The Heart of the Value Story

Improving Care, While Driving Down Costs and Limiting Time in Facilities

A new study provides further evidence that medication therapy and lifestyle changes may be as effective as surgical interventions (percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG] surgery) for treating patients with stable coronary artery disease (CAD).[1] Results from the International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) published in 2019 show that, for applicable people, medication therapy and lifestyle changes might prevent death and heart attacks just as well as the more invasive surgical procedures that were long considered the gold standard. Further, the ISCHEMIA study provides even greater evidence than a similar study reported 13 years ago, the so-called "COURAGE trial" (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation).[2]

This issue brief estimates the savings to the United States (US) healthcare system had the country followed the findings of the COURAGE trial to promote simple lifestyle changes or medication therapy for many CAD patients. Despite trial authors concluding that stents were unnecessary for many CAD patients, they remained the first-line treatment for patients with stable CAD and little or no chest pain, even with significant evidence that less invasive approaches might have been warranted in many patients. The estimates show that, had we practiced the lessons of COURAGE over the last 13 years, **our health system could have saved approximately $21,400 on a per-patient basis, for a total savings of $12.3 billion.**

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Additionally, given the concerns brought about by the COVID-19 pandemic, it is more important than ever to limit low-value care and better allocate healthcare resources. The pandemic has highlighted the high level of potentially unnecessary procedures with a stark reduction in elective procedures that may never be resumed. By highlighting and responding to instances where care may not benefit patients, we can help reshape the inefficiencies in our system and help hospitals better respond to future healthcare crises.

ISCHEMIA Trial Demonstrates That Medication and Lifestyle Changes Can Offer the Same Clinical Benefit as Surgery

Many patients are often prescribed invasive and costly surgery to address CAD, but the ISCHEMIA researchers explored when surgery was needed and when simpler lifestyle or medication alternatives might be more appropriate. The trial identified patients with stable ischemic heart disease who had little or no chest pain as prime candidates for the conservative strategy of medication and lifestyle changes, given the lack of conclusive evidence for an invasive strategy in people without chest pain.

Patients with stable ischemic heart disease who had little or no chest pain may be prime candidates for the conservative strategy of medication and lifestyle changes.

In persons with CAD, surgery is an expensive and risky option, but the option to switch from surgery to a medical and wellness regimen presents an opportunity to generate savings for both patients and the American health system.

The ISCHEMIA trial results corroborated findings from the COURAGE trial 13 years ago, which found that as an initial management approach, optimal medication therapy without routine PCI can be implemented safely in the majority of patients with stable CAD.[1] Nevertheless, PCI remains the gold standard for treating patients with CAD, despite the cost savings and quality of life benefits that medication therapy may have provided had we applied the results of the COURAGE trial 13 years ago.

Estimated Savings From Translating Trial Evidence Into Practice

The results from the COURAGE and ISCHEMIA trials suggest that a large share of invasive procedures may be avoided, leading to higher quality of life for patients and cost savings. Xcenda calculated the magnitude of cost savings resulting from following the ISCHEMIA findings (ie, replacing costly, invasive surgery with medication therapy and lifestyle changes). Xcenda's calculations estimate the potential savings over 1 year, as well as over the past 13 years since the COURAGE trial results were published.

We calculated the potential cost savings by comparing total healthcare costs in a scenario under which patients received either surgery or lifestyle/medication, where appropriate.

Switching less than 5% of patients to statin and anti-atherothrombotic therapy could save more than $1 billion per year.

To determine the cost savings implied by the ISCHEMIA trial, Xcenda reproduced the medication use of patients on the conservative arm of medication and lifestyle changes,[3] and then calculated those costs for 20 years.[a] Xcenda then estimated the number of patients who, according to the trial, would be prime candidates for the conservative strategy, and then calculated the difference in cost between the stenting procedure ($25,000) and 20 years of anti-atherothrombotic and anti-ischemic therapy ($3,400).[4]

Every year in the US, an estimated 23,000 procedures, or 4.6% of people receiving stents, involve patients who do not have chest pain and are candidates to switch and avoid unnecessary surgery.[5] However, the ISCHEMIA researchers believe that this is a conservative estimate, and that medication and lifestyle therapy may be the optimal treatment in a higher percentage of the 50% of "definitely" or "possibly" inappropriate stent procedures performed in the US every year. Estimates suggest that the number of stent procedures performed annually is between 925,000 and 1,000,000.[6-9] With an average coronary stenting procedure costing $25,000, **even switching less than 5% of the patients to statin therapy, combined with lifestyle changes, can save almost $1 billion per year—an astonishing amount** for a change in therapy that (1) is guided by medical evidence, (2) is less invasive, (3) can be managed by a primary care physician, and (4) can be performed in a potentially safer environment.

"It's hard to justify putting stents into patients who are stable and have no symptoms."

