Insights Series

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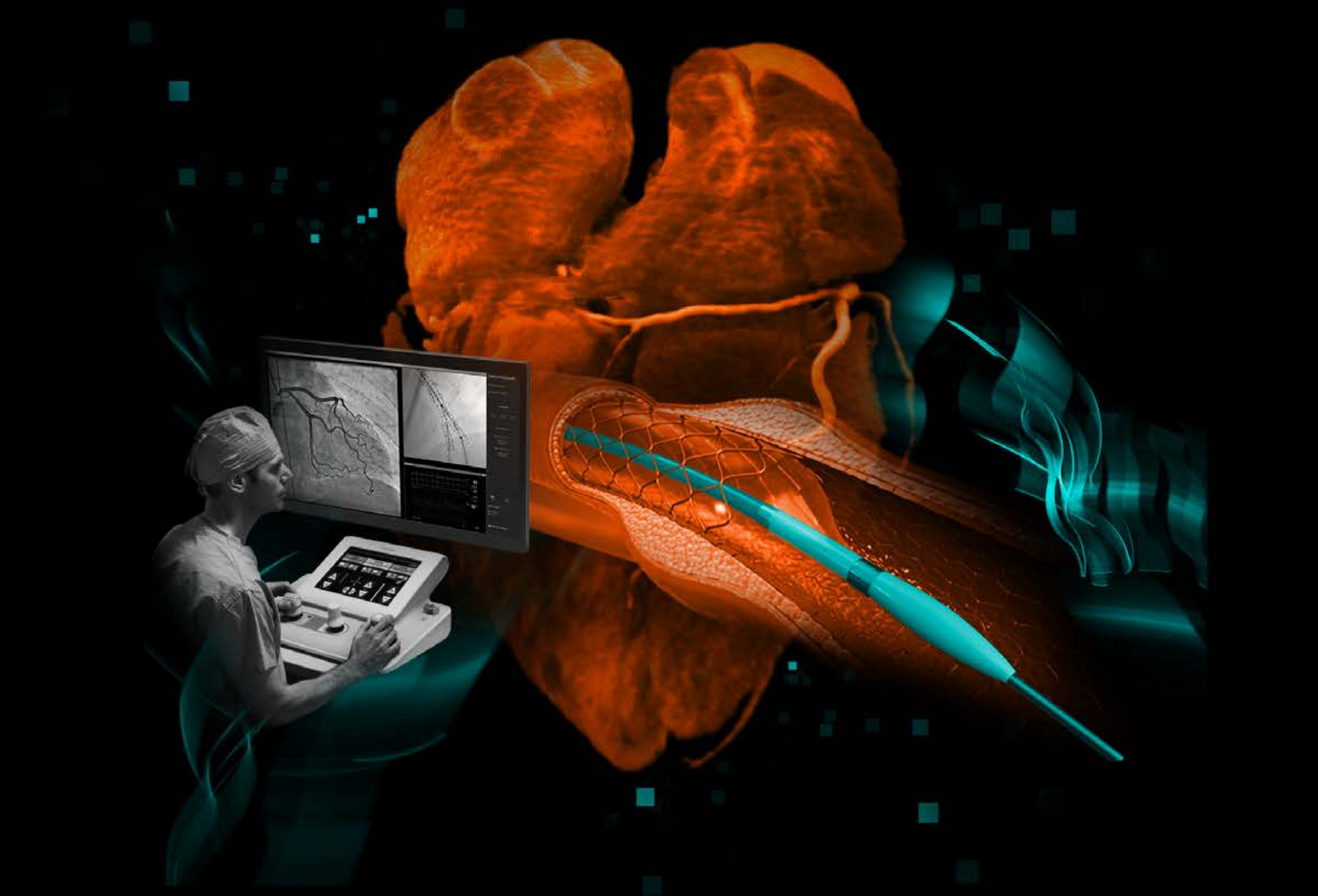

The case for robotic-assisted PCI

What is the value for healthcare executives?

