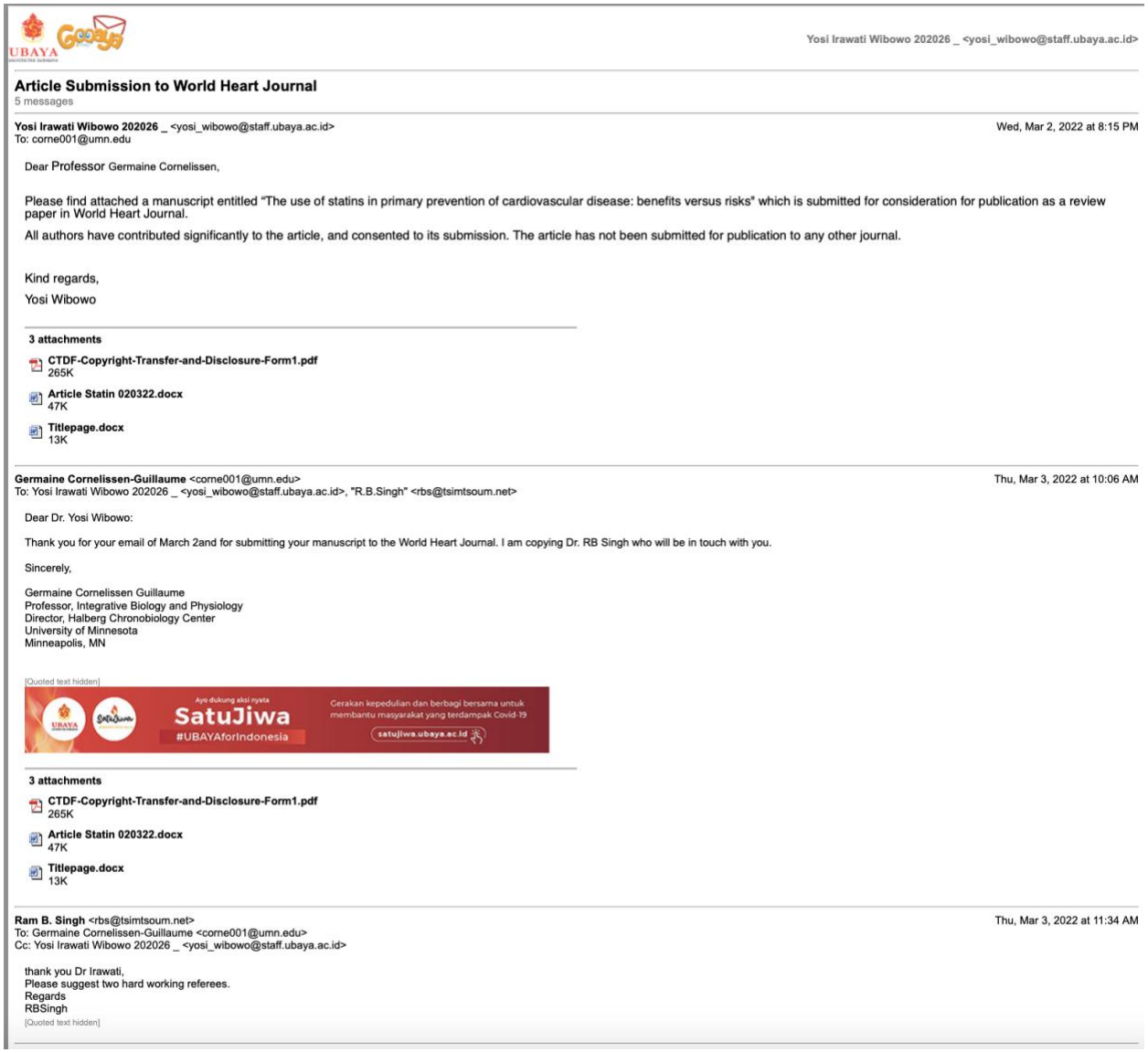
World Heart Journal – corresponding author

1. Submitted to the journal (March 2, 2022)
2. First decision: revision (March 23, 2022)
3. Revision uploaded (April 12, 2022) – Revised manuscript with track changes (attached)
4. Second decision: accepted final draft (April 13, 2022)
5. Notification for publication (Oct 7, 2022)

1. Submitted to the journal (March 2, 2022)



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Yosi Irawati Wibowo 202026 _ <yosi_wibowo@staff.ubaya.ac.id>

Article Submission to World Heart Journal
5 messages

Yosi Irawati Wibowo 202026 _ <yosi_wibowo@staff.ubaya.ac.id> Wed, Mar 2, 2022 at 8:15 PM
To: corne001@umn.edu

Dear Professor Germaine Cornelissen,

Please find attached a manuscript entitled "The use of statins in primary prevention of cardiovascular disease: benefits versus risks" which is submitted for consideration for publication as a review paper in World Heart Journal.

