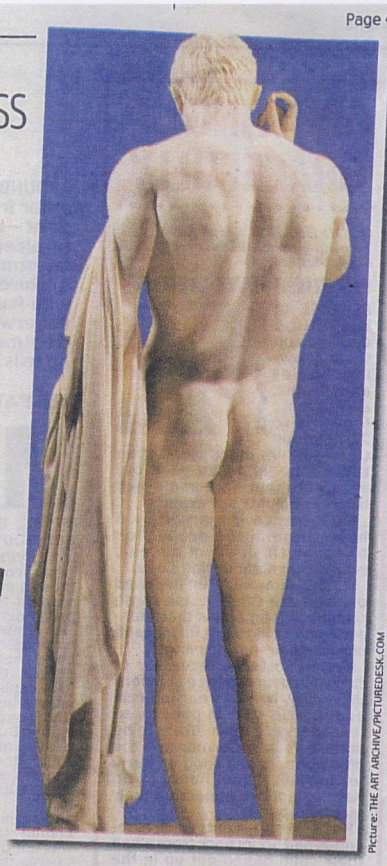
Flaws in the usual test lead to needless ops that can wreck sex lives. So ...

Should you have the new test for prostate cancer?

By JONATHAN GORNALL



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PROSTATE cancer claims the lives of more than 10,000 men in the UK every year yet, unlike breast cancer, there is no national screening programme for the disease.

Experts say this is because the standard test — the PSA test — is unreliable, leading to over-diagnosis and the misery of biopsies and treatment for too many men who actually need neither.

But now a small Cambridge-based company is marketing a new test which, it says, could halve the number of false results, saving lives and ending the uncertainty over the value of mass screening for the cancer that is second only to lung cancer as a killer of men.

Prostate cancer has to be caught early to be successfully treated but, in the early stages, there are rarely physical symptoms to betray its presence.

The current PSA test for the disease measures the amount of Prostate Specific Antigen, a protein produced by the prostate gland and which can be detected in blood samples.

Higher-than-normal amounts can indicate the presence of cancer. However, levels can also be affected by other factors, such as an enlarged prostate (an otherwise benign condition related to aging).

Using a PSA test to screen men without symptoms causes more harm than good, say some experts, as it results in the detection and treatment of many cases of low-grade cancer that would never have troubled the man in his lifetime.

In addition, an estimated seven out of ten patients have a false result from a PSA test, leading to unnecessary and painful biopsies, which can cause side-effects including bleeding, fever and infection.

Meanwhile, treatment — options include surgery, radiotherapy and chemotherapy — can lead to erectile dysfunction, urinary incontinence, bowel problems and even death.

For every life saved, 45 men or more undergo radical treatments that they didn't actually need.

In England, the NHS offers only what it calls an 'informed-choice programme', under which men who ask their GP about screening 'receive clear and balanced information about the advantages and disadvantages of the PSA test'.

The message to patients, however, is clear — don't bother. Tellingly, the NHS guidance for GPs concludes that 'currently, there is no evidence that the benefits of a PSA-based screening programme would outweigh the harms'.

BUT is it possible that the new test — so far available only in the UK — may change this?

Like the standard test, the new one measures the total amount of PSA but also looks at three specific components of that figure: 'free' and 'intact' PSA, and human glandular Kallikrein 2, the crucial new patented biomarker (the test checks a total of four biomarkers).

The relationship between each of these components is then analysed according to a complex formula, producing a more accurate prediction of the necessity for biopsy.

According to studies carried out by the inventors — a team of Finnish, Swedish and U.S. scientists — the four biomarkers can halve the number of unnecessary biopsies performed, sweeping aside the main objection to screening for prostate cancer. The new test means each man can be given a personalised risk estimate.

'As far as I am aware, nobody else in the world has the ability to give an approximation as to whether a cancer is a so-called tiger, an aggressive cancer, or whether it's a pussycat — a lazy cancer which you can live with for many years with no problems,' says Troels Jordansen, the managing director of HealthScreen UK, which has bought the right to market the test in the UK, as ProstateCheck.

'We believe it is going to save lives and save on cost, because the non-aggressive cancers do not need to have a biopsy.'

The new test has the backing of David Neal, professor of surgical oncology at the University of Cambridge and a consultant surgeon at Addenbrooke's Hospital, who has been appointed clinical director for the company's prostate health UK division.

'ProstateCheck combines the four biomarkers with a risk assessment and symptom score and is a major development for the early detection of prostate cancer,' he says.

'If you take 1,000 men with a raised PSA — who would currently be referred for biopsy — and do the four-biomarker test, then you refer 400 fewer.

'You can say to them well, given the pattern of your results, let's say you have a 40 per cent risk of having any prostate cancer, and a 15 per cent risk of having a more unpleasant form of cancer, therefore you should have a biopsy.

'On the other hand, you might be saying you've got only a 15 per cent risk of any prostate cancer, and your risk of having a high-grade prostate cancer is lower than 5 per cent, therefore we'll repeat the blood test in six to 12 months.'

Professor Jack Cuzick, who is Cancer Research UK's expert on screening, welcomes the new test. 'We've been looking at this for some time,' he says.

'I would not recommend PSA screening at the moment — PSA is not specific enough and there are far too many radical treatments for every life saved. This seems to be an important step forward.'

The NHS's resistance to screening for prostate cancer is based on a recommendation made in 1997 by the UK National Screening Committee. The evidence was reviewed again in 2010, but the committee did not change its advice.

A spokesperson for the committee said it had not considered the published evidence behind the new test in that review.

But, she added, the committee was 'committed to keeping abreast of new evidence. This paper is being looked at and relevant data will be considered as part of the next scheduled review, in 2013/14.'

THE credibility of standard PSA testing received a further blow in July, when the U.S. government agency responsible for assessing the science behind preventive medicine withdrew its support for prostate cancer screening using this type of test.

Evidence showed, it said, the risks from over-diagnosis were higher than those posed by no screening at all.

The current NHS advice to GPs was published in 2009, with the note that it would be reviewed in 2012, 'unless significant breakthroughs are made within that timeframe'.

Earlier this month, the charity Prostate Cancer UK launched its MANifesto, a commitment to invest £25 million in research, primarily to develop 'a new-generation test for prostate cancer, one that does not pose the risk of unnecessary treatment to men'.

Dr Kate Holmes, head of research at the charity, said that 'although [study] results suggest that combining the PSA blood test with other specific proteins could lead to a more accurate prostate cancer diagnosis, much wider and more robust research is required before it will be possible to offer men a suitable replacement for the PSA test.

'As things stand there is simply not enough evidence to state confidently which proteins are the right ones to use as the ultimate replacement for the PSA test.'

However, she adds: 'We are aware that a more accurate diagnostic test for prostate cancer is needed if we are to reduce the number of men losing their lives to this disease.'

Everybody, says Mr Jordansen, 'is unhappy with PSA, but if you can eliminate 50 per cent of the biopsies you should be pretty close to the same sensitivities as you get with breast screening.

'And if you can do breast screening and bowel screening, why can't you do prostate screening? It is, after all, one of the largest killers of men.'

HealthScreen is pitching the new test to companies as a welfare benefit for male staff or the husbands of female employees, but it is also available to individuals, for £180, or £210 within the M25.

As for a national screening programme, Mr Jordansen is hopeful that the commercial availability of the test would 'open eyes, minds and doors, and we would obviously be happy to speak to whoever is interested in what we do'.