Continuous Troponin Monitor

By: Shawn Shibu,
Megan Fraser,
Isabelle du Plessis,
Ryan Campbell,
Isabella Westerbeek &
James Montford

Every year, approximately 1.5 million heart attacks and strokes occur in the United States. When the heart is damaged, troponin is released into the bloodstream. After a suspected heart attack, a doctor can order a troponin test to measure troponin T and I levels. If you are experiencing chest pain or other heart attack symptoms such as pain in the neck, back, arm, or jaw, intense sweating, light-headedness, dizziness, nausea, shortness of breath, or fatigue, your doctor will recommend this test. Current guidelines recommend rechecking troponin levels one or more times over a 24-hour period for patients being evaluated for a heart attack to look for changes over time.

What changes are we making?

Our team wants to help more people suffering from myocardial infarction. Although this troponin monitor would not be widely available to the general public due to the unnecessary cost, it would be available for prescription through GP and/or hospital services for people at risk of heart attacks. Coronary Heart Disease (CHD) is an example of something that could influence the monitor's prescription, as an estimated 3.8 million men and 3.4 million women die from CHD each year.

General Info

- High-sensitivity Troponin tests can detect elevated Troponin levels in people without symptoms of cardiovascular disease according to 2019 AHA/ASA Journals. This means the test results can be used to help predict whether you're at increased risk for a future cardiac event, like a heart attack or stroke.
- Troponin T blood tests have a sensitivity of 79% and a specificity of 93%. Troponin I blood tests have a sensitivity of 83% and a specificity of 95%.
- While it is possible for tests to yield false positive or negative results, troponin tests are usually highly accurate.
- In the UK there are as many as 100,000 hospital admissions each year due to heart attacks: that's one every five minutes.
-Around 1.4 million people alive in the UK today have survived a heart attack.
-Unaffected by other conditions (such as rhabdomyolysis and renal failure), Troponin I has stimulated great interest in the scientific community, due to its high specificity.

How it works

Elevated cardiac Troponin levels can be identified by a variety of means. In a secondary care environment they are often identified using high sensitivity assays . A blood sample is taken from the vein in the arm and is analysed using platforms and verified by a biochemist.

Commercially, these blood tests can cost around £125 whereas a continuous troponin monitor would cost significantly less and give constant readings which would aid in early diagnosis of heart attacks, rather than waiting for a doctor to consider other illnesses.

The sensor would identify a change in conditions that occurs when troponin binds to RNA or DNA and that would register a change in potential difference in the sensor, allowing the user to be aware of changes in their troponin levels

Novelty

Many in-hospital rapid troponin tests are available to detect cardiovascular diseases/distress and heart attacks. However, there are no Troponin monitors for patients to use on a daily basis that can assist those at risk of heart attacks in quickly identifying when they occur, meaning they can rapidly seek out treatment.

Troponin Monitor

Our initial inspiration came from the Continuous Glucose Monitor, which many diabetic patients wear, and we wondered, "Why not make a continuous monitor for a cardiovascular patient's troponin concentration within the bloodstream?"

If the concentration were to increase to a certain level (0.4ng/ml) then the patch would alert the patient that a heart attack may have occurred. This alert would notify the patient to seek immediate medical attention in order to reduce the severity of the heart attack and thus the risk of death.

Our device would also reduce heart attack misdiagnosis, particularly in elderly patients and women, who are frequently misdiagnosed. (Panic Attacks, for example.)

Future Advancements

In the future, we hope to enhance our troponin monitor so that it can release Aspirin, Clopidogrel, Ticagrelor, and/or Prasugrel therefore reducing the risk of death on the way to the hospital.

We would also consider integrating the device into other Smart Healthcare Systems and Data, such as Apple Watches, to increase wearer convenience.

How the approach can be shown and implemented notes

Pre-clinical research

Beginning with 3D printed stem cells. We will inject known concentrations of troponin into the cells and see if the CTM can recognise the known concentrations. Once the CTM has been proven to work on the 3D printed cells, we will proceed to stage two and begin testing the device on animals. We will inject a known concentration into an animal once more to see if the CTM can correctly identify troponin levels in different animals.