All authors have contributed significantly to the article, and consented to its submission. The article has not been submitted for publication to any other journal.

Kind regards,

Yosi Wibowo

3 attachments

CTDF-Copyright-Transfer-and-Disclosure-Form1.pdf
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Titlepage.docx
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Germaine Cornelissen-Guillaume <corne001@umn.edu> Thu, Mar 3, 2022 at 10:06 AM
To: Yosi Irawati Wibowo 202026 _ <yosi_wibowo@staff.ubaya.ac.id>, "R.B.Singh" <rbs@tsimtsoum.net>

Dear Dr. Yosi Wibowo:

Thank you for your email of March 2and for submitting your manuscript to the World Heart Journal. I am copying Dr. RB Singh who will be in touch with you.

Sincerely,

Germaine Cornelissen Guillaume
Professor, Integrative Biology and Physiology
Director, Halberg Chronobiology Center
University of Minnesota
Minneapolis, MN

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3 attachments

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Ram B. Singh <rbs@tsimtsoum.net> Thu, Mar 3, 2022 at 11:34 AM
To: Germaine Cornelissen-Guillaume <corne001@umn.edu>
Cc: Yosi Irawati Wibowo 202026 _ <yosi_wibowo@staff.ubaya.ac.id>

thank you Dr Irawati,
Please suggest two hard working referees.
Regards
RBSingh
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2. First decision: revision (March 23, 2022)

Yosi Irawati Wibowo 202026 _ <yosi_wibowo@staff.ubaya.ac.id> Tue, Apr 12, 2022 at 10:32 PM
To: "Ram B. Singh" <rbs@tsimtsoum.net>

Dear Professor Singh,

Please find attached the revised manuscript (track changes version).
We also include the response letter to facilitate the review process.

Best regards,
Yosi

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2 attachments

Response World Heart J.docx
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3. Revision uploaded (April 12, 2022) – Revised manuscript with track changes (attached)

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Yosi Irawati Wibowo 202026 _ <yosi_wibowo@staff.ubaya.ac.id>

Fwd: Revise and resubmit.
6 messages

Antonius Adji Prayitno Setiadi <adji_ps@staff.ubaya.ac.id> Wed, Mar 23, 2022 at 11:50 AM
To: Yosi I W <yosi_wibowo@staff.ubaya.ac.id>

Bu Yosi ini ada permintaan revisi naskah ya
GBU,

Dr. A. Adji Prayitno S., M.S., Apt.
Lecturer at Faculty of Pharmacy, Universitas Surabaya
Jalan Raya Kalirungkut, Surabaya 60293, Indonesia
Phone: +62 31 2981170 Fax: +62 31 2981171
E-Mail: adji_ps@staff.ubaya.ac.id

---------- Forwarded message ---------
From: **Ram B. Singh** <rbs@tsimtsoum.net>
Date: Wed, Mar 23, 2022 at 7:22 AM
Subject: Revise and resubmit.
To: <adji_ps@staff.ubaya.ac.id>
Cc: Ram Bahadur Singh <rbs@tsimtsoum.net>

Dear Dr Irawati,
Please revise your paper as per following comments. Please wait till you get further comments about your paper from other free.
Regards
RBSingh
Refree 1, March 23,2022
Write as given subheads below.
Introduction. Write what is unknown or less known and why your paper is relevant
Methods for Selection of Studies
Synthesis of data/results
Table 1 may be divided in two, a figure showing mortality and rest in table or otherwise. Make the table easy to see.
Discussion
Write what are comments from 2022 AHA statistics?
Limitations at the end before conclusions
Please 1-2 references from 2021,2022 and from WHJ
Reference in square brackets in the text and the list of ref [ref].

