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## Statin prescribing for primary prevention of cardiovascular disease:

a cross-sectional, observational study

### Abstract

#### Background

The updated (2014) National Institute for Health and Care Excellence (NICE) guideline lowered the recommended threshold for statin prescription from 20% to 10% 10-year cardiovascular disease (CVD) risk.

#### Aim

To determine the characteristics of patients prescribed statins for primary prevention according to their CVD risk.

#### Design and setting

Cross-sectional study in primary care settings in the three east London CCGs (Newham, City and Hackney, and Tower Hamlets).

#### Method

Data were extracted from electronic health records of 930 000 patients registered with 137 of 141 general practices for a year ending 1 April 2014.

#### Results

Of 341 099 patients aged 30–74 years, excluding those with CVD or diabetes, 22 393 were prescribed statins and had a 10-year CVD risk recorded. Of these, 9828 (43.9%) had a CVD risk  $\geq 20\%$ , 7121 (31.8%) had a CVD risk of 10–19%, and 5444 (24.3%) had a CVD risk  $< 10\%$ . Statins were prescribed to 9828/19 755 (49.7%) of those at  $\geq 20\%$  CVD risk, to 7121/37 111 (19.2%) of those with CVD risk 10–19%, and to 5444/146 676 (3.7%) of those with CVD risk  $< 10\%$ . Statin prescription below the 20% CVD risk threshold targeted individuals in the 10–19% risk band in association with hypertension, high serum cholesterol, positive family history, older age, and south Asian ethnicity.

#### Conclusion

This study confirms continuing undertreatment of patients at highest CVD risk ( $\geq 20\%$ ). GPs prescribed statins to only one-fifth of those in the 10–19% risk band usually in association with known major risk factors. Only 3.7% of individuals below 10% were prescribed statins.

#### Keywords

cardiovascular prevention; cardiovascular risk; primary care; statins.

### INTRODUCTION

Before 2014, National Institute for Health and Care Excellence (NICE) guidance recommended statin treatment in individuals at a 10-year cardiovascular disease (CVD) risk of 20%.<sup>1</sup> In 2014, NICE reduced this treatment threshold to 10%<sup>1</sup> and in the US a CVD risk level of 5.0–7.5% was recommended based on trial evidence of CVD benefit.<sup>2,3</sup>

Two studies examined statin treatment for primary prevention in the UK up until 2010–2011.<sup>4,5</sup> They concluded that statin prescribing for primary prevention was poorly targeted according to the guidance at the time. van Staa *et al* used a 2011 nationally representative sample of general practices with 300 914 patients prescribed statins, excluding those with diabetes and CVD.<sup>5</sup> From 2007 to 2011, 30.4% of 'eligible' patients with a 10-year CVD risk of  $\geq 20\%$  were prescribed a statin. Of those with a 10–19% CVD risk, 18% were prescribed statins and in those at  $< 10\%$  risk, statins were prescribed for 3.5%. The authors concluded that:

*'There appeared to be a substantive overuse in patients with low CVD risk as well as underuse in those with high CVD risk.'*<sup>5</sup>

Wu *et al* used a separate national general practice database for the earlier years 2008–2010.<sup>4</sup> The cohort of 365 718 patients

excluded those with CVD and included those with diabetes. In total, 28.5% of those with diabetes or a 10-year CVD risk of  $\geq 20\%$ , and 10.1% of patients below this threshold, were prescribed lipid-lowering medication. The authors concluded:

*'... most statins are prescribed to patients who are not eligible for treatment ... Overall we find more evidence to support the view that prescribing of statins is influenced more by single risk factors treated as categories (age  $\geq 65$  years; diabetes; total cholesterol  $\geq 7$  mmol/l) ...'*<sup>4</sup>

Since the national NHS Health Check started in 2009, statins have been promoted in the east London Clinical Commissioning Groups (CCGs) of Newham, City and Hackney, and Tower Hamlets with a systematic programme incentivising uptake and statin prescription in patients with a CVD risk of  $\geq 20\%$ .<sup>6</sup> Of those aged 40–74 years who are eligible in any 1 year, 67% are currently attending an NHS Health Check.<sup>7</sup> These three CCGs were also top in London in the 2013 national Quality and Outcomes Framework for control of CVD risk factors for patients with diabetes and coronary heart disease, with the highest per capita statin prescribing nationally.<sup>8</sup>

