Reviewer's report

Title: Statin use and association with colorectal cancer survival and risk: case control study with prescription data linkage

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Reviewer: Harminder Singh

Reviewer's report:

This is an interesting paper which should be published after suggested revisions and clarifications. The paper demonstrates the practical challenges in doing such a study. My suggestions and comments:

General comments:

1. The power of the study is perhaps the biggest limitation of the study. As noted in the first paragraph of discussion, a post hoc power calculation was done—but the results of the power analysis are not provided. Please provide details of the power calculation. I am afraid the study may not have had the power to detect large differences for any of the outcomes studied.

2. A flow sheet of the SOCCS recruitment and ultimate participation in this particular study would be helpful. E.g. Did 52% of the 40% approached cases participate? And of those linkage could be performed for a proportion (what proportion?) And of those data on how many could be analyzed?

3. As noted by the authors, 2 above could have introduced a selection bias. Are there some data to compare those who were participated in the study/were used in the analysis to those who were not?

4. Do you have data on screening and/or endoscopy use among the different groups? Screening can affect cancer incidence and mortality. Health care utilization is often different among those exposed to drugs chronically and those not and could lead to differences in screening rates.

Methods

5. Why use logistic regression for mortality analysis? Such analysis would discard the potential differences in follow-up time. Survival analysis alone should be adequate.

6. What was the primary aim of SOCCS study? Recruitment is part of the study methods and could not have been the primary aim on its own.

7. Please elaborate as to what is community health index. This would be helpful for the readers who are not familiar with the systems in Scotland.

8. Page 6/7: Please provide the reasons as to why valid analysis could be done for 68% of cases and 88% of controls?
9. Page 8: Please provide the reasons in this section for selection of 2 months and 7 months for statin exposure. For the risk analysis was not the assessed statin use pre-diagnosis, rather than pre-recruitment?

10. Page 9: how was the family history categorized into low vs. medium/high?

11. Page 9: what was the reason for adjusting for IBS? IBS is not a risk factor of colon cancer or colon cancer outcomes and is not associated with statin use.

12. Page 9: Please define regular NSAID intake in this section.

13. Past history of cancer: does that include non-invasive cancers? Was the information on past cancers obtained from the patients?

14. BMI: Did the calculation use weight and height at the time of the cancer diagnosis or cancer surgery? If so, this may not be reflective of past weight when healthy; and should be mentioned as a potential limitation.

Discussion:

15. Page 15 last paragraph: This study did not undertake a meta-analysis.

Declaration of competing interests:

I declare that I have no competing interests.