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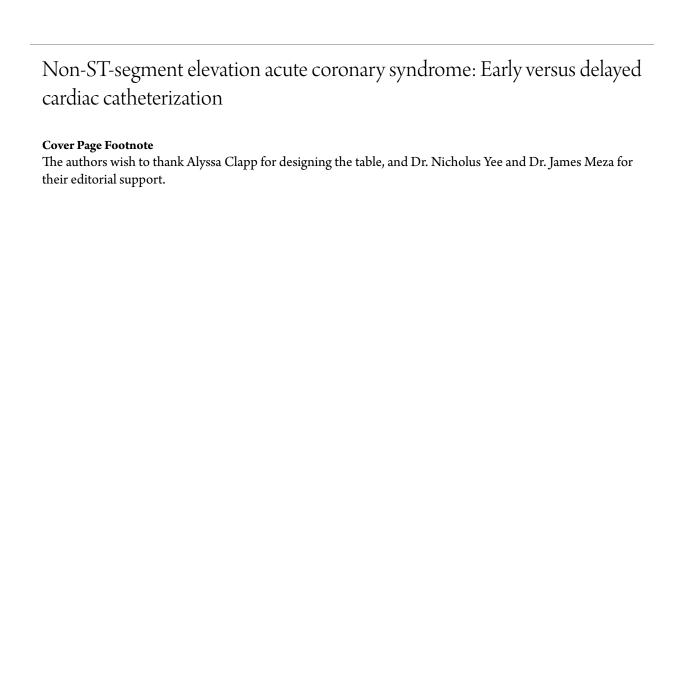


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INFORMED CONSENT:

Non-ST-segment elevation acute coronary syndrome: Early versus delayed cardiac catheterization

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ABSTRACT An informed consent conversation regarding early vs. delayed cardiac catheterization for patients with NSTEMI.

Keywords: ACS, cardiac, catheterization, NSTEMI, heart attack, acute coronary syndrome, delayed, conservative

Clinical Context

JB is a 52-year-old man with a relevant past medical history of sleep apnea, hypertension and obesity who presented to the emergency department because of an episode of dizziness. His symptoms started earlier that day when he was pedaling on a bike. After he stopped and stood up, he felt the room was spinning so he sat down on a chair and his symptoms resolved. Earlier, while at work, he had similar symptoms, but these resolved spontaneously. He denied any chest pain, trouble breathing, palpitations, loss of consciousness, or recent illnesses. He is a non-smoker and does not have diabetes.

On presentation to the ED, JB was mildly tachypneic, and hypertensive, but otherwise his examination was normal. CT with PE protocol was done and did not show a pulmonary embolism (PE). An ECG showed sinus rhythm with no ST-T changes. His troponin was elevated to 4.58 and later increased to 5.96. He was diagnosed with NSTEMI.

Before the attending physician could meet with the patient, the cardiologist scheduled and performed a heart catheterization—without informing the primary inpatient team. In hindsight, the patient was asked how much explanation he received prior to receiving catheterization. He told us, "The doctor came in and told me to sign this paper because I needed a heart test." He could not recall a conversation related to potential benefits or risk of harm with the procedure. He is active while at work and is very adamant about going back to work as soon as possible. JB's case prompted the team to discuss whether he should have proceeded directly to catheterization versus waiting for his symptoms to recur.

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Clinical Question

In patients with an NSTEMI, does immediate cardiac catheterization provide any mortality benefit?

Related Literature

A literature review was performed by searching PubMed using the terms (NSTEMI[tiab] OR "Non-ST*"[tiab] OR ACS[tiab]) AND "invasive"[tiab] and using the Clinical Trials filter. The search yielded 204 results, which were reviewed for the ability to answer the clinical question. Meta-analyses studying invasive strategies were found with this search, and their results and references were reviewed for additional relevant citations. Of the papers published in the last 15 years, seven were determined to be the highest quality and most relevant to the topic. These papers each measured all-cause mortality as an outcome. They also compared an early or routine catheterization strategy against a selective or conservative strategy. Patients within an early catheterization group would undergo catheterization by default after their NSTEMI. Patients who were conservatively managed would only be catheterized if they had recurrence of chest pain.

The most recent trial is the ICTUS trial. This trial studied 1200 patients. They found that the early invasive group actually had a worse mortality rate over 10 years than the conservative group (26.7% vs 23.7%, p=0.25). This outcome is clinically significant, but was not statistically adequate.

