

## Appropriate Percutaneous Coronary Intervention

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Since Andreas Gruentzig introduced the percutaneous balloon angioplasty treatment in 1977, the procedure has seen an unprecedented growth worldwide. With the advent of coronary stents, interventional cardiologists are now performing more complex coronary lesions. Because of its huge growth, the procedure has recently come under close scrutiny and the appropriateness of its use has been questioned.

In a recent article in USA TODAY, on June 19, 2013, Peter Eisel reported that 'Six common surgeries done unnecessarily' in USA. Among these are caesarian section, hysterectomy, spinal surgery, knee & hip replacement, pacemaker implantation and percutaneous coronary Intervention (PCI). Though PCI is not a surgery but an invasive procedure it was in the list as it is perceived by general mass as a mini-surgery. In 2011 a cardiologist's license was revoked in Maryland following an allegation that he did put 30 stents in a single day and some of them were unnecessary. In December 2012 a cardiologist from Louisiana started a 10-year prison sentence for doing unnecessary PCIs and fraudulent billings.

It is therefore time to look into some of the reports on this issue more carefully to have a detailed insight. Approximately 600 000 PCs are performed in the United States each year.<sup>1</sup> In a study done in US over the period of 2009-2010, 71% were done in acute coronary syndromes and rest 29% were in non-acute patients. PCIs done during acute coronary syndrome were appropriate in almost all cases. However in non-acute setting, only 50% of procedures were considered as 'appropriate', 38% as 'uncertain', and 12% as 'inappropriate'.<sup>2</sup> Moreover, there was substantial variation among the hospitals in

percentage of inappropriate PCIs in non acute settings, ranging from 0 to 55%. Much of this can be due to the lack of documentation of the patients' clinical scenarios. The variation of practice pattern of intervention was quite noticeable among hospitals in US. This is very important because it means interventional cardiologists do not seem to have consistency with regard to how they choose patients for PCI in non-acute and in elective setting.<sup>3</sup>

In the non-acute or elective setting, most studies of revascularization have been based on and reported according to angiographic finding of 'significant' stenosis as  $\geq 70\%$  diameter ( $\geq 50\%$  for left main CAD) Physiological assessment by fractional flow reserve (FFR), has been used in deciding appropriateness of revascularization and  $FFR \leq 0.80$  can also be considered to be 'significant'.<sup>4</sup>

Despite the widespread use of PCIs, the appropriateness of these procedures in contemporary practice is unknown. Data from 2001 to 2009 in US show that coronary angiogram (CAG) vs. PCI ratio in US is about 3 to 1.<sup>5</sup> By 'appropriate', the authors mean there have been sufficient studies to show definite benefit for these patients. The term 'uncertain' is now changed to 'may be appropriate' and the 'inappropriate' now changed to 'rarely appropriate.' The last two terms do not mean that PCIs were unnecessary rather that there is not enough data regarding whether they are beneficial or not.

In another study done in Washington state on 13,291 PCIs performed in 2010 using 'Appropriate Use Criteria'<sup>6</sup> 1% of PCIs for acute indications and 17% of PCIs for non-acute indications were classified as inappropriate.<sup>7</sup>

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The American College of Cardiology along with 5 other professional organizations, developed the 'Appropriate Use Criteria for Coronary Revascularization' to serve as a national standard to quantify the appropriateness of coronary revascularization for a variety of clinical scenarios and support the effective and efficient use of PCI.<sup>8</sup>

The characteristics which were considered for appropriateness criteria in acute cases were i) acute STEMI ii) STEMI-12 h from symptom onset -unstable iii) STEMI-12 h from symptom onset-stable iv) STEMI after successful lytics v) STEMI after failed lytics (rescue PCI) vi) non-STEMI vii) high-risk UA and viii) non-high risk UA.

