THE IRISH TIMES
Sun, Jul 4, 2021
Dublin 17°C

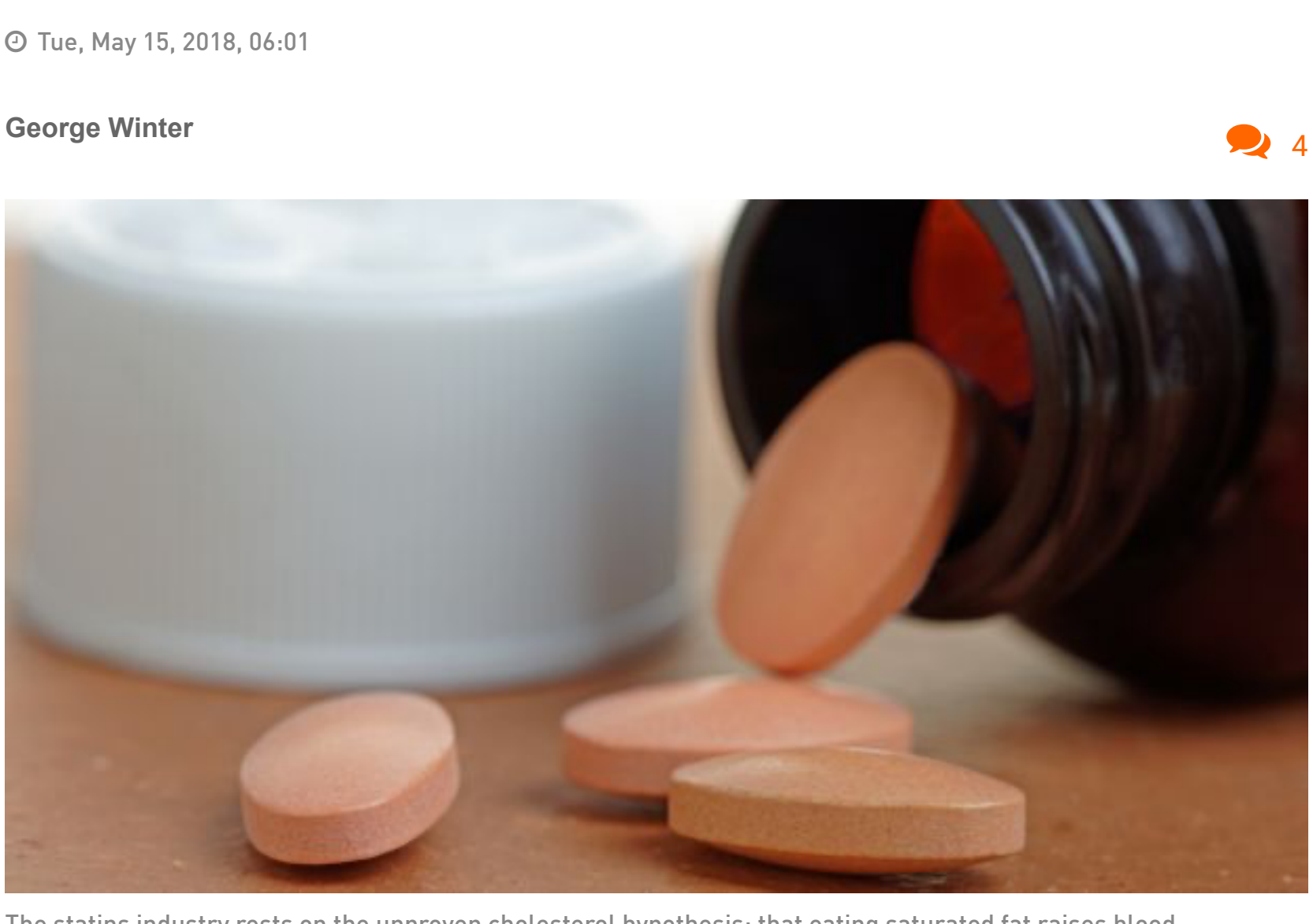
Is statin use a waste of time and money?

Transparency is lacking around efficacy of widely used cholesterol-lowering drug

Tue, May 15, 2018, 06:01

George Winter

4



The statins industry rests on the unproven cholesterol hypothesis: that eating saturated fat raises blood cholesterol concentrations, which clogs coronary arteries, inducing CVD.

In 2016, when Ireland's State-funded sector spent almost €50 million on cholesterol-lowering statins – the world's most prescribed drug – was the money wasted?