A thought leadership paper on "Delivering high-value care"

SIEMENS Healthineers

Preface

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Executive summary

Around the world, the population is growing, and it is growing older. There are more of us, and we are living longer. Hand in hand with those two facts comes another: cardiovascular artery disease, one of the leading causes of death globally, is on the rise. When intervention is required, a gold standard treatment for treating this condition is percutaneous coronary intervention (PCI), whereby cardiologists use a catheter to insert one or more stents in order to open narrowed coronary arteries.

Historically, PCIs have been performed manually, a feat of precision and expertise that is a testament to the skill of the interventionalists who perform them. The fact is, though, that the demands that manual PCI places on human dexterity and visual acuity are such that occasionally, challenges arise that can cost organizations time and money, physically affect physicians, and sometimes even result in negative patient outcomes. Those challenges are as follows:

1. Limited human precision and visualization
2. Variability of care
3. Threats to the health and safety of physicians
4. Limited technology differentiation for attracting talented physicians and patients

This paper explores a potential solution to those challenges. Robotic-Assisted PCI (R-PCI) takes the human judgment, intuition and decision-making of cardiologists and combines it with robotic precision, control, and procedural automation. The movements of the catheter, the guidewire, and the balloon or stent are controlled by the interventional cardiologist, but they are executed by a robot that doesn't get tired, doesn't get uncomfortable, doesn't feel stress, and doesn't get distracted.

The R-PCI system aims to enable less experienced cardiologists to perform interventions that previously, only more experienced physicians would attempt. It also protects cath lab interventionalists from workplace hazards such as dangerous exposure to radiation and the orthopedic damage that can result from wearing protective heavy lead. R-PCI helps set healthcare organizations apart, marking them as suitable destinations of choice for both patients needing PCI, and physicians looking for the best place possible to ply their trade.

Any move to R-PCI could be seen as a disruptive one, and should certainly only be undertaken in conjunction with an open dialogue involving the head of cardiology and the appropriate executive suite members.

Introduction

Relevance of PCI today, and going forward

Coronary artery disease is one the most common cardiovascular diseases and is among the leading causes of death globally. When it comes to treatment for this condition, a common procedure, widely accepted as a gold standard, is percutaneous coronary intervention (PCI). Formerly known as angioplasty with stent, PCI usually involves using a catheter to insert one or more stents to open narrowed coronary arteries.

It should come as no surprise that with populations everywhere growing and aging, heart disease as well as PCIs are on the rise. There are now more than one million PCIs performed around the world every year, and that number has been increasing since 2013, including a 30% increase in elective PCI.[1]

As patients get older and suffer from more comorbidities, PCIs are becoming more complex and demanding. Today, complex PCI procedures account for 40% of all PCI cases, and that number is expected to soon reach 50%.[2] These procedures can last as long as two hours, with much of that time dedicated to wiring lesions. This can be an extremely challenging process, particularly when navigating tortuous vascular anatomies or crossing long, calcified lesions.

Historically, PCIs have been performed manually, by interventionalists possessing extraordinary deftness and skill. But the sheer complexity of the job, and the overwhelming precision that is often required, from time-to-time result in difficulties. And these difficulties sometimes affect patient outcomes.

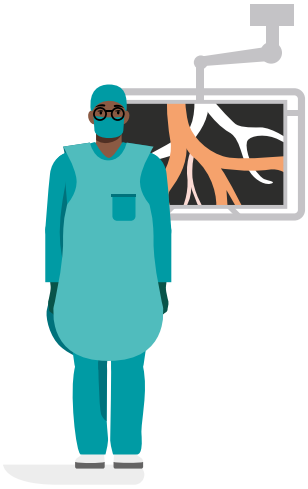
This paper examines various challenges associated with manual PCI, and then explores a potential solution—a rapidly emerging alternative to the complex, demanding procedure so many patients rely on today. The deployment of robotic-assisted PCI (R-PCI) offers an advance in precision, safety, and value that healthcare providers and organizations would do well to consider, and patients are likely soon to demand.