Revised manuscript with track changes

The use of statins in primary prevention of cardiovascular disease: benefits versus risks

Abstract

Background: Cardiovascular disease (CVD) remains as a major global health issue. The use of statins in people with a history of CVD is generally well established, however, debate remains about their use for primary prevention in people without CVD.

Objective: to present studies related to the benefits and risks of taking statins for primary prevention of CVD.

Methods: This is a narrative review of systematic review/ meta-analyses-based articles published between 2006 and 2021.

Results: The studies reported positive outcomes of statins, particularly in relation with reduction in all-cause mortality, non-fatal MI, and non-fatal stroke. Some adverse events also reported, such as muscle problems, diabetes, liver dysfunctions, as well as renal and eye disorders, However, the risks attributable to statins were considerably low, thus did not outweigh the benefits in preventing CVD. It should be acknowledged that the decision to initiate statins for primary prevention should not solely depend on the LDL-C value, but also on overall CVD risk factors for a particular individualas can be seen in three major guidelines from the American College of Cardiology/American Heart Association (ACC/AHA) - 2019, Canadian Society of Cardiology (CCS) - 2021, and the European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) - 2019.

Conclusion: The risks attributable to statins were relatively low, thus did not outweigh the benefits in preventing CVD.

Keywords: statin, primary prevention, cardiovascular risk factor, cardiovascular disease

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Introduction

Cardiovascular disease (CVD) has been a global health problem due to its association with high mortality, morbidity, and total healthcare expenditure [1]. Atherosclerosis is known as the major leading cause of CVD, including: ischaemic heart disease (IHD) or coronary artery disease (CAD), cerebrovascular disease (such as: ischaemic stroke), diseases in the aorta and arteries (such as: peripheral vascular disease [PVD]) [1, 2]. Global health expenditures attributable to CVD have been projected to rise as much as 22% by 2030, i.e from 863 billion US on 2010 to 1,044 billion US on 2030 [2].

There are several factors contributing to the incidence of CVD, known as cardiovascular risk factors, including hypertension, smoking, diabetes mellitus (DM), physical inactivity, unhealthy diet, dyslipidaemia, overweight and obesity, age, sex, family history of premature CVD and psychosocial risk factor [3, 4]. Dyslipidaemia is a general term used to explain lipid abnormalities in human body. One of lipid fractions circulating in human blood is low-density lipoprotein cholesterol (LDL-C). The relationship between a high plasma concentration LDL-C and the development of atherosclerotic plaque has been well studied [5, 6]. Hence, the management of high LDL-C gets the most attention to control the incidence of CVD [4].

Hydroxymethylglutaryl-CoA (HMG-CoA) reductase inhibitors or statins are a group of lipid lowering drugs with a strong effect on LDL-C lowering activity [3, 4]. There are seven statins currently available in the market, i.e pravastatin, lovastatin, fluvastatin, simvastatin, atorvastatin, rosuvastatin, and pitavastatin. Each statin has their own potency in the LDL-C reduction effect, and based on their potency, statins can be classified as high or low potency. High potency statins, e.g. atorvastatin and rosuvastatin, decrease the LDL-C level by >50% while low potency statins, e.g. simvastatin, pravastatin, lovastatin, and fluvastatin, decrease the LDL-C level by <30% [7].

The use of statins in people with a history of CVD is generally well established, however, debate remains about their use for primary prevention in people without CVD [3, 4]. The controversy is mainly related to uncertainty about whether the benefits of statins outweigh the risks and whether widespread use of statins can be justified from a societal perspective. Hence, this narrative review aimed to present studies related to the benefits and risks of taking statins for primary prevention of CVD.

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Methods

This is a narrative review of systematic review/ meta-analyses-based publications. We searched The Cochrane Library (2006 to 2021) and PubMed (2006 to 2021) using the following keywords: Hydroxymethylglutaryl-CoA Reductase Inhibitors, statin OR statins; cardiovascular disease, heart disease, coronary disease; primary prevention. Results from searches on the electronic databases were reviewed to identify systematic review/ meta-analyses-based articles relevant to this review.