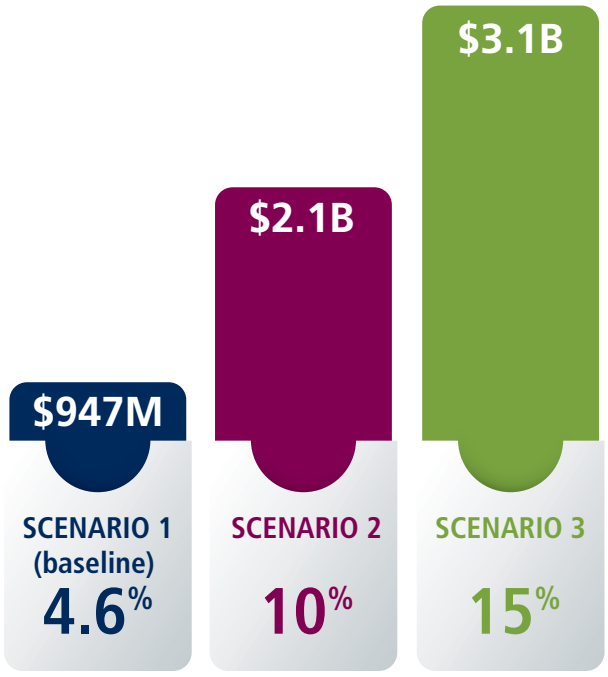
— David Maron, MD, Clinical Professor of Medicine, Director of Preventive Cardiology at the Stanford School of Medicine, and Co-Chair of the ISCHEMIA trial

Although the ISCHEMIA trial does support a role for revascularization among patients with CAD and significant angina, the findings suggest that medication therapy should be the initial treatment strategy, with revascularization reserved only for those patients with persistent, bothersome angina.[10] David Maron, MD, Clinical Professor of Medicine and Director of Preventive Cardiology at the Stanford School of Medicine and Co-Chair of the ISCHEMIA trial, summarized it the following way, "It's hard to justify putting stents into patients who are stable and have no symptoms."[11]

Since the ISCHEMIA researchers believe many more than 4.6% of people receiving stents are candidates for medication and lifestyle therapy, Xcenda calculated savings if 15% or even 10% of potential candidates switched.

The potential savings are remarkable. As the figure below shows, shifting 10% of patients to medication therapy and lifestyle changes can save $2.1 billion per year, and 15% of patients receiving medication therapy and lifestyle changes instead of stents could save the healthcare system $3.1 billion every year.

Estimated Annual Cost Savings From Switching Patients to Medication and Lifestyle Therapy, Instead of Stenting, to Treat Stable Coronary Artery Disease



Percent of switches from stenting to statin and anti-atherothrombotic therapy

[a] In 2014, the mean age of patients who underwent PCI was 64 years, so 20 years of statin therapy was assumed.

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Conclusion

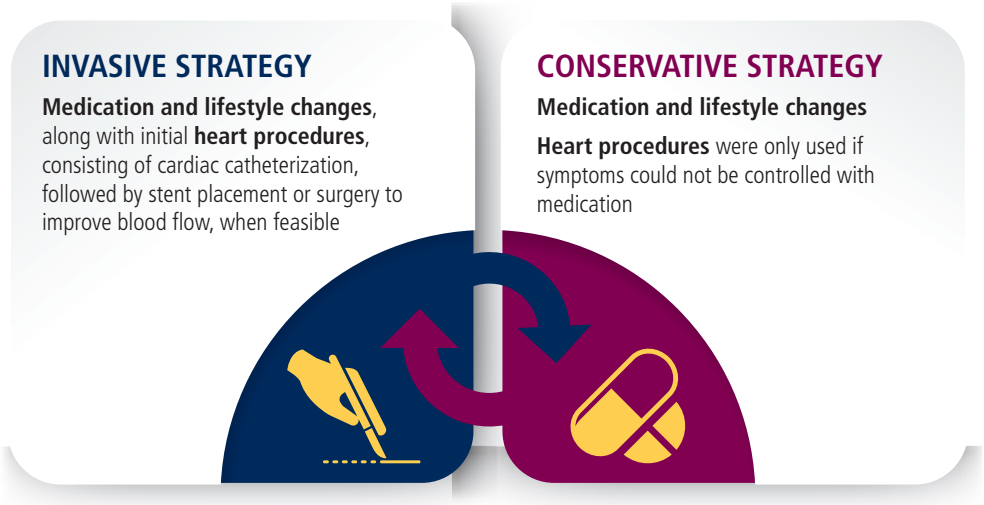
The ISCHEMIA study reiterates, in even more convincing fashion, the conclusions reached in the COURAGE trial 13 years ago: namely, that medication therapy and lifestyle changes in the right patients may offer equivalent outcomes at a reduced cost to the healthcare system and to patients.

Despite the COURAGE trial results showing that stents were potentially unnecessary for many individuals with cardiovascular disease, that invasive procedure remained the first-line treatment for patients with stable CAD and little or no chest pain. The result? Costs that may have been avoided, in addition to the risk, inconvenience, and pain concomitant with stenting and other more invasive procedures, as well as the nontrivial chance of acquiring an infection in the hospital. Had we practiced the lessons of COURAGE over the last 13 years, our health system could have saved approximately $21,400 on a per-patient basis, or, at an absolute minimum, $12.3 billion.