1.000.000

number of PCIs performed every year.[1]

30%

increase in elective PCI (from 2013 to 2017).[1]



The challenge

Notwithstanding its well-recognized value, manual PCI presents challenges for three key stakeholders: the medical team working in the cath lab, the broader healthcare organization, and patients. While there are different ways of thinking about and labelling these challenges, for the purposes of this paper we will group them into four categories:

1. Limited human precision and visualization
2. Variability of care
3. Threats to the health and safety of physicians
4. Limited technology differentiation for attracting talented physicians and patients

Limited human precision and visualization

One fundamental challenge with PCI is that it requires extraordinary, granular precision in the measurement and wiring of a tiny coronary lesion in a moving heart, being looked at through a screen which is six feet (183 cm) away. Little surprise, then, that most coronary lesion lengths are inaccurately estimated. As a result, two out of three stents today are inappropriately selected based on visual assessment.[3] Whether too long or too short, neither is optimal in providing the best possible patient care. But the latter is particularly problematic as these cases require additional stents to cover the full lesion, which raises the prospect of overlapping stents—the consequences of which are not yet known. Without question, PCI is a difficult undertaking, which is underscored by the fact that 9.3% of PCI patients have an unplanned readmission within 30 days.[4]

Precision matters

The incorrect sizing and/or placing of a stent more than doubles the likelihood that a patient will need a repeat procedure within one year and triples their likelihood of suffering a myocardial infarction within one year.[5]

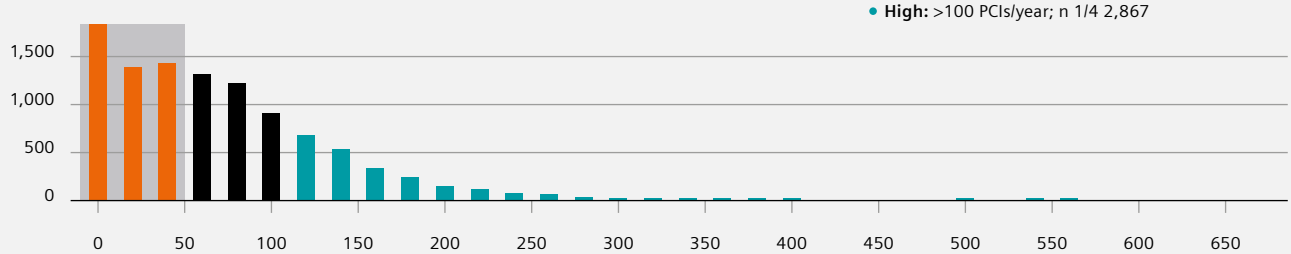
Variability of care

Reducing unwarranted variations really is the name of the game in cath labs where PCIs are being conducted. Variations can add significant costs and reduce quality of care. As noted earlier, 40% of today's coronary interventions are considered complex, typically associated with more chances of unwarranted variations, lower rates of procedural success, and higher rates of recurrence or major adverse cardiac events. In a perfect world, interventionalists would all have the same high level of skill, and the same ability to navigate vessels and cross lesions. This is not a perfect world, however. Some interventionalists perform far fewer procedures than do others, and as is the case with so many things, manual PCI is something you get better at the more often you do it. As a result, not all interventionalists possess the skills and experience to perform complex PCI. This is borne out in the numbers. Patient mortality is 28% higher for low-volume operators performing PCI in low-volume hospitals than for high-volume operators performing PCI in high-volume hospitals.[6]

The shortage of high-volume interventionalists at some institutions can mean patients have to wait a long time for their PCI, and in some cases, they must be referred to other institutions, which is lost income and lost opportunity for the hospital that had to refer them.

Patient mortality is 28% higher for low-volume operators *

Annual PCI operator volumes in the U.S.[6]



*Patient mortality is 28% higher for low-volume operators performing PCI in lowvolume hospitals than for high-volume operators performing PCI in high-volume hospitals.[6]

(y) Number of Operators
(x) Average Annual Volume

Threats to the health and safety of physicians and patients

Physicians

Midcareer cardiologists with 8 to 21 years of practice are more likely to report burnout (39%) than were fellows in training (10%), early-career cardiologists (23%), or late-career cardiologists (28%).[7] This should not be a major surprise. The cath lab is a hazardous place to work. Physicians and staff face serious occupational hazards on two different fronts.