In these localities in which prescribing of statins above 20% CVD risk had been strongly supported, the aim of this study

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### How this fits in

In 2014, the recommended NICE threshold for statin treatment for the primary prevention of cardiovascular disease (CVD) changed from a 10-year CVD risk of 20% to 10%. In 2013–2014, this study found that in individuals at highest risk ( $\geq 20\%$  10-year CVD risk), only one-half were prescribed statins. In the 10–19% CVD risk band, one-fifth were treated with statins. The treatment of those at  $\geq 20\%$  CVD risk (including those aged  $\geq 75$  years) is a feasible goal. However, extension to the lower risk band is unlikely to treat most patients at 10–19% CVD risk. Nor will it address high lifetime risk in patients of younger ages for whom population measures to improve risk factors would have a greater impact.

was to determine factors associated with statin prescribing at lower CVD risk.

### METHOD

The study conformed to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidance on cohort studies (<http://www.strobe-statement.org/>). Data were used from electronic health records in 137 out of 141 general practices serving a registered population of 930 000 patients in the east London CCGs of City and Hackney, Tower Hamlets, and Newham for a period of 1 year ending on the index date of 1 April 2014. Data from four practices could not be accessed because they used a different computer system. All contributing practices used the same web-enabled record system (Egton Medical Information Services, EMIS) with agreed data-entry templates to ensure consistent data entry and coding. Data were obtained for all patients aged 30–74 years and who were registered at least 1 year before the search date. Patients with CVD (angina, ischaemic heart disease [IHD], stroke, and peripheral vascular disease), and types 1 and 2 diabetes were excluded. QRISK<sup>®</sup> was used for all CVD risk estimation. Variables included:

- statin prescription within 6 months;
- sex;
- age group ( $\leq 44$  years, 45–54 years, 55–64 years, and 65–74 years);
- CCG locality;
- ethnic group (white, black African/Caribbean, South Asian, other, and not stated);

- national quintiles of Townsend score [1 [least deprived] to 5 [most deprived]];
- presence or absence of positive IHD family history in first-degree relatives aged  $< 60$  years, with missing values considered negative;
- latest smoking status (currently smoking or not);
- highest recorded systolic blood pressure ( $< 140$  mmHg, 140–159 mmHg, and  $\geq 160$  mmHg);
- highest recorded total cholesterol ( $< 5.0$  mmol/L, 5.0–6.9 mmol/L, and  $\geq 7.0$  mmol/L); and
- antihypertensive drug treatment within 5 years.

The authors used the highest recorded QRISK<sup>®</sup> (<http://www.qrisk.org/>) value within 5 years, to determine 10-year CVD risk banding of:

- $< 5\%$ ;
- 5–9%;
- 10–14%;
- 15–19%; and
- $\geq 20\%$ .

Values of blood pressure and cholesterol exceeding clinical ranges were excluded.

### Statistical analysis

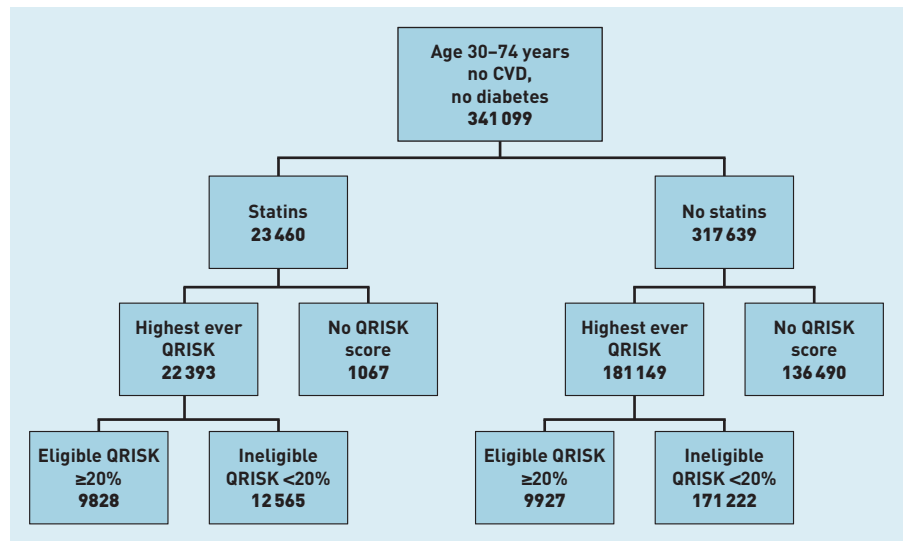
All analyses were performed using Stata (version 12). Multivariate regression analysis was used to assess the relationship between statin prescription and explanatory variables. The model was adjusted for clustering by practice and  $P < 0.05$  was considered to represent statistical significance.

