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Opinion

Should the Best Medical Therapy for Stable Coronary Artery Disease Obviate the Need for Elective Percutaneous Coronary Intervention (PCI)? *Is it time to Constrict the (Elective) Stents?*

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ABSTRACT

Percutaneous Coronary Intervention [PCI] has been a revolutionary advance in cardiology, and many lives have been saved as a result of the widespread application of primary PCI. However, elective PCI has not yet been proven to save lives or reduce the risk of myocardial infarction. Despite this lack of evidence, elective PCI has been misused and in some cases, abused for nonmedical reasons.

The considerable cost of elective PCI can be reduced, and the resources could potentially be utilized for better public health outcomes. The following article intends to highlight the lack of evidence supporting the use of elective PCI, which is a problem not only in North America and Europe but also throughout the world.

Better regulation of the elective PCI procedure could reduce health care expenditures and divert resources to cardiovascular disease prevention.

INTRODUCTION

One of the most controversial issues in clinical cardiology is whether a cardiologist should initiate optimal medical therapy with follow-up for symptoms in patients with symptomatic but stable ischemic heart disease or subject them to elective Percutaneous Coronary Intervention [PCI] on top of optimal medical treatment [1-3]. There is, however, no controversy that primary PCI is a lifesaving procedure in the setting of acute coronary ischemia. The pathophysiology of chronic stable coronary ischemia is different from that of acute coronary ischemia. Therefore, one should not expect the same favorable result with the same treatment when dealing with a different disease process [3].

Primary PCI is lifesaving, but elective [nonacute] PCI is NOT!

Primary PCI for ST-segment elevation acute coronary syndromes is one of the major breakthroughs of the past 25 years and has replaced thrombolytic therapy as the method of choice for reperfusion [4]. Primary PCI achieves superior reperfusion and reduces mortality, reinfarction and intracranial bleeding more effectively than pharmacological reperfusion [4]. Primary PCI is also an effective treatment strategy for non-ST-segment elevation acute coronary syndromes, reducing mortality, reinfarction and duration of hospital stay [5]. However, extrapolation of the success of primary PCI to elective PCI might not be justified [1, 3,6,7].

Does elective PCI provide effective and sustained angina relief?

Relief of the symptoms of angina pectoris has been shown to be more rapid with elective PCI than with optimal medical treatment alone in the COURAGE trial [8]. However, this symptomatic benefit does not persist and becomes nonsignificant at 6 months [9]. Furthermore, this "temporary superiority" of elective PCI for angina relief was achieved with the help of multiple antianginal medications. Even after a successful PCI, interventionists use triple anti-anginal therapy almost as often as in the medical treatment arm, making it difficult to determine whether the resolution of angina was due to relief of the coronary obstruction or addition of the anti-anginal medications. Approximately 85% of PCI patients were still on a beta-blocker, and more than 45% were on calcium antagonists and/or nitrates despite a good angiographic result [8].

The ORBITA trial recently raised the possibility that the angina-relieving effect of elective PCI may in a large part be a placebo effect [10]. In this trial, patients with severe coronary stenosis and stable angina pectoris were randomized into either a true-PCI or sham-PCI arm. There were no differences between the groups in either angina resolution or treadmill time [10].

Should we be treating coronary ischemia or should we be treating coronary atheromas?

For many decades, cardiologists have thought that chronic coronary ischemia was associated with poor clinical outcomes and the resolution of ischemia with good outcomes. This "ischemia dogma" had never been challenged until the publication of the STICH [Surgical Treatment for IsChemic Heart Failure] study [11]. The presence of ischemia at baseline did not predict which patient was to benefit from revascularization, and the prognosis of the patients did not differ by the presence or absence of baseline ischemia. Some authors began to challenge the "dogma" of ischemia by asking "Is ischemia dead after STICH?" [12], some asked "Should ischemia guide revascularization?" [13], and some even asked "Is ischemia truly bad for you?", implying that ischemia in and of itself may not be bad but it might be a surrogate marker for coronary plaque burden [14].

A more modern and specific way of detecting coronary ischemia, Fractional Flow Reserve [FFR]-guided treatment strategies, has been tested in a prospective randomized trial, i.e., the FAME-2 trial [15]. This trial failed to show any prevention of hard events when elective PCI was guided by the FFR technique. The claimed benefit of the FFR-guided but unblinded elective PCI procedures on the prevention of urgent revascularizations has therefore remained questionable [16,17].

The growing skepticism about the relief of chronic coronary ischemia set the stage for the ISCHEMIA trial [NCT01471522], which has completed enrollment. This trial may help us to understand whether the resolution of ischemia with an elective PCI will provide an incremental clinical benefit over intensive medical treatment targeted to modify and stabilize coronary atheromas.

Why, then, are we still doing elective [nonacute] PCI?

Despite all the clinical trials and preponderance of literature suggesting that "… elective PCI does not reduce the risk of future MI or death, and does not provide sustained angina relief…" [7, 8], what might be the potential reasons for the persistence of elective PCI procedures in daily practice? Some of the "**nonvisible**" triggers for elective PCI procedures include misperception-based patient requests, peer pressure and global economic/consumerist pressures [18,19].

CONCLUSION

The number of elective PCI cases has declined since 2006, coinciding with the publication of the COURAGE and BARI-2D trials [6]. Despite this evidence, approximately 500,000 patients undergo elective PCI procedures every year for symptomatic relief of stable angina in the USA and Europe [20]. The clinical benefit of these

procedures is arguable at best and procedure-related complications, including per procedural [and long-term] death, stroke, and kidney injury have reached a level that may have major public health implications [20]. A "restricted" use of elective PCI might allow us to avoid these unneeded iatrogenic complications and "redirect" some of our resources from "Elective PCI Centers" to community-based "Preventive Cardiology Centers".