Clinical Research

Beginning with healthy people who have troponin levels between 0 and 0.04ng/mL. This would imply that the CTM is effective even at low levels of troponin. The device would then be made more widely available to an audience that corresponded to the intended audience for it.

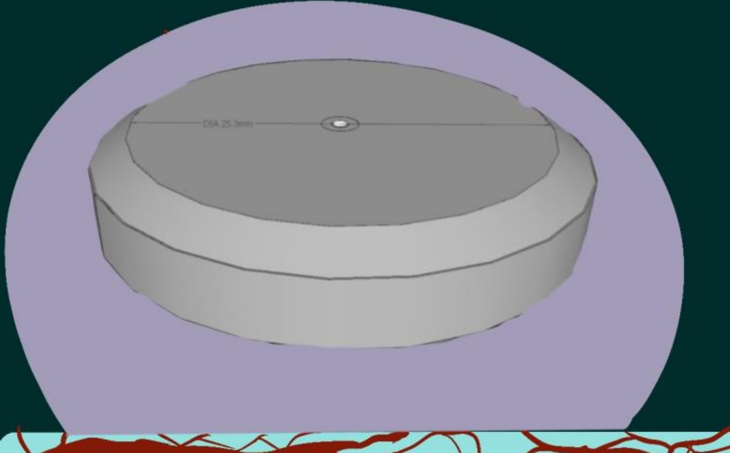
Cardiovascular trials

Phase 1 - $2.2 million
Phase 2 - $7 million
Phase 3 - $25.2 million
Review phase - $2 million
Phase 4 - $27.8 million
Total - $64.1 million

Clinical Trial Expenses

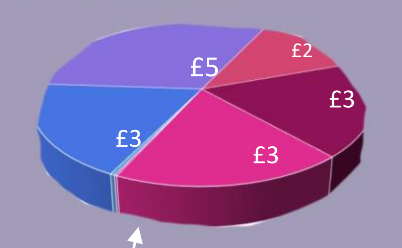
The average cost of phase 1, 2, and 3 clinical trials across therapeutic areas is $4, $13, and $20 million respectively

Based on current technology, troponin monitoring using a biosensor seems within reach. Studies by the KAUST Institute have shown a working cardiac troponin T sensor using field effect transistors which has a limit of detection (LOD) of 0.1 microgram during preclinical trials which is accurate to identify the spike in troponin levels 4 hours after a heart attack. The aptasensor would be able to fit in a relatively slim sensor casing along with a battery life comparable to a continuous glucose monitor. The integration of this sensor along with ECG, HR And SP02 sensors (which can be found on smartwatches) could provide a clearer image of what is occurring during a myocardial infarction.



Public acceptability

Ease of use:
•Sends data wirelessly to a display device through transmitter
•Phone displays real-time troponin spikes.
•Easily insert small sensor beneath skin using applicator



Small part is negligible

Advantages

•Freedom from syringes – no need for multiple blood tests. Reapply every 7 days.
•Easy to understand
•Mild/no pain

Disadvantages

•False alert - troponin levels are misidentified as high, they can cause a scare and unnecessary A&E visits
•Expensive for large populations over long periods of time
•Would have to take monitor off when swimming/bathing as not waterproof

Price breakdown

•. Could get it on NHS but would still eventually circle back round to taxpayers etc.
•Most monitor models can be covered by private insurance, but it won't necessarily cover the cost of supplies e.g. reservoir cartridges, infusion sets, tubing, cannula, batteries, tape and adhesive.
•Majority of people have health insurance included with their job and therefore, lowers cost.
•App on phone - most people already own phones so not an additional cost.
•Inequality in access to healthcare e.g. Low income developing countries. Could be the most beneficial to these countries due to people having to travel further to the nearest hospital, less transport links etc so having more time to get to healthcare facilities would save more lives. Could aim in the future to give our design to NGOs.