### RESULTS

Figure 1 describes the statin prescription at each stage of the analysis by CVD risk. From a total of 341 099 patients aged 30–74 years without CVD or diabetes, 203 542 (59.6%) had their CVD risk recorded. Of the remaining 137 557 with no CVD risk calculated, 1067 (0.8%) were on statins (Figure 1).

Table 1 describes the CVD risk distribution of patients who were prescribed statins in the preceding 6 months compared with those who were not. Of the 19 755 patients with a CVD risk of  $\geq 20\%$ , 9828 (49.7%) had been prescribed a statin in the preceding 6 months. Of those 37 111 patients in the 10–19% CVD risk band, 7121 (19.2%) were prescribed statins. Of the total 22 393 patients prescribed statins for primary prevention, 9828 (43.9%) had a CVD risk

Figure 1. Flow chart to illustrate statin by CVD risk.



of  $\geq 20\%$  and conversely 56.1% were  $< 20\%$  CVD risk.

Of the 12 565 patients prescribed statins whose CVD risk was  $< 20\%$  7121/12 565 (56.7%) had a CVD risk of 10–19%. Of those with CVD risk  $< 10\%$ , 5444/146 676 (3.7%) were prescribed statins. In other words, statin prescription in those with CVD risk  $< 10\%$  represented 5444/22 393 (24.3%) of total statin prescription for primary prevention.

In the unadjusted analyses of those patients prescribed statins below the 20% threshold (Table 2), females (7.8%) were more likely than males (5.9%), to be prescribed statins ( $P < 0.001$ ). Statin prescription below the 20% threshold was more likely in Newham (9.6%) than in the other two localities (5.4%, 5.5%); among South Asians than other ethnic groups (9.5% versus 6.3–6.9%); in those in the second least deprived quintile (14.0% versus the most deprived, 6.7%); and among those with a positive family history of premature IHD (9.0% versus in those without, 6.2% [ $P < 0.001$ ]).

Statin prescription was particularly associated with antihypertensive medication, raised blood pressure, and high cholesterol. Statins were prescribed to

23.5% of those on antihypertensive therapy versus 3.4% of those who were not; in 35.9% of those with a serum cholesterol  $\geq 7$  mmol/L versus 2.1% in those with serum cholesterol  $< 5$  mmol/L; and in 20.5% of those with a systolic blood pressure  $\geq 160$  mmHg versus 3.0% in those where it was  $< 140$  mmHg.

Table 3 shows the adjusted odds ratios (OR) for relevant variables that were significantly associated with statin prescription in patients  $< 20\%$  CVD risk. Statin prescription was more likely at older ages, in people of South Asian ethnicity, and in those with a positive family history of premature IHD, raised blood pressure, and treated hypertension ( $P < 0.001$ ). The highest OR (20.5) was associated with a cholesterol of  $\geq 7$  mmol/L, age 65–74 years (OR 7.6) and antihypertensive therapy (OR 5.0). Female sex (OR 0.76) and black African/Caribbean ethnic group (OR 0.81) were associated with significantly lower statin prescription ( $P < 0.001$ ). The association with deprivation was not significant.

