

Synopsis

Bypass surgery (CABG) and Angioplasty (PTCA) have shown to improve the quality of life in chronic stable angina patients. These modalities haven't shown to improve all-cause mortality.

Clinical trials like EAST, RITA, MASS, BARI, BARI-2D, and COURAGE has shown the limitation of bypass surgery and angioplasty in patients with chronic stable angina.

There is a huge discrepancy between what the cardiologist wants to deliver which is a reduction in symptoms and improved quality of life. What stable patients want to achieve is a decrease in the chance of myocardial infarction (heart attack) and improved survival by doing interventional procedures like bypass surgery and angioplasty.

Current Status Of Bypass Surgery and Angioplasty Effectiveness In Chronic Stable Angina Patients

Management of chronic stable angina patients is shrouded with mystery. Many times the patients were advice for CABG (Bypass Surgery) by one physician and in turn advised for PTCA (Angioplasty) by another physician, and the patients are confused. The relevance of interventional procedures (CABG& PTCA) in India how we can able to manage patients with chronic stable angina cost effectively is a major question right now? So my presentation here is to reveal the secret of cardiology on the management of chronic stable angina and also about the introduction of a new treatment called EECP (Enhanced External Counter Pulsation)

What is EECP treatment? I have been doing a lot of presentation across India, probably more than 100 presentations about the management of chronic stable angina with a new developing treatment modality called Enhanced external counterpulsation, Which is FDA approved and also covered by major guideline in cardiology, particularly American Journal of Cardiology and the European society of cardiology with the level of evidence 2b and level of evidence 2a respectively. The major question most of the time when I am presenting about EECP, In chronic stable angina patients, is whether it is to an insurance company or policymakers is would you able to provide EECP into these group of patients where you can able to differ or eliminate interventional procedure like PTCA or CABG. This could be an enormous cost saving.

To answer this let's look at the clinical data available in support of intervention in the management of chronic stable angina (CSA). So before the acceptance of (PTCA) angioplasty, surgical procedure CABG (bypass surgery) was a common one in clinical practice. CABG procedure is done for patients with

multivessel disease. Then slowly PTCA was introduced into the clinical practice and started using for patients with single-vessel disease, the stent was employed for single or double vessel disease eventually. So it is an understanding that PTCA was done for a single or double vessel disease in patients with chronic angina with the stable symptom with evidence of ischemia and CABG for multi-vessels disease, and this strategy is derived from some studies previously to show there might be some mortality benefit in offering CABG as a treatment procedure.

Now after the greater acceptance of PTCA, slowly PTCA start competing with CABG and now we have PTCA for even multivessel disease. In early 90's they devised a clinical trial called EAST, which is Emory angioplasty v/s surgery trial in that about a couple of 100 or close to 1000 patients have recruited and it is a randomized control trial. So they randomize patients who have gone for a CABG and PTCA and most of the patients who selected for this trial are with the multivessel disease with preserved LV function who have symptoms of mild to moderate with evidence of ischemia. So when these group of patients were treated either by PTCA or CABG and followed up to 3 years they found out PTCA and CABG when compare to each other does not offer any outcome benefits. In a simple sense, the primary composite endpoint of death or myocardial infarction or non-fatal MI does not have any significant difference between both the groups. So they concluded in patients with chronic stable angina with multi vessels disease based upon the preference of the physician and the patient either CABG or PTCA can be advised. The only advantage CABG over the PTCA is in patients who have undergone CABG the recurrent or repeat procedure is comparatively less which is around 13% in 5 years but when you offer PTCA the recurrent procedure are needed in more than 50% of the patients within 3 years.

Now after looking at the trial, they decided to do another trial called Randomized interventional treatment for angina (RITA). RITA is another Randomized control trial design to check intervention treatment for chronic stable angina patients. So in this trial thousand of patients were recruited and again they tested the same strategy of competing or comparing CABG with PTCA directly. So in this trial also the results were very similar and they could not achieve any statistically significant difference in the outcome (myocardial infarction, death). Even in quality of life as well as patients cost-effectiveness, still, they were not able to achieve any difference in CABG or PTCA. So the guideline made it very clear that the patient can be chosen for PTCA or CABG it depends upon the patients and the physician preference with no change in mortality. Clinically what we can offer to these groups of patients is a significant improvement in the quality of life only.