A BMJ study investigated statin use among Ireland's over-50s. Lead author Paula Byrne, of Galway's NUI – a health research board scholar in the structured population health and health services research PhD programme – told *The Irish Times* that "while statins are recommended preventive treatment for those who've had a cardiovascular event, our research focused on primary prevention; ie using statins when there's no history of a cardiovascular event. Significantly, almost one-third of over-50s took statins. Of these, 65 per cent did so for the primary prevention of cardiovascular disease (CVD), a contested area in statin use. Some people taking statins for primary prevention potentially reduce their CVD risk by such a small amount as to be arguably meaningless."

The presentation of risk part-fuels the statin controversy, with **United States and Danish researchers** attacking "the deceptive approach statin advocates have deployed to create the appearance that cholesterol reduction results in an impressive reduction in cardiovascular disease outcomes through their use of a statistical tool called relative risk reduction (RRR) . . . which amplifies the trivial beneficial effects of statins."

Byrne explains: "Data from the Oxford-based Cholesterol Treatment Trialists' (CTT) collaboration show that taking statins reduces one's risk of dying from a vascular event by 15 per cent (RRR). Consider a 45-year-old woman whose baseline risk of developing CVD is only 3 per cent. This risk level is considered 'moderate' according to European guidelines for the management of dyslipidaemias, and she could qualify for statin therapy if her 'bad' cholesterol exceeded 2.6 mmol/L and lifestyle changes hadn't reduced her cholesterol levels sufficiently. But her absolute risk of dying from a vascular event while on statins drops from 3 per cent to 2.55 per cent, since 15 per cent of 3 per cent is 0.45 per cent." Byrne wonders whether treating that woman maximises scarce healthcare resources: "From the individual's perspective, will she think that an absolute risk reduction of 0.45 per cent justifies taking a statin for life and risk potential side-effects?"

'Contemptible breaches'

Dr Maryanne Demasi asks "**have we been misled by the evidence**?" noting the CTT collaboration's withholding of statin trial data: "One of the most contemptible breaches in transparency. Neither the doctors prescribing statins nor the millions of people taking these medications have had access to independent analysis of the efficacy data."

Addressing such claims, Dr Angie Brown – medical director of the Irish Heart Foundation – said: "It's crucial for the complexities and the veracity of multicentre studies to be understood by physicians and scientists to help appropriately modify advice and treatment that's given to patients and the public. But the discussion of the details and statistical analyses can be confusing and lead to undue worries for patients about their treatment. We always advise individuals to discuss their concerns and treatment with their doctor."

Responding, Galway-based Prof Sherif Sultan – president of the International Society for Vascular Surgery – said "patients do not command guardians to shield them from information. We need transparency."

The statins industry rests on the unproven cholesterol hypothesis: that eating saturated fat raises blood cholesterol concentrations, which clogs coronary arteries, inducing CVD. Several studies challenge this dogma. Thus, **a 42-country investigation** stated: " High CVD risk is correlated to the proportion of energy from carbohydrates and alcohol, or from potato and cereal carbohydrates. . . Our results do not support the association between CVDs and saturated fat, which is still contained in official dietary guidelines."

Sugar is the dietary culprit, and healthy lifestyle changes, not statins, should be promoted.

And **a BMJ analysis of 19 studies** of 68,094 elderly people concluded that high blood concentrations of "bad" cholesterol is "inversely associated with mortality in most people over 60 years".

RELATED
- Drug interactions: when medicines mix
- Two-thirds of Irish people taking statins do so for prevention
- Side-effects from medicine? It could be the 'nocebo effect'

Sugar as culprit

Study co-author Prof Sultan said "In plain English, this means the lower your cholesterol, the younger you die. This is inconsistent with the cholesterol hypothesis, which created the war on fat and cholesterol, commanding 60 years of global human experiment that is currently being acknowledged as an awful failure with atrocious generational consequences. Sugar is the dietary culprit, and healthy lifestyle changes, not statins, should be promoted."

Prof Sultan's co-author Dr Uffe Ravnskov received the 1999 Skrabanek Award from Trinity College Dublin for original contributions to medical scepticism. Ravnskov **considers that the cholesterol hypothesis** "is sustained by a number of social, political and financial factors, most of which have little to do with science or any established success in public health".

I invited comment from three Irish consultant cardiologists. The first didn't reply; the second didn't "want to be associated with an article that is anyway detrimental to statin therapy and people's perception of these drugs"; the third agreed to participate, but withdrew when I suggested that the cholesterol hypothesis is discredited and that non-industry-funded evidence for primary prevention with statins – including complete results and side-effects data – is non-existent, explaining: "Those questions are probably outside my scope of knowledge."