## DISCUSSION

### Summary

This study confirms the finding of previously

Table 1. Patients in each cardiovascular disease risk group prescribed statins within the preceding 6 months

	Cardiovascular disease risk, n (%)					TOTAL
	$< 5$	5–9	10–14	15–19	$\geq 20$	
No statins	99 796	41 436	19 235	10 755	9927	181 149
Statin	1826 (1.8)	3618 (8.0)	3629 (15.9)	3492 (24.5)	9828 (49.7)	22 393 (11.0)
TOTAL	101 622	45 054	22 864	14 247	19 755	203 542

**Table 2. Characteristics of those ineligible for statins (CVD risk <20%) by statin status**

	Not on statin, n [%]		On statin, n [%]	
Total	171 222		12 565	
Male	86 628	(94.1)	5383	(5.9)
Female	84 594	(92.2)	7182	(7.8)
<b>Locality</b>				
Tower Hamlets	54 289	(94.5)	3136	(5.5)
City and Hackney	59 870	(94.6)	3394	(5.4)
Newham	57 063	(90.4)	6035	(9.6)
<b>Age group, years</b>				
≤44	73 355	(97.8)	1661	(2.2)
45–54	65 287	(93.8)	4291	(6.2)
55–64	26 430	(85.5)	4499	(14.5)
65–74	6150	(74.4)	2114	(25.6)
<b>Ethnicity</b>				
White	71 917	(93.7)	4866	(6.3)
South Asian	37 165	(90.5)	3884	(9.5)
Black African/Caribbean	36 514	(93.1)	2698	(6.9)
Other	10 455	(93.4)	738	(6.6)
Not stated	3484	(96.2)	136	(3.8)
Missing	11 687		243	
<b>National Townsend quintile</b>				
1 least deprived	49	(85.0)	8	(14.0)
2	364	(85.1)	64	(15.0)
3	1614	(89.3)	193	(10.7)
4	30 268	(92.9)	2305	(7.1)
5 most deprived	138 614	(93.3)	9967	(6.7)
Missing <sup>a</sup>	313		28	
<b>Family history of premature IHD (aged &lt;60 years)</b>				
Yes	39 432	(91.0)	3909	(9.0)
No	131 790	(93.8)	8656	(6.2)
<b>Antihypertensive therapy</b>				
Yes	23 756	(76.5)	7311	(23.5)
No	147 466	(96.6)	5254	(3.4)
<b>Smoking status</b>				
Not smoking	134 541	(92.7)	10662	(7.3)
Current smoker	36 410	(95.0)	1900	(5.0)
Missing <sup>a</sup>	271		3	
<b>Total cholesterol, mmol/L</b>				
<5	38 268	(97.9)	830	(2.1)
5.0–6.9	67 319	(90.8)	6816	(9.2)
≥7	8610	(64.1)	4823	(35.9)
Missing <sup>a</sup>	57 025		96	
<b>Systolic blood pressure, mmHg</b>				
<140	105 320	(97.0)	3247	(3.0)
140–159	40 213	(90.6)	4163	(9.4)
≥160	19 926	(79.5)	5151	(20.5)
Missing <sup>a</sup>	5763		4	
<b>QRISK % 10-year risk</b>				
<5	99 796	(98.2)	1826	(1.8)
5–9	41 436	(92.0)	3618	(8.0)
10–14	19 235	(84.1)	3629	(15.9)
15–19	10 755	(75.5)	3492	(24.5)

<sup>a</sup>% calculated without missing values. IHD = ischaemic heart disease.

published studies which show that at least half the statins for primary prevention in the UK are prescribed to patients whose risk

falls below the 20% CVD risk threshold,<sup>4,5</sup> most of which represents appropriate targeting of CVD risk according to the most recent 2014 NICE guidance.<sup>1</sup>

Of those individuals whose CVD risk was not recorded, only 0.8% were prescribed statins. Statin prescription in those with a CVD risk of <10% represented 24.3% of total statin prescriptions; in other words 75.6% of statin prescribing was within currently recommended limits ≥10% CVD risk. Like Wu *et al*, the authors of this study found that statin prescription below the 20% CVD risk is associated with several individual risk factors, including factors recommended by NICE guidance such as high cholesterol with a positive family history of premature IHD and hypertension.<sup>9</sup>

### Strengths and limitations

As this study is more recent and covers CCGs with a better than average implementation of the NHS Health Check programme, it has resulted in high levels of statin prescribing. In those with CVD risk recorded, risk factor recording was complete in all but three individuals for smoking status, in 96.9% for blood pressure, and in 68.9% for serum cholesterol, for whom missing values were imputed. Family history assumed missing values were negative. However, like the Wu *et al*<sup>4</sup> and van Staa *et al*<sup>5</sup> studies, the current study has limited data on CVD risk for those not on statins and 40% of the eligible population aged ≥30 years did not have CVD risk estimated. This means that it was not possible to provide a detailed analysis of those eligible patients who do not use statins because of the uncertainty of their risk profile and eligibility. Differences in methods of assessing CVD risk estimation and eligible populations should also be taken into account in direct comparisons of data. The localities in the current study have higher than average uptake of NHS Health Checks illustrating that even here, statin use at highest CVD risk of ≥20% is far from optimal.