The ongoing ISCHEMIA trial [NCT 01471522], the results of which should be available by the end of 2019, is the largest comparative effectiveness trial in patients with stable ischemic heart disease. This trial has completed the enrollment of 5179 patients with stable ischemic heart disease, moderate-to-severe ischemia on a perfusion scan and angiographic evidence of significant coronary stenosis. Patients were randomized into either an optimal medical therapy-only arm or optimal medical therapy plus an elective PCI arm. The end points are all-cause mortality, myocardial infarction, stroke, new heart failure and kidney injury as well as quality of life. With the combined data from the ORBITA [10] and ISCHEMIA [NCT 01471522] trials, we may need to reconsider the rules for elective PCI. Until the results of the ISCHEMIA trial are available, however, it would be prudent to institute and evaluate the effects of optimal medical therapy before considering elective PCI for patients with chronic angina pectoris.

REFERENCES

1. Fassa AA, Wijns W, Kolh P, Steg PG. Benefit of revascularization for stable heart disease: the jury is still out. Eur Heart J. 2013; 34: 1534-1538. https://goo.gl/ouvrXx
2. Gibbons RJ, Miller TD. Should extensive myocardial ischemia prompt revascularization to improve outcomes in chronic coronary artery disease?. Eur Heart J. 2015; 36: 2281-2287. https://goo.gl/yFC8RV
3. Bangalore S, Maron DJ, Hochman JS. Evidence-based management of stable ischemic heart disease: challenges and confusion. JAMA. 2015; 314: 1917-1918. https://goo.gl/xycjYM
4. Grines CL, Cox DA, Stone GW, Garcia E, Mattos LA, Giambartolomei A, et al. Coronary angioplasty with or without stent implantation for acute myocardial infarction. Stent Primary Angioplasty in Myocardial Infarction Study Group. N Engl J Med. 1999; 341: 1949-1956. https://goo.gl/xcnzee
5. Bavry AA, Kumbhani DJ, Rassi AN, Bhatt DL, Askari AT. Benefit of early invasive therapy in acute coronary syndromes: a meta-analysis of contemporary randomized clinical trials. J Am Coll Cardiol. 2006; 48: 1319-1325. https://goo.gl/cwxeQd
6. Bangalore S, Gupta N, Généreux P, Guo Y, Pancholy S, Feit F. Trend in percutaneous coronary intervention volume following the COURAGE and BARI-2D trials.Insight from over 8.1 million percutaneous coronary interventions. Int J Cardiol. 2015; 183: 6-10. https://goo.gl/Hxb2Gx
7. Hochman JS, Steg PG. Does preventive PCI work?. N Engl J Med. 2007; 356: 1572-1574. https://goo.gl/JvrrpY
8. Boden WE, O'Rourke RA, Teo KK, Hartigan PM, Maron DJ, Kostuk WJ, et al. Optimal medical therapy with or without PCI for stable coronary disease. N Engl J Med. 2007; 356: 1503-1506. https://goo.gl/aHrWwZ
9. Weintraub WS, Spertus JA, Kolm P, Maron DJ, Zhang Z, Jurkovitz C, et al. Effect of PCI on quality of life in patients with stable coronary disease. N Engl J Med. 2008; 359: 677-87. https://goo.gl/RmPcT2
10. Al-Lamee R, Thompson D, Dehbi HM, Sen S, Tang K, Davies J, et al. Percutaneous coronary intervention in stable angina (ORBITA): a double-blind, randomised controlled trial. Lancet. 2018; 391: 31-40. https://goo.gl/1H51S2
11. Velazquez JE, Lee KL, Deja MA, Jain A, Sopko G, Marchenko A, et al. Coronary-artery bypass surgery in patients with left ventricular dysfunction (STICH trial). N Engl J Med. 2011; 364: 1607-1616. https://goo.gl/di9nku
12. Gibbons RJ, Miller TD. Is ischemia dead after STICH?. J Am Coll Cardiol. 2013; 61: 1871-1873. https://goo.gl/ZcT4Sp
13. Weintraub W. Should is chemia guide revascularization?. J Am Coll Cardiol. 2012; 60: 191-192. https://goo.gl/2dDXEyJ
14. oshi VN, Dweck RM. Is ischemia really bad for you?. J Am Coll Cardiol. 2013; 62: 2148-2149. https://goo.gl/Vvp1LR
15. De Bruyne B, Pijls NHJ, Kalesan B, Barbato E, Tonino PA, Piroth Z, et al. Fractional flow reserve -guided PCI versus medical therapy in stable coronary disease. N Engl J Med. 2012; 367: 991-1001. https://goo.gl/FVQRTP
16. Boden WE. Which is more enduring- FAME or COURAGE?. N Engl J Med. 2012; 367: 1059-1061. https://goo.gl/A7LGB1
17. Goodney PP, Woloshin S, Schwartz LM. Fractional flow reserve-guided PCI in stable coronary disease. N Engl J Med. 2012; 367: 2355-2356.
18. Lee JH, Chuu K, Spertus J, O'Keefe JH. Widespread patient misconceptions regarding the benefits of elective percutaneous coronary intervention. Circulation. 2008; 118: S-1161.
19. Schulman-Marcus J, Weintraub WS, Boden WE. Reconsidering the gatekeeper paradigm for percutaneous coronary intervention in stable coronary disease management. Am J Cardiol. 2017; 120: 1450-1452. https://goo.gl/xztdGh
20. Brown DL, Redberg RF. Last nail in the coffin for PCI in stable angina?. Lancet. 2018; 391: 3-4. https://goo.gl/u6di8A