Healthcare Improvement Scotland | SHTG Advice on health technologies

Plain Language Summary
October 2019

Synovasure® tests for the diagnosis of infected prosthetic hips and knees

What is 'periprosthetic joint infection (PJI)'?

PJI is an uncommon but serious complication of hip and knee replacement surgery, affecting approximately 1% of hip replacements and 1% to 2% of knee replacements.

PJI is categorised based on the time since initial surgery. An early infection develops within 3 months of surgery; a delayed infection develops from 3 months to 2 years after surgery; and a late infection is defined as developing more than 2 years after surgery.

In an early acute infection, there are normally several symptoms like pain, swelling, redness and warmth. This makes diagnosing the infection easier.

Delayed and late infections are often harder to diagnose as the symptoms are less obvious. The most common symptom of PJI is pain. In patients presenting with nonspecific pain, it is important to establish whether the pain is being caused by an infection or not. This ensures that patients receive the most appropriate treatment.

The incorrect diagnosis of a PJI in a healthy patient (a false positive result) can lead to more complex surgical management than is actually required. On the other hand, missing an infection results in patients not receiving the appropriate treatment, and requiring more complex surgery at a later date.

What is the Synovasure® test, and what is the bundle of tests?

The Synovasure® test can help diagnose PJI, and is available in two formats: (1) a point-of-care test kit (POCT) and (2) a laboratory-based test. The advantage of the POCT is that it can be used straight away, without sending any samples to a laboratory. However, the laboratory based test is likely to be more accurate.

The POCT is available for use in NHSScotland, but the laboratory-based Synovasure® test is not currently available in the UK. However, there are plans to open a laboratory within the Golden Jubilee National Hospital (Glasgow), which will offer the Synovasure® laboratory test as part of a bundle of tests. This bundle will include other commonly-used tests that help diagnose infection. The laboratory would be owned and run as a commercial enterprise by Zimmer Biomet (the manufacturer of Synovasure®). The laboratory would serve the whole of the UK and the Republic of Ireland.

What we did

Laboratory-based Synovasure® tests used as part of a bundle

With regards to the bundle of tests being offered by Zimmer Biomet, we reviewed the clinical and cost-effectiveness evidence. We also conducted a cost comparison analysis to assess the value for money of the bundle of tests compared to the current standard of care in Scotland for the diagnosis of PJI.

POCT and laboratory-based Synovasure® tests, not used as part of a bundle

Health Technology Wales have produced an 'Evidence Appraisal Report' specifically relating to the use of Synovasure® alpha defensin tests for PJI diagnosis. This included an evaluation of both the POCT and laboratory based Synovasure® tests. Rather than re-review the evidence, the findings from the Welsh report have been referred to.

What we found

Laboratory-based Synovasure® tests used as part of a bundle

For the bundle of tests, there was a lack of high-quality published clinical and cost effectiveness evidence. In addition, we could not establish how PJI is currently diagnosed in NHSScotland as different tests, and combinations of tests, are used in different hospitals. This meant that it was not possible to draw conclusions around whether the bundle of tests is better than what is currently being done in NHSScotland.

POCT and laboratory-based Synovasure® tests, not used as part of a bundle

Health Technology Wales concluded that the Synovasure® alpha defensin POCT and laboratory-based test show promise in the diagnosis of PJI. However, they also say that the evidence does not currently support routine use, and recommend further research.

What is our advice to NHSScotland?

The main part of our advice relates to the use of the laboratory-based Synovasure® test as part of a bundle. This is what will be offered at the proposed laboratory at the Golden Jubilee Hospital.

In order to support the routine use of the laboratory-based Synovasure® test (as part of a bundle of tests) in the diagnosis of PJI, further research is required to assess its relative accuracy compared with standard diagnostic strategies.

Future work

Further diagnostic accuracy studies are needed on the bundle of tests being offered by Zimmer Biomet, and how this compares with current standard practice. In addition, studies which assess the impact of the bundle of tests compared with standard practice on clinical outcomes (for example, a reduced rate of repeat surgeries) are needed.

This plain language summary has been produced based on SHTG Advice Statement 08 (November 2019).