Treatment thresholds are intended to guide, not replace clinical judgement, and individual risk estimation has substantial spread below any given threshold. Current tools for CVD estimation are relatively crude at an individual level<sup>10,11</sup> and may underestimate risk associated with extreme obesity, prediabetic states, chronic kidney disease, or other aspects such as heavy alcohol consumption or very sedentary lifestyles, which were not included in these studies.<sup>12</sup> For primary prevention in individuals at highest risk of CVD (≥20%), 32 out of 33 will not gain from statin treatment

**Table 3. Characteristics associated with statin prescribing to people with QRISK® <20%**

Characteristic	Odds ratio <sup>a</sup>	95% CI
Female	0.76	0.71 to 0.81
<b>Age, years</b>		
45–54	1.96	1.80 to 2.14
55–64	3.88	3.53 to 4.27
65–74	7.62	6.71 to 8.65
<b>Ethnic group</b>		
South Asian	2.40	2.10 to 2.74
Black African/Caribbean	0.81	0.74 to 0.88
Family history of premature ischaemic heart disease	1.30	1.21 to 1.39
Antihypertensive treatment	5.00	4.64 to 5.38
Current smoker	1.08	1.01 to 1.16
<b>Total cholesterol, mmol/l</b>		
5–6.9	3.49	3.04 to 4.01
≥7	20.52	17.95 to 23.46
<b>Systolic blood pressure, mmHg</b>		
140–159	1.42	1.34 to 1.51
≥160	1.41	1.32 to 1.52

<sup>a</sup>All reported odds ratios were significant  $P<0.001$  except smoking  $P<0.05$ .

in the next 5 years, with rapidly increasing margins of uncertainty below this level.<sup>13</sup>

#### Comparison with existing literature

Statin prescribing was better targeted in this 2014 study than in the two studies up to 7 years earlier. Statin prescription in patients at highest CVD risk in east London (49.7%) was higher than the 30.4% or 28.5% recorded by van Staa *et al* and Wu *et al* respectively, and the 6.8% prescription of statins to those at <20% CVD risk in the east London study, is less than the 10.1% recorded by Wu *et al*. Van Staa *et al* reported that statins were prescribed to 18.2% of those with a CVD risk of 10–19%, and to 3.5% of those with a <10% CVD risk; this is very similar to statin prescription in the current study, where the figures are 19.2% and 3.7% respectively.<sup>4,5</sup>

As in previous studies, statin prescription to patients at <20% risk in the current study was mainly directed towards those who were:

- in the 10–19% CVD risk band;
- older;
- from South Asian ethnic groups; or
- on antihypertensive treatment or with raised blood pressure, raised serum cholesterol, or a positive family history of premature IHD.

Lower rates of prescription of statins in black African/Caribbean patients has been reported in previous studies in secondary prevention.<sup>14</sup>

The current study shows that, statin prescribing below the 20% CVD threshold is targeted towards individuals in the 10–19% risk band who have associated CVD risk factors, particularly high cholesterol, (35.9%) and those on antihypertensive treatment (23.5%). Mandating lower treatment thresholds to 10% would require GPs to achieve a huge increase in workload. At present GPs are reaching fewer than one-half of the 8% of the population at ≥20% risk. Adding a further 18% of the population at 10–19% risk would more than treble this.