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Results and Discussion

1. Benefits of statins in primary prevention of CVD

Mortality outcomes

All-cause mortality. Ray *et al*. (2010) clearly indicated non-significant benefit of using statins for primary prevention of CVD on the overall mortality [8]. The relative risks (RRs) of overall mortality analyzed using random effect and fixed effect method were 0.91 (95%CI 0.83-1.01) and 0.93 (95%CI 0.86-1.00), respectively. Several meta-analyses found significant benefit of using statins for this final outcome with the RR in the range of 0.86-0.93 [9-12]. A recent meta-analysis conducted by Yebyo et al. (2019) reported statins reduced the incidence of all-cause mortality, however, significant effects were only demonstrated for pravastatin, atorvastatin, and rosuvastatin [13].

Although the use of statins showed significant benefits related to the overall mortality in all of the meta-analyses, the 95% of confident intervals (CIs) were relatively close with the value of non-significant difference, which is 1. Furthermore, after excluding studies without reported allocation of concealment, Mills *et al*. (2008) found non-significant benefit of using statins in term of overall mortality, and even preferable for the non-statin users, with the RR 1.14 (95%CI 1.01-1.28) [10]. A study conducted by Brugts *et al.* (2009) also found the 95%CI getting closer to 1 after excluding patients with history of CVD events (RR 0.87; 95% 0.81-0.97) [9]. The other two studies did not further analyze this effect by excluding the possible confounding factors [11, 12]. The summary findings are presented in Table 1.

CVD or non-CVD death. Two meta-analyses analysed the CVD mortality outcome (see Table 1). Mills *et al.* (2008) found significant benefit of using statins for CVD mortality outcome with the RR 0.89 (95%CI 0.81-0.98), however the 95%CI was close to non-significant difference value. After excluding studies with no report on allocation of concealment, the pooled analysis yielded contrary results (RR 1.23, 95%CI 1.02-1.49), thus favoured the group without statins [10]. The meta-analysis by Brugts *et al.* (2009) clearly presented non-significant benefit with the RR 0.88 (95%CI 0.73-1.05) by using both random-effect and fixed effect analysis [9]. Mills *et al.* (2008) did a subgroup analysis by including studies recruited only low risk population. Although the result showed significant benefit for statin group compared with non-statin group (RR 0.66; 95%CI 0.5-

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0.87), this study might suffer from some bias. The inclusion of only CVD low risk patients means to include relatively healthier and younger subject, thus lower CVD mortality for this group might not solely caused by using statins [10]. Only one study analysed the non-CVD mortality, Mills *et al.* found non-significant benefit of using statins for non-CVD mortality with the RR 0.98 (95%CI 0.9-1.07) [10]. A more recent meta-analysis reported that statins were attributed to 21% RR reduction of CVD mortality (RR 0.80, 0.71 to 0.91; individually, only the effect of rosuvastatin and pravastatin reached statistical significance [13].

CVD event outcomes

CVD events (composite). CVD outcomes usually defined as combined outcomes between coronary heart disease (CHD) and stroke. Similar to CVD mortality outcome analysis, Mills *et al*. (2008) also reported significant benefit of using statins in terms of major CVD event outcomes in the beginning of their analysis with RR for statins group 0.85 (95%CI 0.77-0.95). But after excluding studies with no report of allocation of concealment, they found preferable result for group without statins (RR 1.09; 95%CI 1.01-1.20) [10]. Meta-analysis conducted by Taylor *et al.* (2013) divided CVD outcomes into: total CVD events, fatal CVD events, and non-fatal CVD events (RR 0.75, 95%CI 0.70-0.81; RR 0.83, 95%CI 0.72-0.96; and RR 0.77, 95%CI 0.62-0.96; respectively) [12]. While Yebyo *et al.* (2019) reported significant composite major cardiovascular events (excluding fatal stroke and heart failure) on the use of statins (RR 0.74, 95%CI 0.67–0.81) [13]. Since the CVD outcomes are composite outcomes, it is interesting to analyse the result for CHD outcomes and stroke outcomes separately.

Myocardial Infarction (MI). Four studies observed MI outcomes reported some benefits of using statins in term of CHD or MI outcomes (see Table 1). Tonelli *et al*. (2011) showed non-significant benefit of statins for fatal MI with RR 0.96 (95%CI 0.5-1.85) but significant benefit for non-fatal MI with RR 0.64 (95%CI 0.49-0.84) [11]. Brugts *et al* (2009) and Yebyo *et al.* (2019) also found significant benefit of statins only in non-fatal MI (RR 0.56, 95%CI 0.41-0.76 [random effect analysis] and RR 0.61, 95%CI 0.52-0.73 [fixed effect analysis]; and RR 0.62, 95%CI 0.53 to 0.72; respectively) [9, 13]. By excluding studies without allocation of concealment, Mills *et al*. (2008) found non-significant benefit of using statins for MI outcome (RR 1.16; 95%CI 1.01-1.35) [9]. Unfortunately, this study did not differentiate the analysis based on fatal and non-fatal MI.