Conversely, the RITA-3 trial showed a trend towards improvement in mortality rate with early catheterization (12.1% vs. 15.1%, p=0.054) at 5 years², though it was not statistically adequate. This trend towards benefit was no longer apparent at 10 years³ (27.8% vs 27.5%, p=0.94).

The oldest trial was by Cannon in 2001.⁴ Their results showed no difference in all-cause mortality at 30 days (2.2% vs 1.6%, p=0.29) or at 6 months (3.3% vs 3.5%, p=0.74). Four additional trials demonstrated no difference in all-cause mortality at various follow-up times, including LIPSIA-NSTEMI⁵ in 2011 (over 6 months), De Winter⁶ in 2005 (over 1 year), Savonitto⁷ in 2012 (over 1 year) and FRISC-II⁸ in 2016 (over 15 years).

Unfortunately, all of the trials investigating this question were open-label trials. This introduces potential bias from investigators and patients acting differently because they know whether or not they have been catheterized. This is mitigated slightly because the outcome in question is objective. However, potential bias is a concern, especially given that no trial had a large effect size.

All of these trials have different populations, follow-up periods, and methods. Despite the heterogeneity, no trial demonstrated a significant change in mortality when comparing early invasive strategies with conservative ones. Some trials showed clinically significant trends, but this was inconsistent. Given this, it is unlikely that early invasive strategies improve mortality, and certainly it has not been proven. This agrees with a recent Cochrane meta-analysis⁹, which noted other clinical outcomes. For instance, early catheterization has been demonstrated to reduce recurrent angina and re-hospitalization rates.

Informed Consent

Flesch-Kincaid Grade Level for the following passage is 6.0.

"In the emergency department, you were told you had a heart attack. This may not be as serious as it sounds. Sometimes, it only means that a few cells were damaged. This is what we think happened to you. I'm here to talk about what to do next.

"Catheterization is putting a small tube into your heart. They use it to take pictures of the arteries in your heart. If they find a clogged vessel, they may open it up. Sometimes, they leave a mesh tube to keep it open.

"Scientists have been trying to understand the best timing for this procedure. Some think it's best to have a catheterization right away. Others think it's reasonable to wait until you have more symptoms.



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"I have reviewed studies from the last 15 years. I was looking to see if having a catheterization right away can save your life. There are some studies that suggested it was better to catheterize early. However, there are some studies that suggested it was actually worse. Most of the studies actually found it didn't matter. Unfortunately, the quality of the studies wasn't excellent.

"I brought this picture to show you what your choices are today.

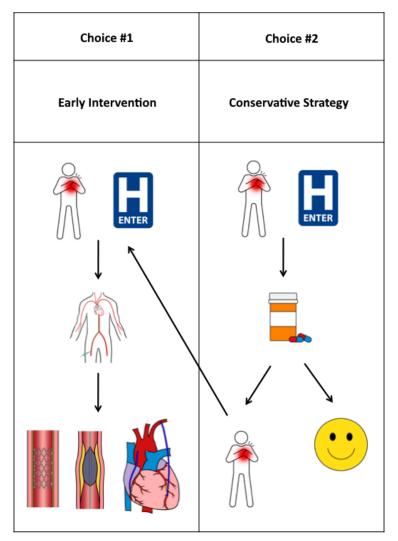


Figure 1. Cardiac catheterization intervention strategies following cardiac arrest

"Overall, I don't think immediate catheterization will save your life. Each choice is followed by different experiences. People who get catheterizations are more likely to have additional procedures. They need to take additional medications to thin the blood for at least 6 months. Procedures may have complications, such as bleeding, infection, or kidney injury. However, they are less likely to have continuing chest pain. They are also less likely to be hospitalized again.

"It's important to know that either choice you make, we will still do our best to take care of you. Even if you decide against catheterization right away, we will still use medication to minimize your risk.

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"Some people are afraid of procedures on their heart. Others want it 'fixed right now.' We can't make this decision for you. I'd appreciate if you could share your thoughts with me."

Epilogue: Unfortunately, we were not able to discuss this with JB before his procedure. He received a left cardiac catheterization that showed 100% proximal to mid stenosis to the right coronary artery (RCA). JB received a drug eluting stent placed in the RCA. He tolerated the procedure well with minimal blood loss and an uneventful post-operative course. He was discharged on dual antiplatelet therapy with Aspirin and Plavix, as well as a high-intensity statin.

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