. Despite working in resource-poor settings and having to adapt to unique local circumstances in each country, the outcomes and complication rates observed are acceptable, demonstrating the feasibility and practicality of this

approach. More importantly, the key achievement of this program has been the fact that implantations performed independently by local cardiologists have increased considerably over the duration of the program, with half the countries now having successfully established their own independent pacing programs. This has been possible not only through the training of African cardiologists by proctor missions, but also by the subsequent initiatives of the initially trained African physicians to reach out to neighboring countries, resulting in transfer of knowledge between different developing countries.(13-17) This experience serves as a potential roadmap to help disperse necessary medical technology to all corners of the developing world.

While some may question the allocation of resources to cardiac pacing as compared to other health needs in sub-Saharan Africa, two issues merit consideration. Firstly, pacing is usually a lifesaving procedure. This is amply demonstrated by the fact that approximately 50% of patients initially shortlisted did not survive the waiting period, prior to mission arrival. If one assumes a death rate without pacing of 50% of selected patients (as we observed) and a population of adults in Sub-Saharan Africa of 973 million,(18) then widespread adoptions of this program, with the eventual goal of reaching one tenth of the implantation rate observed in Western countries, could save approximately 50,000 lives each year. Secondly, cardiac pacing is a key requirement to the advancement of cardiology in any region, without which a reasonable standard of cardiac care is simply not possible. While there has been a major focus on infective diseases in the third world, changing demographic trends are resulting in an increasing burden of morbidity secondary to non-communicable disease, mainly cardiovascular disease. Though there are continued increases in life expectancies in developing nations with corresponding population expansions, years lost to disability have proportionately increased as well, thus contributing to an expanding morbidity pool.(3) Thus it is important to address this discrepancy. For instance, in

the Democratic Republic of Congo, a country with 80 million inhabitants, not a single pacemaker implantation had been performed prior our first mission in 2014 (13) (Figure 3).

Important hurdles to the development of pacing in developing countries include cost, availability of devices, equipment (sterilization facilities, x-ray) as well as lack of skilled personnel.(19,20) The traditional approach to address the gap in technology and skill between developed versus developing countries has been to either sponsor procedures for patients in modern centers in Europe/North America through charitable missions or to help physicians from developing nations to travel abroad for training in advanced centers with the expectation that they would in turn return and benefit their home country. Both these approaches have shortcomings. Indeed, experience suggests that, for a multitude of reasons, doctors from developing countries may be likely to remain in these developed countries, rather than to return home. Furthermore, training in western countries often occurs in the setting of access to the best equipment, facilities and support personnel, which is a problem when translating this experience, to the country of origin.[21,22] Hence indigenous training is the need of the hour; for instance a regional university teaching program was set up in 2017 by Professor Adama Kane at St louis University, Senegal to deliver specific courses in cardiac arrhythmias, pacing and electrophysiology to students from West-Africa.[23]

France is in a vantage position to help countries, especially in Francophone Africa, to address health as a global security issue. Beyond supporting transfer of some patients into expert university hospitals in France, the more sustainable solution may be to actually take technology to the "doorstep" of the country in need and develop the program "in the trenches" adapting to local constraints and challenges. While this may seem initially daunting, we have demonstrated that this is feasible and can result in successful growth of local programs, which is crucial for

long-term results and sustainable development. In developing such programs, it is important to have meticulous planning and a careful start, to ensure early success in the program to establish trust and facilitate local acceptance. In our mission, the first few implantations in any country were especially crucial and good results were important to ensure that the program took root and continued to grow. Although it is possible that cardiologists trained elsewhere, outside of our missions, may have contributed partly to the increase in implantations, due to our strong collaboration network with the cardiologists of these countries, we are aware that the subsequent growth of implantations has been for the major part driven by the cardiologists initially trained by us and by those whom they trained subsequently (South-to-South collaboration).