The first is orthopedic. Because they must wear heavy lead to protect themselves from radiation, many interventional cardiologists end up experiencing frequent orthopedic issues ranging from lumbosacral and cervical spine problems, as well as hip, knee, and ankle lesions. Indeed, interventionalists are seven times more likely to suffer orthopedic problems than other physicians, and 62.8% of interventional cardiologists report an orthopedic injury during their career.[8]

The second and even more serious threat comes from exposure to radiation. Physicians and staff working in cath labs experience the highest rates of radiation exposure of all medical professionals. This exposure has been linked to serious injuries: subclinical carotid atherosclerosis and early vascular aging, cataracts, various bone marrow and thyroid malignancies as well as other different types of cancer.

Organizations can ill-afford to ignore the health threats that accompany working in a cath lab. One interventional physician generates $2.4 million in annual income to an organization in the U.S..[10] If a physician is unable to practice, it is estimated to cost more than $1 million (direct and indirect costs) to replace him or her.[10]

Patients

Manual PCI can also pose threats to patient safety. Because there is a risk of longer procedures, there is also a risk of increased radiation exposure to patients, along with an increase in contrast media. Contrast-induced acute kidney injury represents a common but serious complication of PCI.

62.8%

of interventional cardiologists report an orthopedic injury.[8]

90%

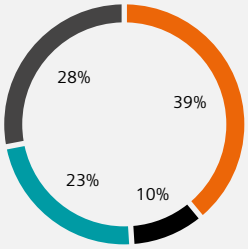
of cath lab physicians believe that radiation poses a significant risk to their health.[9]

26%

believe it will shorten their career.[9]

Mid-career cardiologists report highest prevalence of burnout

Midcareer cardiologists with 8 to 21 years of practice are more likely to report burnout (39%) than fellows in training (10%), early-career cardiologists (23%), or late-career cardiologists (28%).[7]



- Cardiologists with 8 to 21 years of practice
- Fellows in training
- Early-career cardiologists
- Late-career cardiologists

Limited technology differentiation for attracting talented physicians and more patients

Today's manual PCI procedure remains largely unchanged, despite advancements in interventional devices. How the procedure is performed looks very much as it did 40 years ago. What this means is that there has been little in the way of leading-edge innovation around the procedure that allows physicians and organizations to enhance their reputation and that of their institution.

That is a concern for providers both from the standpoint of competing for patients and from the point of view of cardiologist numbers. Interventional cardiologists have a median age of 54 years.[11] Organizations are facing a need to start recruiting the next generation of interventionalists, but the lack of innovation around PCI might be an obstacle to that. The health concerns listed above are another barrier. Young doctors, who come from a much more health-conscious generation, are significantly less eager to expose themselves to harmful levels of radiation or to wear heavy lead coverings that might well end up ruining their spines. Elongating physician careers and making it possible for them to practice medicine safely is a growing concern.

Recruitment in sight

Organizations are facing a need to **start recruiting** the next generation of interventionalists.

The solution

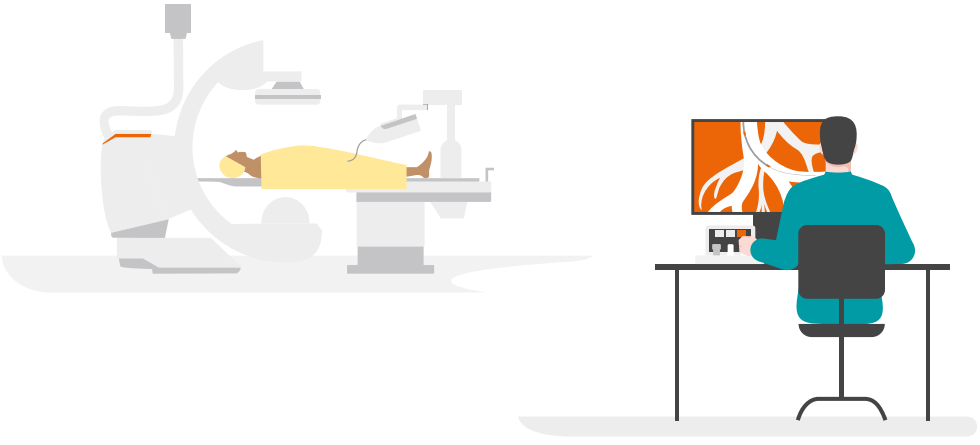
The evidence above underscores the need for improvement in contemporary PCI practices and technologies. Fortunately for healthcare organizations today, that improvement is within their grasp.