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Differentiation of MI might be helpful to identify in which condition statins should be given. Non-fatal MI might be the only final outcome that most studies reported significant benefits.

Stroke. There were five studies observed stroke outcomes in their analysis (see Table 1). Without differentiating the type and severity of stroke, study conducted by Mills *et al.* (2008) and Brugts *et al.* (2009) presented contrary results. Even after excluding studies without allocation concealment, Mills *et al.* (2008) found non-significant benefit of using statins in term of stroke outcome with the RR 0.88 (95%CI 0.78-1.00) [10]. On the other hand, Brugts *et al*. (2009) found significant benefit of statins with the RR 0.81 (95%CI 0.71-0.93) with random effect or 0.82 (95%CI 0.74-0.91) with fixed effect analysis [9]. This might due to the different proportion of patients with haemorrhagic stroke in the studies included in each meta-analysis in which the use of statins might be less beneficial. Moreover, there was a difference in the proportion of patients with particular severity of stroke included in each meta-analysis. The other two meta-analysis studies emphasised the importance to differentiate the level of stroke severity [11, 12]. Both studies found non-significant benefit of statins for fatal stroke with the RR 0.91 (95%CI 0.65-1.29) and 0.63 (95%CI 0.18-2.23); while significant benefit of statins for non-fatal stroke was reported. The recent meta-analysis by Yebyo *et al*. (2019) confirmed this finding (fatal stroke: RR 0.89, 95%CI 0.85–0.93; non-fatal stroke: RR 0.83, 95% CI 0.75–0.92) [13].

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The relationship between LDL reduction and outcomes in primary prevention of CVD

There were two meta-analyses study the relationship between LDL reduction and final outcomes in primary prevention setting. Presented as beta (β) coefficient, Mills *et al*. (2008) reported no relationship between LDL reduction and overall mortality and CVD mortality outcomes (β coefficient -0.07; 95%CI -0.22 to 0.06, p=0.29 and 0.11; 95%CI -0.11 to 0.34, p=0.33, consecutively) [10]. This is in line with the findings from Ray *et al.* (2010) where no significant relationship between LDL-C reduction with overall mortality outcomes was reported, either measured as an absolute reduction (p=0.62) or percentage reduction in LDL-C (p=0.46) [8]. These findings, together with the findings on the effectiveness of statins on the various outcomes, have strongly indicated no further benefits in tightly and rashly controlling LDL-C in primary prevention setting.

2. Risks of taking statins as primary prevention of CVD

Statins have been reported to be associated with some adverse effects, such as cancer, muscle problems, diabetes, changes in liver function tests (aminotransferases), as well as renal and eye disorders (see Table 2).

Cancer. Studies on the effects of statin use and cancer events are presented in Table 2. Most of those studies showed no significant effects of statin therapy on incidence or mortality of cancer in any sites. Just one meta-analysis of case-control studies from Taylor *et al*. (2008) found a significant association between statin usage and cancer prominently in colon cancer (odds ratio [OR] 0.89; 95%CI 0.82-0.97) [14]. The questionable finding on the significant association between statin and colon cancer should be addressed since most studies were conducted in Western countries which colon cancer was common due to habitual diets. On the other hand, recent studies have been increasingly explored anticancer properties of statins due to its antiproliferative effects [15].

Diabetes Mellitus. Four meta-analyses used to identify an association between DM and statins (see Table 2). Alberton *et al.* (2012) analysed the risk of DM from every single statin separately. There was no association found between simvastatin and risk of DM [21]. Two meta-analyses analysed the effect of statins as a group and the risk of DM [22, 23]. Both studies found statin prescription increased the risk of DM. Unfortunately, the studies included in each meta-analysis did not accounted several DM risk factors, especially familial history of DM, into the findings. Cooney *et al*. (2009) tried to differentiate the association of intensive versus moderate dose of statins and risk of DM [24]. It was reported that intensive dose of statins increased the risk of new-onset DM compared to moderate dose of statins. Interestingly, 75% of DM diagnoses were based on a non-biochemical method, i.e. initiation of glucose lowering treatment within the study period. Unfortunately, the studies did not consider how many participants who were already in DM treatment at the starting process of recruitment. A recent meta-analysis confirmed no association on the use of statins for primary prevention with the incidence of diabetes [25].