Our work reflects a real-world experience and results should be interpreted thoughtfully; rigorous and complete follow-up for all cases could not be ensured. The reported complication rates should be interpreted with caution as there could have been some underreporting and incomplete follow up. Further studies with more rigorous long term follow up are required. Also, there may be concerns regarding the adequacy of training for the local cardiologist, as compared to international standards, however our experience suggests that outcomes are reasonable and further long-term data would undoubtedly be useful. Healthcare needs and economic/political conditions are varied and diverse and therefore our results may not be generalizable. While no formal cost effectiveness analysis was performed, the main long term sustenance of this program is based on implantation by local cardiologists with only a first few on site missions by the traveling team, hence we feel that it is very likely to be cost effective per life saved as compared to many other contemporary therapies in cardiology.

Although implantation rates increased over time, they still remain many-fold lower than in developed regions. An important limitation to the success of such programs is the availability

of devices at affordable costs and for this all relevant parties including local government, NGOs and industry need to be actively engaged to find ways to make the therapy affordable. Finally, our work serves to demonstrate that "doorstep technology delivery" can be potentially applied to other areas in cardiology (especially interventional cardiology), but also more generally in medicine to reduce healthcare gaps in developing countries. As part of the *Cardiology and Development* initiative, we aim to address not only cardiac pacing but also other common disease conditions, such as rheumatic heart disease and sickle cell disease in Africa.(7-11) The network built could also be potentially useful to enhance collaboration in other needed areas, especially relevant to the third world.

Conclusions

Our findings demonstrate the feasibility and effectiveness of a specific on-site proctorship program to develop cardiac pacing in Sub-Saharan Africa based on "doorstep" delivery of technology and training to develop local expertise. However, persisting unmet needs and major gaps in implantation rates (still 500-fold lower, compared to industrialized nations) require further diligent efforts.

Main messages

- Many countries in Sub-Saharan Africa, lack access to the lifesaving technology of cardiac pacing.
- Through a multinational program, we demonstrated the feasibility and effectiveness of a proctorship-based approach to the development of local cardiac pacing capabilities in Sub-Saharan African nations.
- Further studies should focus on the long-term outcomes of such programs as well as the issue of making such technologies available and affordable through engagement of all relevant stakeholders.

FIGURES LEGENDS

Figure 1. Africa-Pace network

Overall, 14 countries involved in the Program since 1996. In 11 of these countries, cardiac pacing programs were initiated for the first time (first pacemaker implant in the country was through the mission, dark yellow).

Figure 2. Number of pacemaker implanted in countries where cardiac pacing programs were initiated for the first time (1996-2018).

The figure depicts the progressive increase in the number of implantations performed over the years, across the 11 of these countries where cardiac pacing programs were initiated for the first time. In dark blue during the missions, in light blue by local cardiologists. 95% confidence intervals are indicated by the error bars.

Figure 3. First mission in Congo Brazzaville, January 2012

The Congolese media record the first time Dr Ikama implants a pacemaker into a patient in Congo Brazzaville. *Photograph courtesy of Yasmine Saed-Quiblier.*

Central Illustration. Africa-Pace program: A proctorship-based approach to the development of local cardiac pacing capabilities in Sub-Saharan African nations.

Over the past 2 decades, this project has successfully performed pacemaker implants in 14 African countries, making cardiac pacing available for the first time in most of these countries (blue arrow and line). The key achievement of this program has been the fact that implantations performed independently by local cardiologists have increased considerably over the duration of the program, with half the countries now having successfully established their own independent pacing programs (green line). This has been possible not only through the training of African cardiologists by proctor missions, but also by the subsequent initiatives of the

initially trained African physicians to reach out to neighboring countries, resulting in transfer of knowledge between different developing countries (South-to-South collaboration, green crossed arrows).