Well, there is always a competition between CABG and PTCA to prove which is better. Now a new question arises what about medical management? Most of the patient refuses interventional procedure which is very common in India or also they might not be a candidate. So managing these patients with medical management alone is it good enough? so the trial of RITA-2 was initiated. Rather than comparing two interventional procedures CABG with PTCA, they now compare PTCA with medical management. Well, this trial also designed to do follow up for 5 years because they thought to follow-up the patient more time would yield some benefits in outcome favoring PTCA. Well again whether it is

medical management or PTCA along with medical management the outcome doesn't change. Study endpoints like myocardial infarction (MI), death or non-fatal MI did not change by offering PTCA along with medical management when compared with medical management alone. So the guideline again said you may be able to choose whether it is the medical therapy or an interventional procedure based on patient preference, quality of life, the anginal symptom and exercise tolerance.

These studies have caused controversy to erupt since PTCA has not established superiority over simple medical management alone. This is in spite of exposing the patients to the adverse effect of the PTCA procedure and high cost involved. There are two further major trials that have been designed, one is Medicine, angioplasty or surgery (MASS) trial and the other is a Bypass angioplasty revascularization Investigation (BARI) trial, these trials were designed because the primary endpoints of MI were not clearly defined in previous EAST and RITA trials. So they thought if they define the Myocardial infarction (MI) very clearly then they may have some outcome benefits that can be demonstrated. The MASS trial was a large trial which they recruited a couple of 1000 patients in both CABG, PTCA, and medical management and followed them for 5 years, again to their surprise even after following for 5 years there is obviously no change in the outcome. The mortality the primary composite endpoint or recurrence of MI did not change whether you offer a CABG, PTCA or medical management. But when comparing CABG with PTCA which the study was not statistically powered to, CABG showed some advantage in mortality due to a reduction in non-Q-wave MI and then repeat hospitalization. So it is concluded after MASS trial if a patient is stable with ischaemic symptom and with the multivessel disease either CABG, PTCA or medical management can opt as an

option. But over PTCA, CABG might provide some effect to protect the future incident of myocardial infarction.

Following that the BARI trial results were also announced in 2007 which shows in the follow-up of 5 years of PTCA vs CABG, they did not show any difference in clinical benefit or outcome benefit. This is similar to what we know from MASS, RITA, and the EAST trials. Now when they did the sub-group analysis in BARI trial, they found out in patients with triple vessel disease with diabetic CABG seems to show some benefit in outcome.

So based on this observation they tested this new observation of effectiveness of CABG in patients with the multi-vessel disease with diabetes in Bypass angioplasty revascularization type 2 diabetes (BARI 2D) trial. It is another large randomized control trial where thousands of diabetic patients were involved and followed them for 5 years to see the benefits of CABG in patients with the multi-vessel disease with the stable symptom, proven ischemia with mild to a moderate symptom. In that, they found out in the patients with diabetes the incident of MI, death and cardiac mortality was less in the CABG group. But the overall mortality that's all-cause mortality did not change in whatever treatment

opted. So all these trials have clearly shown any of the interventional Procedure over medical management will not give any protection against future myocardial event but its only a quality of life improvement, So if you have a patient with poor quality of life you can able to offer them an intervention if the medical management will not able to achieve improvement in quality of life and exercise tolerance.

Now this is where the major controversy in cardiology lies, because usually the patients are made to believe by taking a CABG or PTCA these procedures would give them some protection against future myocardial event (Heart attack), but it clearly showed in all these trials if you choose to do CABG or PTCA it might not offer you any advantage in death and improved survival except quality of life improvement. Well in academic discussion the proponent of CABG and PTCA claim that's exactly the point why they are doing CABG and PTCA to improve the quality of life and decrease the symptoms of the patients. Where the patients can able to walk more distance than before. But the point is this is not what the patient is expecting from the physician, there is a lot of lacuna (disparity) between what the physician expects to provide and what the patient wants to achieve (with PTCA and CABG). So if you really tell the patients that I am going to offer you CABG or PTCA only for the quality of life improvement, we don't know how many patients really come back for CABG and PTCA, When simply medical management can able to do the trick.

To conclude this finally another major trial which is like a game changer or which can change the guideline was launched and the results were published in 2007 which is called The Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial. The COURAGE trial directly pitted PTCA with medical management, So we have a PTCA (angioplasty) with medical management and you have a medical management alone. So it is a general expectation since you have an angioplasty where you are fixing the lesion and then you have medical management, this strategy will be superior when compared with medical management alone. We would definitely believe to have more improvement in outcome with PTCA group but to there shocking disbelief, when the final result of courage trial was announced the superiority myth of angioplasty was shattered. Again courage reflects the same finding, which has been done in all these EAST, RITA, BARI, MASS, and BARI 2D clinical trials. To strengthen the previous trials results the COURAGE trial also come up with similar results shows PTCA would not have any effect on the outcome but it does have improvement in the quality of life. So the patients who are assigned to PTCA, they have more freedom from angina and they walk more distance when compared to medical management alone. But that difference also slowly faded away after 5years. Whether it is medical management or angioplasty there is no difference after 5 years.