The solution is to take the best in human judgment, intuition and decision-making and combine it with robotic precision, control, and procedural automation. Robotic-assisted PCI does precisely that. It emerged as a technology transformation 10 years ago, designed to help overcome the key challenges inherent in manual PCI procedure. Today, there are Robotic Systems, FDA-cleared and CE-marked, that are well-established in early adopter organizations.

R-PCI combines a robotic bedside unit with a control unit, which allows for manipulation of catheters, guidewires, and devices, from a short distance away from the procedure table. Guided by video images from the angiography system into robotic movements and using the control unit/joystick and touchscreen controls, the cardiologist can operate the robotic bedside unit in the cath lab, and precisely steer the catheter, the guidewire, and the balloon or stent. This level of precision is crucial to the success of the procedure and to the long-term outcome of the patient. With precise anatomical measurements and automated procedural movements, the robotic system helps operators navigate complex anatomies more consistently and predictably, aids in selection of the appropriate stent and helps to ensure accuracy in device-positioning.

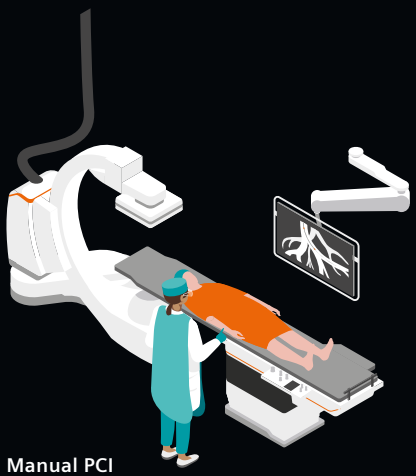
Support to operators

R-PCI system helps operators by enabling robotic precision, control, and procedural automation. It aids in selection of the appropriate stent and helps to ensure accuracy in device-positioning.



Manual PCI vs R-PCI

R-PCI is not a system that replaces physicians. Rather, it is a system that gives cardiologists the precision, control, and endurance they need to enhance their clinical judgment, intuition, and decision-making. It acts as a co-pilot of sorts, helping cardiologists do their best work.



Manual PCI

R-PCI

The future of healthcare includes robotics

Robotic procedures are estimated to grow by 72% globally, surpassing four million by 2025. They were first introduced about 25 years ago in the fields of gynecology and urology.[12] Since then, the potential these procedures hold for improved standardization, outcomes and access has seen them gradually take hold in other fields. Robotic surgery is clearly here to stay.

"That's the nice thing about this technology. It is being used for precision, delivery, and control, all key aspects for putting the right stent in the right place ."[13]

Paul T. Campbell, MD
Interventional Cardiologist,
Atrium Health NorthEast, North Carolina, U.S.

Enhanced technical precision

The first challenge identified in manual PCI is limited technical precision, such as inappropriate stent selection and positioning, as well as the expected risk correlation with outcomes. No matter their experience and skill level, the procedures that cardiologists are asked to perform in a cath lab push human boundaries of manual dexterity and eyesight capacity.

Which is why the solution seems so obviously to be to delegate pure mathematics, utter precision and complex measuring to computers that were created specifically for these tasks.

R-PCI allows for direct measurement of coronary anatomy down to a fraction of a millimeter. What this means is that cardiologists can confidently determine lesion length and know that they are selecting the right stents. In addition, the system enables precise stent positioning with 1mm movements. It doesn't get tired, it doesn't get uncomfortable, and it doesn't get distracted.

Complemented accuracy

Cardiologists can determine lesion length and know that they are selecting the right stents.