The results of ISCHEMIA are one example of why the healthcare stakeholders need to continue examining value across the healthcare system, including in the hospital setting. This paradigm shift may assist to reduce wasteful healthcare spending and drive patient-centered healthcare.

APPENDIX: ISCHEMIA Study Background

ISCHEMIA enrolled more than 5,000 participants in 37 countries to settle a long-standing dispute in cardiology.[12] The study compared 2 standard ways to treat ischemia to see if one was better at reducing the risk of heart attack or death or improving symptoms in patients with stable CAD:



Medications included anti-atherothrombotic and anti-ischemic medications (eg, statins), whereas lifestyle changes focused on smoking cessation, nutrition, physical activity, weight control, and medication adherence.[13]

The trial showed that adding heart procedures to taking medications and making lifestyle changes did not reduce the overall rate of heart attack or death compared with medications and lifestyle changes alone. However, for people with chest pain symptoms, heart procedures improved symptoms more effectively than medications and lifestyle changes alone. The more chest pain patients had before treatment, the more their symptoms improved after getting a stent or bypass surgery.[14]

1. Hochman JS; ISCHEMIA Research Group. International study of comparative health effectiveness with medical and invasive approaches (ISCHEMIA): primary report of clinical outcomes. December 3, 2019. https://www.ischemiatrial.org/system/files/attachments/ISCHEMIA%20MAIN%2012.03.19%20MASTER.pdf. Accessed January 8, 2020. **2.** Boden WE, O'Rourke RA, Teo KK. Optimal medical therapy with or without PCI for stable coronary disease. *N Engl J Med*. 2007;356:1503-1516. https://www.nejm.org/doi/full/10.1056/NEJMoa070829. Accessed January 8, 2020. **3.** Maron DJ, Hochman JS, Reynolds HR, et al. Supplementary appendix to initial invasive or conservative strategy for stable coronary disease. April 9, 2020. https://www.nejm.org/doi/suppl/10.1056/NEJMoa1915922/suppl_file/nejmoa1915922_appendix.pdf. Accessed April 13, 2020. **4.** Masoudi FA, Ponirakis A, de Lemos JA. Trends in U.S. cardiovascular care: 2016 report from 4 ACC National Cardiovascular Data Registries. *J Am Coll Cardiology*. 2017 Mar 21;69(11):1427-1450. https://www.sciencedirect.com/science/article/pii/S0735109716373387?viewFullText=true. Accessed December 24, 2019. **5.** Johnson CY. Stents and bypass surgery are no more effective than drugs for stable heart disease, highly anticipated trial results show. *The Washington Post*. November 16, 2019. https://www.washingtonpost.com/health/2019/11/16/embargoed-drugs-are-effective-invasive-procedures-patients-with-stable-heart-disease-major-trial-finds/. Accessed December 24, 2019. **6.** Fanaroff AC, Dai D, Sherwood M. Temporal trends and regional patterns of operator percutaneous coronary intervention volume in the United States: a report from the NCDR CATHPCI registry. *J Am Coll Cardiol*. 2016;67(13 Suppl). **7.** Kim A, Zamanian K. PCI Procedure volume recovers with new focus on complex PCI in the U.S. interventional cardiology market. *Diagnostic and Interventional Cardiology*. September 13, 2018. https://www.dicardiology.com/article/pci-procedure-volume-recovers-new-focus-complex-pci-us-interventional-cardiology-market. Accessed January 7, 2020. **8.** iData Research. Over 965,000 angioplasties are performed each year in the United States. August 29, 2018. https://idataresearch.com/over-965000-angioplasties-are-performed-each-year-in-the-united-states/. Accessed January 7, 2020. **9.** CardiologyAdvisor. PCI for STEMI. https://www.thecardiologyadvisor.com/home/decision-support-in-medicine/cardiology/pci-for-stemi/. Accessed January 7, 2020. **10.** Hochman M, Cohen P. ISCHEMIA trial validates slow medicine. *MedPage Today*. December 16, 2019. https://www.medpagetoday.com/blogs/slowmedicine/83917. Accessed Jan. 21, 2020. **11.** White T. Stents, bypass surgery show no benefit in heart disease mortality rates among stable patients. *Stanford Medicine News Center*. November 15, 2019. https://med.stanford.edu/news/all-news/2019/11/invasive-heart-treatments-not-always-needed.html. Accessed January 8, 2020. **12.** International Study of Comparative Health Effectiveness With Medical and Invasive Approaches (ISCHEMIA). Clinicaltrials.gov: identifier NCT01471522. https://www.ischemiatrial.org/. Accessed December 23, 2019. **13.** National Heart, Lung, and Blood Institute (NHLBI). ISCHEMIA trial protocol v1.0. Protocol version date: January 18, 2012. https://clinicaltrials.gov/ProvidedDocs/22/NCT01471522/Prot_000.pdf. Accessed December 23, 2019. **14.** ISCHEMIA. ISCHEMIA study results. https://www.ischemiatrial.org/ischemia-study-results. Accessed December 23, 2019.