But not outside cardiologist Dr Robert Dubroff's.

Postponement of death

Dubroff **wrote that many experts** cite randomised controlled trials (RCTs) of statins supporting the cholesterol hypothesis, "but we should not ignore the dozens of cholesterol-lowering trials that do not". He cites "44 cholesterol-lowering RCTs that reported no mortality benefit", with several reporting substantial harm. And **six studies on statins in primary prevention** found that the median postponement of death was 3.2 days.

Should statins be debated in the media?

Paula Byrne thinks so: "It's about informing patients to enable more shared decision-making based on a patient's individual baseline risk. However, we should be aware of the potential harms for people with high baseline risk deciding to stop statins based on media reports when this may not be in their best interests in terms of health outcomes. Central to good science is reproducibility, and keeping information from independent analysis stokes fears, which may or may not be justified.

"One should be able to debate controversial areas without fear; indeed, it's the nature of science to inquire and challenge. There should be no sacred cows."

TIME CAPSULE: HISTORY OF STATINS

1784 – Cholesterol isolated from gallstones.

1950s – Steps in cholesterol synthesis established.

1959 – Triparanol, first cholesterol-lowering agent, withdrawn in 1960s because of side-effects.

1976 – First statin – Compactin – characterised; phase-2 clinical trials started in 1979; stopped in 1980.

1987 – Lovastatin becomes first commercial statin.

2012 – **Irish study reports**: "An increased risk of new onset treated diabetes was found in those treated with statins showing significant duration and dose effect."

2018 – **Dutch researchers report**: "Statin users switch to anaerobic metabolism sooner during maximal exercise performance, are more prone to muscle fatigability during repeated muscle contractions, and have a reduced mitochondrial oxidative capacity of the muscle than non-statin users."

Topics: Angie Brown | Dr Uffe Ravnskov | Maryanne Demasi | Paula Byrne

READ MORE
Statin side effects: Is it all in your head?

Also in Health & Family »
Co Cavan: one walk, one run, one hike, one swim, one cycle, one park and one outdoor gym – Your essential, outdoor, family-friendly guide to Co Cavan
'Puddle parents' can give children the freedom to explore – Connecting with nature is the perfect way to encourage creativity and curiosity
Fibromyalgia: 'Everything is uphill, my flesh hurts just being on my bones' – 'I savour every joy that comes my way, try to be thankful for the resilience this gifted me'
Expelled: 'My son is locked out of the system. He has nowhere to go' – A teenager with a severe intellectual disability has been excluded from his special school. He's not alone in falling through the cracks of a broken system
Co Armagh: one walk, one run, one hike, one swim, one cycle, one park and one outdoor gym – Your essential, outdoor, family-friendly guide to Co Armagh
Legalising drugs: 'Drug use should be treated as normal adult behaviour' – Irish youth workers have banded together to seek an end to drug prohibition to remove criminal risk from users
Was I too hasty in leaving my uncertain boyfriend? – Ask Roe: He said he needed time to think about how he was feeling and it floored me
Co Tipperary: one walk, one run, one hike, one swim, one cycle, one park and one outdoor gym – Your essential, outdoor, family-friendly guide to Co Tipperary
Flexing our 'volunteer muscle' benefits us as well as our communities – Volunteering: the chance to spread our wings and use our talents for a worthwhile cause
Co Sligo: one walk, one run, one hike, one swim, one cycle, one park and one outdoor gym – Your essential, outdoor, family-friendly guide to Co Sligo

THE IRISH TIMES GET HEALTHY

Most Read in Life & Style
1 'We're surviving by wrapping frozen towels around us': Irish struggle with Canada's heatwave
2 Ross O'Carroll-Kelly: 'I'd rather rip out my molars with a pliers than holiday in Ireland again'
3 Lake people of Lough Derg: 'I love looking at the water. It makes me calm'
4 Fibromyalgia: 'Everything is uphill, my flesh hurts just being on my bones'
5 Chris O'Dowd: 'It feels like a very rich time in Ireland for culture'
6 Legalising drugs: 'Drug use should be treated as normal adult behaviour'
7 Back to basics: The makeup artist's guide to concealer
8 Co Sligo: one walk, one run, one hike, one swim, one cycle, one park and one outdoor gym
9 The best thing about my garden: The wall, the trees, the beasts
10 Oldest man alive: Guinness World Records confirms new title holder's age