Trop-advisor

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Introduction
Myocardial infarction (MI) is a type of acute coronary syndrome (ACS) in which blood flow to the myocardium is restricted, causing cell death via the decrease of oxygen supply to cardiac muscles. Common causes include the narrowing of coronary arteries by plaque formation and fatty streaks, as well as partial or complete blocking of coronary arteries by blood clots.

What is the problem?
There is an increasing number of patients with coronary heart disease both in the UK and globally that lead to MI among other conditions. Number of deaths where a heart attack was the underlying cause in England and Wales in 2021 is 20,061.

The NHS predicts in its long-term plan that numerous hospital admissions for heart attacks will occur in the next decade. This has already placed an increased burden on the A&E department, where the supply and demand for hospital beds are mismatched, increasing wait times. Putting pressure on the short-staffed A&E department will cause the quality of care provided to be diminished.

BAME communities receive worse clinical outcomes than white patients when presenting MI, in particular during the COVID-19 pandemic. Thus, an innovative solution that can reduce inequalities and provide a preventive strategy for cardiovascular risks by early detection is ACS is necessary.

Comparison to existing solutions: Currently, troponin assays can only be carried out at the point of care, such as cardiology wards, with many cases not being dealt with fast enough. The 99th percentile, i.e. upper limit of normal (ULN) of troponin level based on healthy individuals, is used as a threshold for MI. This approach is non-personalised and can often lead to misdiagnosis.

Audience
Patients with a family history of heart attacks, recovering from MI, and diabetic patients have a higher chance of developing MI. Determination of whether a patient should be given this device will be further advised by the use of myocardial enzymes.

Proposed Solution
We designed a wearable wristband that consists of two microneedles containing “on-device” electrochemical troponin I and CK-MB sensors respectively, used to perform a minimally invasive assessment of these biomarkers in the intracellular fluid at regular time intervals at home, to maximise the opportunities to improve care for patients with a high risk of MI.

How the Solution Works

A microneedle cartridge is attached onto the wristband, and measurements of troponin I and CK-MB are made at timed intervals advised by cardiologists. The microneedles are hollow, containing a sensing lobe.

The operation of the microneedle is controlled by a solenoid. The microneedle is partially composed of a chip and surrounded by a wire coil. The microneedle inserts into or extracts from the epidermis depending on the presence of current in the electric circuit.

10 µm of ISF can subsequently be exerted up to the sensing lobe by capillary action for detection by an electrochemical method.

The collected data is sent to a mobile device, utilising the concepts of IoT and Body Sensor Networks (BSNs) for continuous monitoring as a personalisation and to monitor the patient’s risk to improve prevention strategies.

The microneedles remain in the epidermis for days, providing continuous monitoring of troponin levels. This feature is similar in principle to continuous glucose monitors, and is meant to address the disputable nature of most microneedle solutions. The change in troponin level over time can be monitored; if a large change in troponin level is detected, the consultant will be alerted and the patient is advised to seek immediate medical attention.

Why Microneedles?
The needle is sharp enough to minimise nerve contact when penetrating through the epidermis, hence it does not elicit pain receptors in the dermis, providing a minimally invasive and painless way to detect biomarkers in the intracellular tissue fluid.

Key features of the solution
1. An evidence-based innovation that promotes equity in cardiac care in vulnerable populations and BAME communities, through measuring personalised cardiovascular risks of individual patients.
2. Early detection tools ‘out-of-hospital’ care, providing timely responses and alerting patients to seek medical attention prior to onset of serious conditions. Differences in troponin levels allows more effective triage, prioritising emergency treatment, bearing in mind the necessity of life-long medication like statins and beta blockers.
3. An intuitively designed wristband that does not require medical expertise to use.

References

Product Testing and Clinical Investigation
Prior to implementation, educating the public on MI and its associated risks is necessary for effective implementation, and can be achieved through product testing and trials. We aim to increase the public’s understanding of heart diseases so positive feedback can be expected.

1. Pilot stage
Pilot participant with a history of heart disease and taking beta blockers, with an implantable cardiac device, with the purpose of gathering feedback on the impact of the device on the daily routine.

2. Feasible stage
Feasible participant with a history of heart disease and taking beta blockers, with the purpose of assessing the acceptability and feasibility of the device.

3. Post-marketed stage
Feasible participant with a history of heart disease and taking beta blockers, with the purpose of gaining evidence on the device’s impact on the lifestyle of participants.

Ethical Considerations in Clinical Investigation
Informed consent will be obtained from all volunteers after a thorough explanation of the sensor mechanism. Anonymity and confidentiality are maintained, with no harm being done to the volunteers. Test results will only be shared with the relevant stakeholders and all volunteers. All volunteers have the right to withdraw during the testing period.

Feasibility in Commercial Production
Being a personalised clinical device that aligns with the NHS long-term plan, it has the potential to receive sufficient funding for continuous research, development, and mass production. Expected to be cost-effective as the foreseeable reduction in A&E expenses and manpower supersedes the cost of production, it will become increasingly affordable in coming years.

Limitations
The wristband utilises the concept of IoT and focuses on early detection of MI, with a high sensitivity and specificity. The use of microneedles may cause skin irritation and can impair articulation. Despite these minor setbacks, our product boasts minimal invasiveness, personalised and efficient detection, and high accessibility with innovations in miniaturisation.