During the procedure, the robotic system adds extra control and enhanced precision at every step. R-PCI is associated with reduced additional stent utilization, due to a significantly lower incidence of longitudinal geographic miss compared to manual PCI—12.2% to 43.1% respectively.[13] Overall R-PCI has demonstrated 99.1% clinical success in complex cases, comparable with manual PCI clinical success and procedure times.[14]

"With the help of created algorithms taken from the best interventional operators you can get rid of the trial and error method for vessel navigation. It is as if Tiger Woods hits a golf ball and we can make the robot hit the golf ball the same way. That way everyone gets the opportunity to play at that high level."

William Lombardi, MD
Director, Complex CAD Therapies,
University of Washington Medical Center Seattle, U.S.

Reducing unwarranted variations

The next challenge revolves around the variations that exist from cardiologist to cardiologist, and cath lab to cath lab. These are variations in operator skill, procedure techniques, and patient outcomes. These stem, in large measure, from one other important variation—in the number of procedures that interventionalists perform.

To improve as an interventionalist and achieve the demanding level of skill and precision required for these complex procedures, cardiologists must perform them often. But in the U.S., for example, the average interventionalist only performs 50 PCIs per year. Only one in three perform more than 150 per year.[15] This gap in procedure volume may lead to variability of care between operators and institutions.

Current manual methods for navigating vessels and crossing lesions is often referred to as "trial and error", which says a great deal about its reliability. R-PCI with automated movements is designed to replicate the manual techniques of highly skilled operators, with the intent to help reduce time associated with wiring lesions, standardize procedures, and reduce variability across operators. As an example, pre-clinical trials have shown that the R-PCI time needed to wire lesions can be as much as 53% lower when equipped with the automated Rotate on Retract movement.[16]

Standardization support

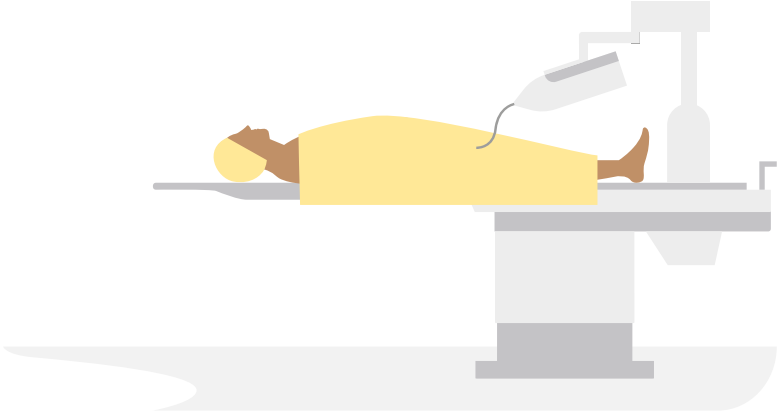
R-PCI with automated movements is designed to replicate the manual techniques of highly skilled operators.

Overall, more standardized procedures, increased procedural efficiency and risk mitigation—reduced trial and error—give cardiologists greater support and confidence when undertaking complex coronary interventions.

From an organizational point of view, R-PCI can mean an increase in patient volumes as it reduces or eliminates the deferrals to other institutions that occur with manual PCI.

–53%

wiring time: R-PCI with automation vs. R-PCI without automation.[16*]



** Disclaimer: Compared to robotic wiring without automation, preclinical study data may not be predictive of clinical results.[16]*

"The precision provided by robotic assistance and the reduction in radiation exposure can be of fundamental importance."

Holger Nef, MD
Vice Chairman Cardiology,
University Hospital of Giessen and Marburg

Making the cath lab safer for physicians

Physicians

Beyond the confidence that accompanies the precision, control, and automation of R-PCI, interventionalists have a very personal reason for considering the technology—it makes their workplace less hazardous. As noted above, there are two distinct threats facing cardiologists performing manual PCI. Robotic assistance eases both.

During an R-PCI procedure, cardiologists work from a workstation, comfortably positioned on an ergonomic chair. And for the most part, they are not required to wear lead. This can make a real difference in the lives of people who once did their jobs from underneath a heavy covering of lead. It can potentially reduce musculoskeletal strain, cut down on orthopedic injuries, and quite possibly prolong careers.