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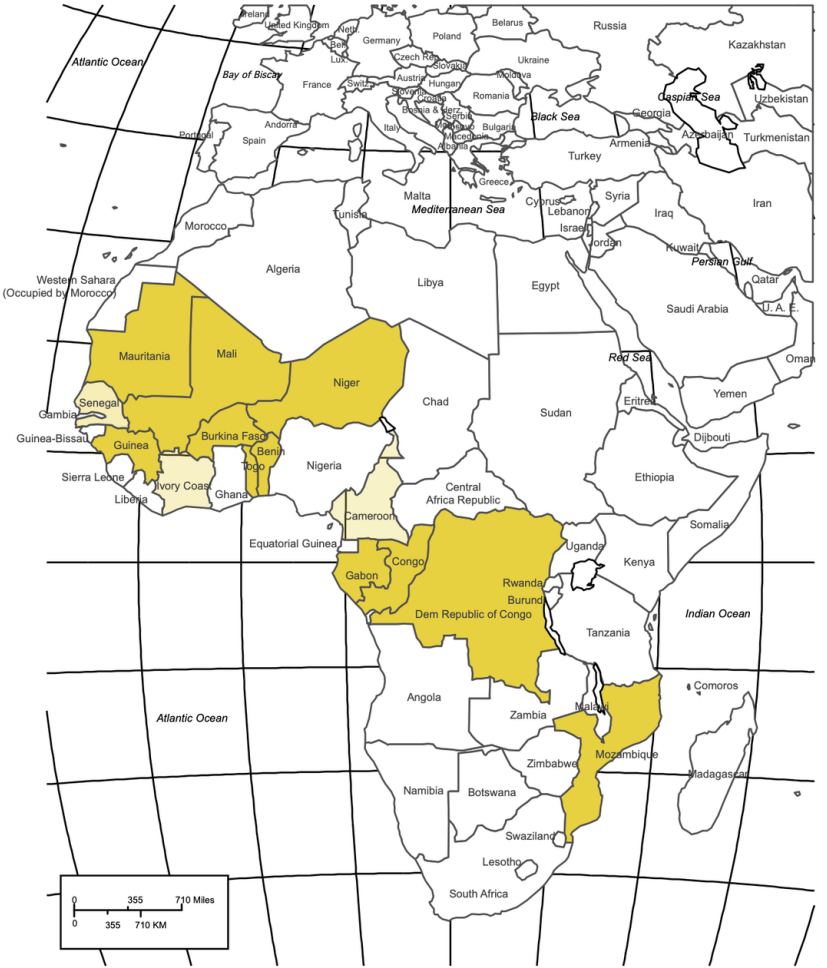
Table 1. Patients Characteristics, Pacing Indications, and Management

	N=542	1996–2000	2001–2005	2006–2010	2011–2018	P Value
Age, mean ±SD	63.9±11	61.2±12	62.9±10	63.0±13	66.4±11	0.07
Males, N (%)	336 (62)	42 (65)	79 (62)	101 (60)	114 (63)	0.94
Associated Cardiac Pathologies						
Hypertension	304 (64)	37 (62)	72 (63)	100 (66)	95 (64)	0.95
Rheumatic Heart Disease	67 (14)	11 (19)	20 (17)	18 (12)	18 (11)	0.26
Coronary Artery Disease	78 (16)	8 (13)	17 (15)	24 (16)	29 (19)	0.77
Others	53 (11)	6 (10)	12 (10)	18 (12)	17 (11)	0.17
Conduction Disorders						
Sinus Dysfunction	33 (6)	3 (5)	7 (6)	11 (7)	12 (7)	0.94
Permanent AV Block	471 (87)	59 (90)	116 (90)	145 (86)	151 (83)	0.17
Paroxysmal AV Block	38 (7)	3 (5)	5 (4)	11 (7)	19 (10)	0.09
Primary Cardiac Symptom						
Syncope/dizziness	211 (44)	28 (47)	52 (45)	65 (43)	66 (43)	0.90
Shortness of breath	250 (53)	31 (53)	62 (55)	77 (51)	79 (55)	0.30
Peri-operative complications						
Pneumothorax	4 (1)	2 (2)	1 (<1)	1 (<1)	0 (0)	0.13
Hematoma (major)	13 (2)	4 (6)	3 (2)	4 (2)	2 (1)	0.12
Lead dislodgment	12 (2)	3 (2)	4 (3)	3 (2)	2 (1)	0.47
Tamponade	2 (<1)	1 (1)	1 (<1)	0 (0)	0 (0)	0.28
Early infection	2 (<1)	1 (1)	0 (0)	1 (<1)	0 (0)	0.34