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Muscle disorders. A recent meta-analysis classified muscle problems as self-reported symptom or clinically confirmed disorders, to resolve the inconsistency and variety of definitions of outcomes in trials included. The results showed that statins are associated with a small increased risk of muscle symptoms, but no adequate evidence for muscle disorders [25]. Most of the previous reviews also reported no associations between statins and rhabdomyolysis (Table 2).

Aminotransferase levels. Statins increased the risk of elevated liver enzymes, either aspartate transaminase (AST) or ALT (alanine transaminase) (see Table 2). The use of atorvastatin was significantly associated with elevated AST and the use of simvastatin was significantly associated with elevated ALT [21]. The more intensive the dose, the more increase the risk of elevated liver enzymes [26]. The recent meta-analysis confirmed the association of taking statins with liver dysfunction (OR 1.33, 95%CI 1.12 to 1.58; absolute risk difference [RD] 8, 95%CI 3 to 14) [25].

Renal insufficiency and eye problems. A meta-analysis by Cai *et al.* (2021) confirmed associations between statins and renal insufficiency and eye problems (Table 2) [25]. However, the diagnoses and measurements of these two outcomes in the included trials in this review were varied, thus the associations might be limited to non-specific renal disorders and cataracts.

Further, Cai *et al.* (n= 58 trials) constructed network meta-analyses on the associations of individual statins with adverse effects [20]. Rosuvastatin was associated with an increased risk of self-reported muscle symptoms (OR 1.09; 95%CI 1.01 to 1.16), renal insufficiency (OR 1.13; 95%CI 1.00 to 1.28), diabetes (OR 1.14; 95%CI 1.00 to 1.30), and eye conditions (OR 1.26; 95%CI 1.04 to 1.52). Atorvastatin (OR 11.41; 95%CI 1.08 to 1.85) and lovastatin (OR 1.81; 95%CI 1.23 to 2.66) increased the risk of liver dysfunction. For comparisons among different statins, higher risk of liver dysfunction was reported for fluvastatin and pravastatin compared to fluvastatin and pravastatin; while atorvastatin and rosuvastatin had a higher risk of diabetes than pitavastatin [20]. Overall, the risks attributable to statins were low, thus did not outweigh the benefits in preventing CVD.

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3. Guideline recommendations on the use of statins for primary prevention of CVD

While continuous research has proven statins' potential benefits, many major guidelines have included statins for primary prevention of CVD [27]. Table 3 presents summary recommendations from three major guidelines, i.e. guidelines from the American College of Cardiology/American Heart Association (ACC/AHA), Canadian Society of Cardiology (CCS), and the European Society of Cardiology/European Atherosclerosis Society (ESC/EAS). The AHA statistics update in 2022 reported the increasing use of statins among US adults with a 10-year predicted ASCVD risk ≥7.5% from 27.9% (between 2005 to 2006) to 32.5% (between 2015 to 2016) [31].

Limitations

While this narrative review could provide a broader perspective on the use of statins for primary prevention; as for all narrative reviews, selection bias cannot be excluded.

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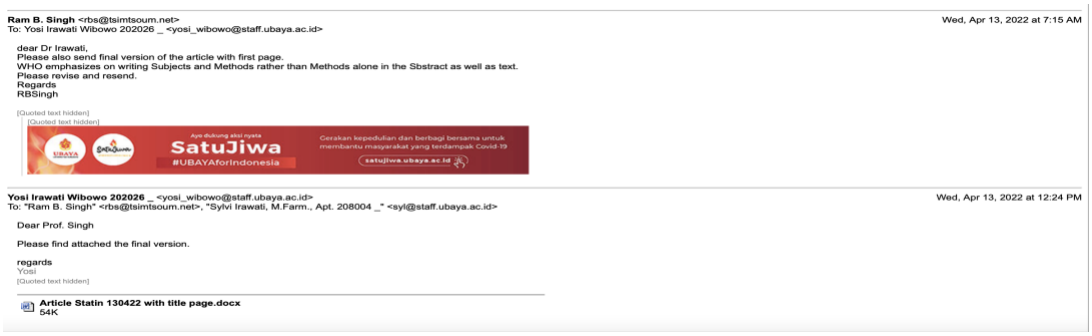
4. Conclusion

The risks attributable to statins were relatively low, thus did not outweigh the benefits in preventing CVD. However, the decision to initiate statins for primary prevention should not solely depend on the LDL-C value, but also on overall CVD risk factors for a particular individual.