The characteristics which were considered for appropriateness criteria in no-acute cases were i) angina severity (no symptoms, Class I, Class II, Class III & Class IV) ii) number of antianginal medications (0, 1, 2 or more) iii) antianginal medications ( $\beta$ -blockers, Nitrates, CCB, Others) iv) noninvasive risk assessment (low-risk, intermediate-risk, high-risk & unknown) v) coronary artery disease severity & vi) prior bypass.

For Bangladesh, the impact of coronary artery disease on the morbidity and mortality and the consequent economic implications on the individuals and families will be huge in the coming years. A meta-analysis published in June 2012 from International Center for Diarrheal Diseases in Bangladesh (ICDDR,B), reported mortality from cardiovascular diseases (CVD) to be 4 times higher in 2010 and predicted 21 times higher in 2025 compared to its corresponding rate in 2003.<sup>9</sup> With the increase on CVD death in the country there was also progress in the field of interventional cardiology. This progress is steadily growing over the last 15 years. Though cardiac catheterization started in 1981, the first angioplasty in Bangladesh was done in 1995 when there was a single center in the country. In 1997, only 34 angioplasties were done compared to 8081 in the year 2011. At present there are 30 centers with catheterization laboratories facilities in the whole country, 18 of them being situated in the capital city of Dhaka.

In the year 2011 there were about 27,169 CAGs done in Dhaka out of which 8081 patients had angioplasties (PCI). The ratio of PCI vs. CAG was about 30% which is comparable to the US statistics. The facilities outside Dhaka are limited and in the same year 3285 CAGs and 340 PCIs (ratio ~10%) were done in the rest of the country.<sup>10</sup> The population of US is approximately double that of Bangladesh. The number of angioplasties in US is about 600,000 per year. However the number of angioplasties done per year in Bangladesh is still less than 10,000 and many of these are being done in non-acute or elective clinical setting.

The question of how many of inappropriate PCIs are done in Bangladesh will remain unanswered for quite some time and strategies to prevent it will be a mammoth task but much needed. To prevent inappropriate PCIs practice in Bangladesh will be difficult as the issue is complex and multifactorial. The decision to put a stent or not, is sometimes influenced by the decision of the cardiologist and in some instances, the patient and relatives who think putting a stent in a narrowed vessel or with visible stenosis on angiography would prevent myocardial infarction and death. This misconception is even noted in the developed countries. In a recent survey in the USA, among patients who already signed informed consent and were waiting in the cardiac catheterization laboratory prior to the procedures, almost three quarters of them thought that without PCI, they would probably have MI within 5 years, and 88% believed that PCI would reduce risk for MI.<sup>11</sup>

Over the last few years however, there is a declining trend in PCI procedures in US for several reasons. COURAGE<sup>12</sup> trial which enrolled 2,287 patients with stable angina who did not have survival affecting coronary anatomic lesions (such as significant left main or proximal left anterior descending artery lesions) reported that PCI did not reduce the risk of death, myocardial infarction, or other major cardiovascular events when added to optimal medical therapy. This had an impact on referral for interventions. PCI procedures also declined after the publication of

FAME trial which showed that if the lesion was not significant physiologically, it could be left safely without PCI with ongoing optimal medical therapy.

The goals of revascularization for patients with CAD are to 1) improve survival and/or 2) relieve symptoms. To prevent inappropriate PCI in Bangladesh will remain difficult unless all the parties involved—patients, doctors and the industry make a concerted effort. Dr. Salim Yusuf, a Canadian cardiologist who has frequently argued that stents are overused told The New York Times: "We're going to have a hell of a time putting the genie back in the bottle. It's a \$15-\$20 billion industry. You have huge vested interests that are going to push you back."