Data are number (%), unless otherwise specified. Percentages were calculated on the basis of the total number of known events.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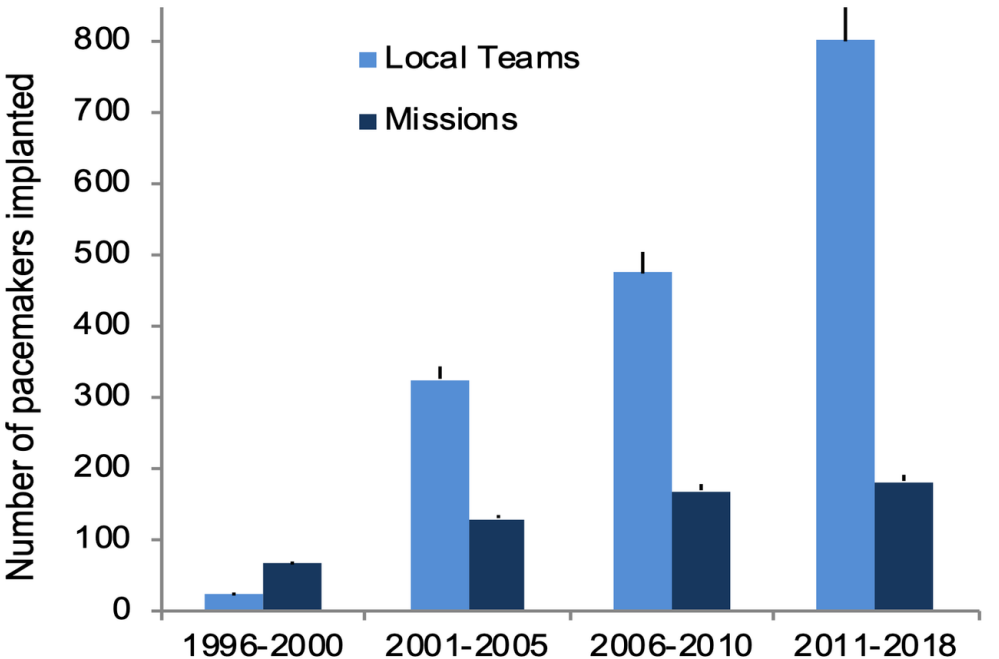
Cyprus
Lebanon
Syria
Israel
Iraq
Iran
Jordan
Kuwait
Persian Gulf
Qatar
U. A. E.
Saudi Arabia
Oman
Yemen
Red Sea
Eritrea
Djibouti
Ethiopia
Somalia
Kenya
Uganda
Rwanda
Burundi
Dem Republic of Congo
Tanzania
Indian Ocean
Comoros
Madagascar
Mozambique
Malawi
Zambia
Zimbabwe
Angola
Namibia
Botswana
Swaziland
Lesotho
South Africa
Atlantic Ocean
Morocco
Western Sahara
(Occupied by Morocco)
Algeria
Tunisia
Libya
Egypt
Mauritania
Mali
Niger
Chad
Sudan
Senegal
Gambia
Guinea-Bissau
Guinea
Burkina Faso
Benin
Togo
Nigeria
Sierra Leone
Liberia
Ivory Coast
Ghana
Cameroon
Central
Africa Republic
Equatorial Guinea
Gabon
Congo
0 355 710 Miles
0 355 710 KM


Number of pacemakers implanted
800
700
600
500
400
300
200
100
0
Local Teams
Missions
1996-2000
2001-2005
2006-2010
2011-2018