4.Second decision: accepted final draft (April 13, 2022)



Ram B. Singh <rbs@tsimtsoum.net> Wed, Apr 13, 2022 at 7:15 AM
To: Yosi Irawati Wibowo 202026 _ <yosi_wibowo@staff.ubaya.ac.id>

dear Dr Irawati,
Please also send final version of the article with first page.
WHO emphasizes on writing Subjects and Methods rather than Methods alone in the Sbstract as well as text.
Please revise and resend.
Regards
RBSingh

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To: "Ram B. Singh" <rbs@tsimtsoum.net>, "Sylvi Irawati, M.Farm., Apt. 208004 _" <syl@staff.ubaya.ac.id>

Dear Prof. Singh

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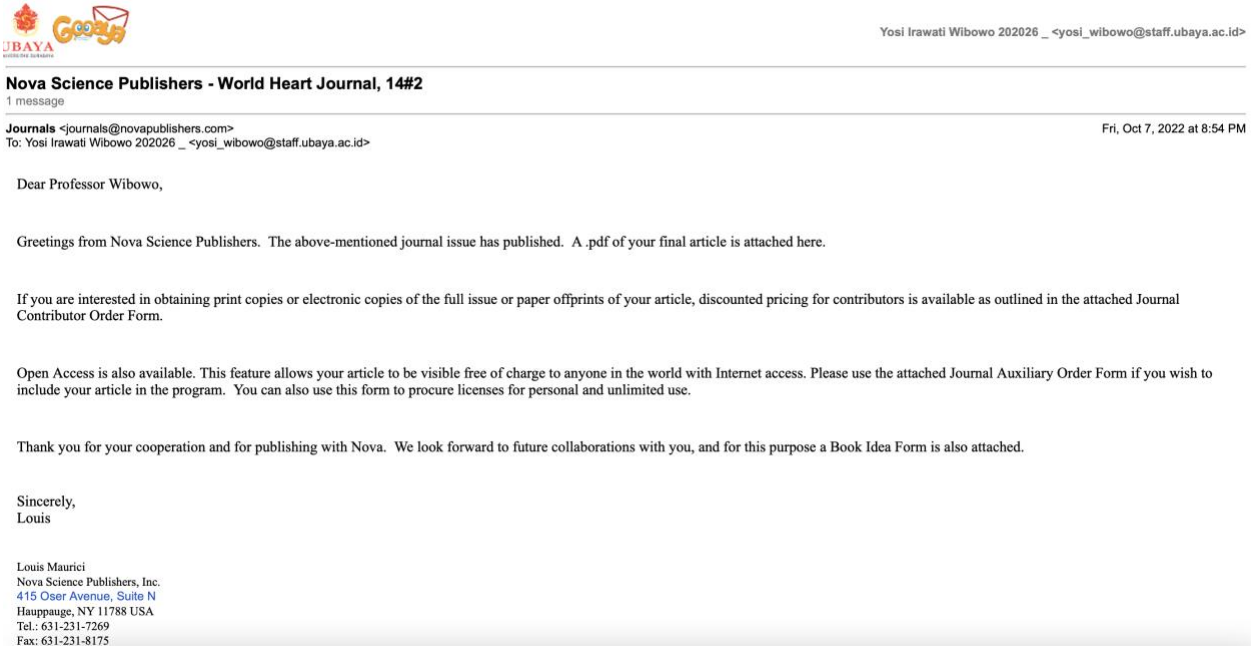
5.Notification for publication (Oct 7, 2022)



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Nova Science Publishers - World Heart Journal, 14#2
1 message

Journals <journals@novapublishers.com> Fri, Oct 7, 2022 at 8:54 PM
To: Yosi Irawati Wibowo 202026 _ <yosi_wibowo@staff.ubaya.ac.id>

Dear Professor Wibowo,

Greetings from Nova Science Publishers. The above-mentioned journal issue has published. A .pdf of your final article is attached here.

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