In Bangladesh, we need to design a peer-review process for all non-acute or elective procedures where PCI being contemplated for the management of CAD. Cardiologists should be encouraged to document the presence of angina, Canadian class, describe the stress test and non-invasive imaging tests if any to correlate with the angiographic lesions and explain the basis for coronary intervention. Premier teaching hospitals should adopt policies regarding this issue and take the lead in recording these points and create a database. Non-invasive evaluation before the invasive procedures should be encouraged and when no preprocedure data available, physiologic and anatomic evaluation tools such as FFR and Intravascular Ultrasound procedures should be made available. Course curriculum for the trainee physicians also need to be reorganized to emphasize on these aspects. Finally, patient education is needed to focus on the clinical setting of CAD and risks benefits of the invasive procedures in an individual patient's clinical context and its implications.

As cardiovascular physicians, it is our moral obligation in the socio-economic condition of Bangladesh that we protect our patients and families from unnecessary procedures and deliver the most effective care that is appropriate as supported by the contemporary literature.

## REFERENCES

1. Cadet JV. AHA adjusts angioplasty stats to lower annual figure, December 19, 2010. Published Online. (The Complete Update is now published online).
2. Chan PS, Patel MR, Klein LW, et al. Appropriateness of Percutaneous Coronary Intervention. *JAMA* 2011;306(1):53-61.
3. Edward L. Hannan, Kimberly Cozzens, Zaza Samadashvili, Gary Walford, Alice K. Jacobs, David R. Holmes, JR, Nicholas J. Stamato, Samin Sharma, Ferdinand J. Venditti, Icilma Fergus, Spencer B. King III. Appropriateness of Coronary Revascularization for Patients Without Acute Coronary Syndromes. *J Am Coll Cardiol* 2012;59 (21):1870-76.
4. Tonino PA, Fearon WF, De Bruyne B, et al. Angiographic versus functional severity of coronary artery stenoses in the FAME study fractional flow reserve versus angiography in multivessel evaluation. *J Am Coll Cardiol* 2010;55(25):2816-21.
5. Robert RF, Don CW, Powell W, et al. Trends in Coronary Revascularization in the United States From 2001 to 2009 Recent Declines in Percutaneous Coronary Intervention Volumes. *Circ Cardiovasc Qual Outcomes* 2011;4(2):193-97.
6. Patel MR, Dehmer GJ, Hirshfeld JW, Smith PK, Spertus JA. Appropriate Use Criteria for Coronary Revascularization Focused Update; a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, American Society of Nuclear Cardiology, and the Society of Cardiovascular Computed Tomography. *J Am Coll Cardiol* 2012;59(14):857-81.
7. Bradley SM, Maynard C, Bryson CL. Appropriateness of Percutaneous Coronary Interventions in Washington State. *Circ Cardiovasc Qual Outcomes* 2012;5(4):445-53.
8. Patel MR, Dehmer GJ, Hirshfeld JW, Smith PK, Spertus JA. ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization: a report by the American College of Cardiology Foundation Appropriateness Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, and the American Society of Nuclear Cardiology Endorsed by the American Society of Echocardiography, the Heart Failure Society of America, and the Society of Cardiovascular Computed Tomography. *J Am Coll Cardiol* 2009;53(6):530-53.
9. Saquib N, Saquib J, Ahmed T, Khanam MA, Cullen MR. Cardiovascular diseases and Type 2 Diabetes in Bangladesh: A systematic review and meta-analysis of studies between 1995 and 2010. *BMC Public Health* 2012;12:434.
10. Haq MM. Cardiovascular Disease in Diabetic Patients and Progress of Interventional Cardiology in Bangladesh. Paper Presented at BMA UK Annual Conference in UK. September 2011.
11. Rothberg MB, Sivalingam SK, Ashraf J, Visintainer P, Joelson J, Kleppel R, Vallurupalli N, Schweiger MJ. Patients' and cardiologists' perceptions of the benefits of percutaneous coronary intervention for stable coronary disease. *Ann Intern Med* 2010;153(5):307-13.
12. Boden WE, O'Rourke RA, Teo KK, et al. Optimal medical therapy with or without PCI for Stable Coronary Disease. *N Engl J Med* 2007;356(15):1503-16.