As for radiation exposure, that too can be significantly reduced. The reason operators don't have to wear lead while sitting at their workstation is that the station is already radiation-shielded. Physicians can also opt to work the controls and fluoroscopic imaging from a control area outside the procedure room. What this means is that for primary operators performing R-PCIs, there is a reduction in radiation of more than 95% compared to their colleagues doing manual PCI while wearing traditional lead. R-PCI operator head-level radiation is 80.0% less than manual PCI with suspended lead.[17, 18]

The current estimate is that a cardiologist performing R-PCI would be exposed to less radiation in 20 years than a manual interventionalist is in just one year.[19]

Patients

From a patient safety perspective, R-PCI creates a safer environment by reducing 20% their exposure to radiation,[20] and by lowering 35% the required contrast media.[21]

95%
less radiation for the primary operator

20%
less radiation for the patient

"Performing interventions from a workstation improves your overall life. It allows you to make better use of your time, for example: When you're waiting for things, which you often do in a cath lab, working at a workstation allows you to do your procedure notes, your orders, or to catch up on your EMR."

William Lombardi, MD
Director, Complex CAD Therapies,
University of Washington Medical Center Seattle, U.S.

Stand out, or risk falling behind

We know that we have a growing and aging population, and one of the biggest implications for PCIs is that demand for the procedure is going to increase, for many years to come. Something else we know is that increasingly, patients are acting as consumers, going where they know they will be well and safely treated, and where they can expect the best possible outcomes. Finally, as we noted above, we know that there is a growing demand for expert interventionalists, in a field where burnout is a significant problem.

The opportunity to differentiate the healthcare provider using R-PCI is particularly relevant for organizations aiming to have, or already having, cath labs positioned as centers of excellence in interventional cardiology, academic hospitals, and for forward-thinking organizations.

All of that results in two noticeably clear imperatives for healthcare organizations and providers. Cardiology centers need to attract patients, and the cath lab must become a place where people want to stay, and outsiders want to join. Meeting, and ideally exceeding, the expectations of patients is a priority for all healthcare providers. Meeting the expectations of employees is also key as this affects recruitment and retention. R-PCI is key to delivering on both of those imperatives.

Institutions that adopt R-PCI have the potential to treat more patients, and physicians deciding which organization to join will almost always choose the one offering the best and newest technology.

From the point of view of physicians, access to leading technologies such as robotic-assisted PCI allows them to participate in leading-edge clinical innovation, establishing them as leaders in clinical practice and enhancing their reputation and that of their institution.

And for patients, who increasingly are inclined to "shop around" for the best possible care and the best possible experience, they will be attracted to institutions that, thanks to R-PCI, can offer both.

The potential economic impact of R-PCI

The quality benefits of R-PCI—helping protect key personnel and potentially reducing the number of complications and unplanned readmissions—can also help organizations by expanding services into more complex cases, growing patient volumes, and improving staff retention and recruitment. All of this translates into economic benefits.

The R-PCI economic impact needs to balance the specific capital/service investment against projected cost savings and anticipated revenue growth. Hospitals can expect savings on stents of as much as 15% due to reduced usage and, a 35% savings in contrast media due to procedural automation. In addition, there will likely be additional patient volumes, improved productivity, and lower costs because of fewer cardiologist sick leaves along with better staff recruitment, retention, and replacement.[22]

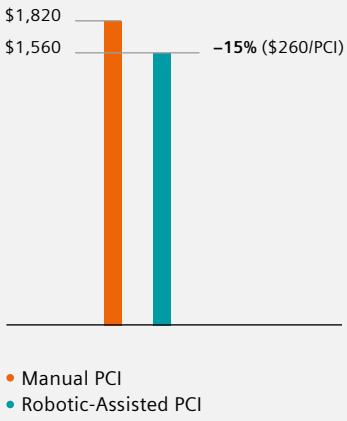
The economic impact will vary depending on the specific healthcare system, and the characteristics of each center. One financial model based on U.S. data showed that a R-PCI system has an estimated payback period of approximately 3 years, based on investment, cost savings and revenue growth estimations.