So to conclude all these trials in the clinical perspective, coronary lesion or a coronary obstruction if treated with angioplasty by stenting it by using drug eluding stent or bare metal stent or doing CABG by grafting it may not able to reduce the outcome (heart attack and improve survival) but can improve symptoms. So in this condition, the interventional procedure in patients with chronic stable angina will not give any protection against the future occurrence of the myocardial event but it may provide only the improvement in the quality of life.

Then an alternative argument came from the proponent and said look probably fixing all the lesions some times may not be a correct solution. Some of the lesion might really not

significant enough to cause ischemia (lack of blood supply), so rather than fixing the lesions by stenting and grafting, we should look at the ischaemic burden which is done by myocardial perfusion scanning and stent and graft the vessel which is causing ischemia. This is an old thought because all lesion cannot cause ischemia and all ischemia may not be due to lesions (obstruction) alone. Now what they did is again they took BARI and COURAGE data and they made a sub-group analysis to show Whether ischemia itself can able to predict the outcome. To there disbelief, when they took ischemia as selection criteria rather than lesions (anatomical obstruction) for doing PTCA and CABG, still, it did not change the outcome.

So here is the complex scenario for every physician and every patient to understand. Patients have gone for a CAG, which is a coronary angiogram and found out multiple lesions. It may be a single vessel or double vessel or multiple vessels and now the strategy is to fix these lesions, then we may change the outcome. Unfortunately, with all the clinical trials, we reviewed if we try to fix these lesions and then look at the outcome there is no change in outcome. So the question is if you are able to fix the lesions but did not change the outcome then which really predict the outcome. Which is? Is the lesion (obstruction) or ischemia (lack of blood flow). The subgroup analysis of BARI and COURAGE clearly showed ischemia was not able to predict the outcome.

So what they did is they looked at which is the factor which determines the outcome. So they looked at ischemia, is that more ischemia from mild, moderate and severe is going to predict the outcome or the lesion stenosis more anatomical burden is going to decide the outcome. They found out it is actually the multiple lesion which predicts the outcome rather than the ischemia.

So we have a clear Predictor, multiple obstructions are the predictor of the outcome but by fixing these lesions would not change the outcome. It is strange as it is. So probably the answer lies in another aspect it is not the major vessel obstruction greater than 70% obstruction which gets the stent and graft which causes the events but probably it is because of smaller lesion 30-40 or 50 percent lesion which are the culprit vessels which may dislodge and cause future myocardial infarction. Since these small lesions were never fixed during angioplasty and bypass these are all the culprit which causes future myocardial event.

So our major point is about emergent of a new Enhanced External Counter Pulsation treatment. The policymakers and insurances companies should come out with this simple solution to a complex problem. Can we provide EECP treatment to patients with triple vessel disease, who has chronic stable angina with proven ischemia? and would that patient will be able to differ or eliminate the requirement of an interventional procedure? Now by advocating EECP treatment along with medical management,

EECP would not act only on lesions but throughout the coronary vascular bed to improve the overall collateralization in the myocardium. It also has a significant effect to improve the overall endothelial function, so it might have protection on the future occurrence of myocardial infarction. Advising EECP in chronic stable angina in a single, double or triple vessel disease, we obviously not denying them any benefit or advantage over future cardiac events or prolong survival. In fact, EECP may possibly provide the prevention effect on myocardial infarction and improve survival, which cannot be offered by CABG and PTCA. So it is very safe to differ CABG and PTCA by advocating EECP as an alternative treatment to highly invasive procedures.

So my take-home message is very simple .when a physician/cardiologist is offering a PTCA or CABG for chronic stable angina, Whether it is a single vessel or double vessel or multivessel disease, Whether its preserved LV function or mild LV dysfunction or moderate LV dysfunction or even severe LV dysfunction advocating CABG and PTCA might not have a protective effect on future cardiovascular events . Its clear advising EECP is clearly justified as an alternative procedure for the CABG and PTCA in this group of patients who are called as chronic stable angina patient, whom most of the PTCA and CABG procedures are currently performed.



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