#### Implications for research and practice

Data from the current and national studies confirm that in those at lower CVD risk, GPs currently prescribe statins largely in accordance with current NICE guidance, although only a minority of those individuals are potentially eligible. It would be preferable if treatment at the 10% CVD risk level was considered a permissive rather than a mandatory requirement of programmes.<sup>1</sup> This preference is not due to a lack of robust, cost-effective evidence of benefit at the 10% threshold or even the US recommended 5.0–7.5% threshold.<sup>15</sup> The authors' concern is threefold:

- It is neither feasible nor politically desirable to medicalise 30–50% of the adult population while there are already very effective and feasible ways of preventing CVD in the first place.
- The 20% risk threshold already means that in practice, half of those treated with statins are 'scattered' below this level. If a 10% CVD risk level is mandated it will result in many more individuals being treated below the 10% level, where the ratio of benefit to harm from treatment and cost effectiveness are open to some doubt.
- Trying to treat three times as many patients does not make sense when currently only half at highest risk are identified and of these, only one-third are treated (that is, only 15% of those at highest risk are currently treated). Meanwhile, patients aged ≥75 years, almost all of whom have CVD risk >20%, continue to be largely ignored and are not included as part of the NHS Health Check programme. This study makes it clear that GPs are already treating a minority of patients in the 10–19% CVD risk band and the new NICE guidance, which is permissive rather than mandatory, supports this pragmatic

approach, recognising the need for case-by-case assessment of estimated CVD risk, known risk factors, and patient preference.

US guidance confirms that there is trial evidence for CVD benefit from statins available down to a 5% CVD risk threshold,<sup>3</sup> but this would involve around 50% of the UK population aged >40 years in treatment programmes. At the proposed NICE 10% CVD threshold, this would be 25–30% of the population. The NHS Health Check programme identifying those at 20% risk already targets 10% of the adult population aged 40–74 years for treatment with statins and nationally the programme is treating less than one-third of these. A previous attempt in 2004 for pharmacists to directly treat patients at a 10% CVD risk threshold failed because this was not a feasible method of delivery for large population groups.<sup>16</sup>

There is robust evidence that legislative control of dietary sugars, fats, salt, smoking, alcohol, and air pollution and improvements in the built environment to promote physical activity would have far greater impact and equity than a poorly delivered programme of statins and antihypertensives targeting patients below 20% CVD risk.<sup>17</sup> Clinicians are already prescribing statins to some patients below the 20% threshold. But exercising informed clinical judgement is very different from mandating a treatment programme down to the 10% level.

This study considered patients in the 30–74 years age band to enable comparison with previous studies. NICE guidance

recommends statin treatment in individuals aged  $\geq 75$  years as there is robust evidence that statins are highly effective in reducing CVD events in this age group.<sup>1</sup> If statin prescription is to be systematically extended, it would be better targeted at those aged  $\geq 75$  years who are almost universally at  $\geq 20\%$  CVD risk, for whom it would be a feasible and highly cost-effective programme with evidence of benefit from both statin and antihypertensive treatment to 85 years, with no reason to suppose these benefits are not applicable to many of those even older.<sup>15,18</sup>

In east London in 2013–2014, statins were prescribed to 50% of patients identified as being at highest risk of CVD compared with 30% in earlier national studies. For those below this CVD risk level, statin prescription was on a similar scale to that in previous studies and largely directed to individuals with CVD risk  $>10\%$ , older ages, on antihypertensive treatment, or with other increased risk factors for CVD. The problem is not so much overtreatment at lower risk levels, as undertreatment for those at highest risk.

Nationally, less than one-third of those identified as being at highest risk of CVD are treated and a systematic programme enfranchising those aged  $\geq 75$  years is not available. Improvement of current programmes targeting statin use at over 20% CVD risk and inclusion of patients aged  $\geq 75$  years in the NHS Health Check programme would yield greater and more feasible gains from the limited resources currently available in primary care than extending treatment at lower risk.

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### Ethical approval

All data were anonymised and managed according to the UK NHS information governance requirements. Ethical approval was not required for the use of anonymised data in this observational study.

### Provenance

Freely submitted; externally peer reviewed.

### Competing interests

John Robson was Chair of the 2008 NICE guideline on lipid modification (CG67) that recommended a 20% CVD risk threshold for statin treatment. John Robson was also a co-author of QRISK®. John Robson and Isabel Dostal are also evaluating the NHS Health Check programmes supported by a National Institute for Health Research grant. John Robson, Kambiz Boomla and Sally Hull have promoted the implementation of the NHS Health Check programme in east London.

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### Discuss this article

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