R-PCI demonstrates 15% reduction in stent usage compared to manual PCI

- Average number of stents required in robotic-assisted PCI: **1.2**[21]
- Average number of stents required in manual PCI: **1.4**[22]
- **15%** savings on stents.[21, 22,]

Financial impact

- Average price of Drug-Eluting Stent (DES): **$1,510**
- Average price of Bare-Metal Stent (BMS): **$670**
- Blended average stent price: **$1,300**
- Savings for stents per robotic-assisted PCI: **$260**



"This technology has a very bright future. After incorporation of more and more Artificial Intelligence, the technology will make the interventions simpler and simpler. There will be less and less scope for human error."

Tejas M. Patel, MD, DM, FACC, FSCAI, FESC
Chairman and Chief Interventional Cardiologist,
Apex Heart Institute in Ahmedabad, India

The future is here

To study the projected future of R-PCI is to open a new window on the healthcare of tomorrow. Looking ahead, we can see R-PCI is poised to expand even further as the field evolves, and the current limitations that are always present with this new technology are gradually overcome. This will be accomplished by increased compatibility with other devices, the ability to manipulate multiple stents or catheters simultaneously, not to mention the real possibility of fully remote PCI procedures, or "tele-stenting," to address the problem of delivering care to people in remote areas. In addition, there is room for expansion of these robotic platforms to other types of interventions, including neurovascular and peripheral vascular conditions.

Numbers today

As of today, R-PCI has been used in approximately 10,000 interventions in more than 15 countries around the world, including 76 centers in the U.S., 15 in Europe and Middle East, and another 15 in Asia-Pacific.

Conclusion

Robotic technology is becoming increasingly common in healthcare. Today there are numerous examples of procedures where robots are used to enhance the skills and abilities of humans. We see this in urologic, orthopedic, and gynecologic surgeries. Given this and given what we know about R-PCI, it would be difficult to frame an argument against considering its potential adoption by healthcare organizations with an eye on the future.

R-PCI allows cardiologists to retain full control of the procedure but do so in the knowledge that there will be assistance in avoiding visual misjudgments, ability to measure anatomy to help select stent length, and no misplaced stent thanks to millimeter precise positioning.

R-PCI is designed to provide low-volume interventionalists with the assistance of robotic techniques that can help duplicate some of the manual skills of highly skilled operators.

The process also protects physicians from the workplace hazards that have existed in cath labs for so long. With R-PCI, there is no longer a need for the primary operator to work under heavy lead, helping reduce the risk of both orthopedic damage and dangerous exposure to radiation.

R-PCI helps set healthcare organizations apart, both by enabling differentiation for attracting more patients needing PCI, and by making the cath lab a safer and more secure place to work. Both differentiators would certainly help attracting physicians looking for the best place possible to ply their trade.

Clearly the decision to move to a robotic system could be perceived as a disruptive one, and needs to be made in alignment with the strategic direction of a hospital and its cardiology center, and in an open dialogue involving the head of cardiology and the appropriate executive suite members. Timing and strategy should come together, resulting in an informed and evidence-based decision that fits best for the organization, its staff, and their patients.

Suggested follow-up on

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- Siemens Healthineers Insights Series, issue 31: The future of interventional services—Advancing robotics in healthcare. Available at: **siemens-healthineers.com/insights/news/future-interventional-services**

Information:

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Dr. Luis Lasalvia, Vice President and Global Medical Officer, drives for more effective and patient centric healthcare in actual practice, by integrating medicine, technology, and finance. His clinical expertise is coupled with extensive team leader experience in the pharmaceutical and medical device industries. He has covered multiple roles as strategist, practicing physician, deal maker and negotiator, and technology scouter.

Entrepreneur and innovator with international background, Luis has participated in projects in more than 50 countries in all continents, innovating, and creating novel and action-oriented insights, by proactively collaborating, and working together with organizations and top leaders around the globe.

Dr. Luis Lasalvia has been guest speaker, panelist, and moderator at approx. 500 conferences and events around the world, submitted several patents in the U.S. and Europe, and authored more than 50 papers and articles in peer review journals and other prestigious publications.

Medical Doctor (Republic University, Montevideo), Master International Business (Pompeu Fabra University, Barcelona), and Postgraduate degrees in Business Administration and in Marketing. Completed Entrepreneurship, risk management, and innovation executive studies at The Wharton School of Business, New York University, and Harvard Business School.

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