Author’s response to reviews

Title: Challenges of one-year longitudinal follow-up of a prospective, observational cohort study using an anonymised database: recommendations for trainee research collaboratives

Authors:

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Version: 1 Date: 06 Mar 2019

Author’s response to reviews:

March 01, 2019

Dear Dr Kruger

We appreciate the consideration given our manuscript “Challenges of one-year longitudinal follow-up of a prospective, observational cohort study using an anonymised database: recommendations for trainee research collaboratives” and were pleased that it was reviewed favorably by a second reviewer. Please find our responses to the reviewer and a summary of the changes that were made.

Editor Comments:

1. Title Page: order of aus mismatches how they have been entered in the system. Please correct that.

In accordance to our previous collaborative papers, the name of the byline should be ‘STARSurg Collaborative’ as listed on the manuscript

2. Please include an abbreviation section before the declarations.

This has been included. In addition, Figure 1 has been updated to improve clarity of reasons for exclusion

3. Please include an author contribution statement in your declaration section and ensure all authors are named with their initials.

An author contribution statement has been incorporated into the declaration section as follows:

“Author Contribution Statement

JCG, AB, JB, TMD, SKK, KMM, MFB, HAC, BG, MM, PD, CK, HJ, LM, EW, CK, JEF, EMH, AB, and DN coordinated the study nationally.

All listed collaborators collected data.

SKK and KMM analysed the data.

SKK, KMM, AB, TMD, EW, CK, JEF, EMH, AB, DN, and JCG drafted the manuscript.

All authors contributed to critically revising the manuscript and have approved the final manuscript.

4. Please rename "Introduction" to "Background"

This has been amended

5. Please upload collaborators as additional file

A file containing all collaborators have been submitted as an additional file

Reviewer 1

1. I cannot understand the justification for excluding patients who died within 30 days of index surgery from Surgery. Authors should as a minimum emphasize the included population in the abstract and the methods section i.e. patients were included provided they were alive 30 days post index surgery. Otherwise, the paper is totally misleading.

This 1-year follow-up did not include patients who died within 30 days from index of surgery it is not possible to follow up these patients. To clarify this, we have revised the sentence in Methods section, paragraph 4, line 4:

“Patients were excluded from one-year follow-up if they had died within 30 days of index surgery, as there would be no additional data to collect from these patients since the 30-day follow-up that had already been completed previously.”

2. The second paragraph of 'outcome measures' is difficult to link anywhere in the manuscript. What message are the authors trying to pass across? It is not linked to the primary and secondary outcomes. It is confusing.

Thank you for highlighting the lack of clarity in this paragraph. We have rearranged this material to make it clearer. This section now follows on from the list of clinical endpoints. The following were added under Methods section, paragraph 6”
“The primary outcome for this report was the mortality follow-up rate for mortality. This was the proportion of patients for whom the primary endpoint (mortality) was followed-up at 1-year. The secondary outcome was the data completeness rate in centres that registered to collect one-year follow-up. The data completion rate was the proportion of patients with complete data for all six clinical endpoints.”

3. The use of the term 'registered' might be reconsidered as it appears to depict willingness to participate which is not in line with the language in this manuscript. Suggest use 'were enrolled' alongside reasons for non-enrolment.

We have used the term ‘registered’ as centres made an active decision to participate in the study and had to register the study locally to complete follow-up. Reasons for non-participation are outlined in the first paragraph of the results and have been updated as below:

“Of the 47 centres that did not register, 35 were unable to obtain patient ID link sheets, and 12 were not granted audit and/or Caldicott Guardian approval prior to the data collection deadline”.

4. Is it possible to give a background description of REDCap system in the methods?

We have described REDCap in greater detail in the methods section in paragraph 3 line 2 as below:

“The REDCap platform was developed in 2004 at Vanderbilt University, which is a secure data collection tool meeting the Health Insurance Portability and Accountability Act (HIPAA) compliance standards.”

5. Abstract line 51-59: 'factors associated with increased likelihood of achieving increased likelihood of achieving ≥95% data completeness were total number of patients to be followed-up, and central versus local storage of patient identifiers (72.5% vs 48.0%, respectively, p=0.006) here two factors were listed but only one set of numbers (p-value) was provided. It is thus confusing which factor this belong to. Authors should add the number or at least the p-value for the other factor to make it more explicit.

Thank you. These data have been added into the results section of the abstract as follows:

Factors associated with increased likelihood of achieving ≥95% data completeness were total number of patients to be followed-up (77.4% in centres with <15 patients, 59.0% with 15-29 patients, 51.4% with 30-59 patients, and 36.8% with >60 patients, p=0.050), and central versus local storage of patient identifiers (72.5% vs 48.0%, respectively, p=0.006).

6. What is the difference between data completion rate and follow-up rates. Authors should introduce this earlier in the introduction and why it is important major.

We have clarified this in the manuscript. The follow up rate is the proportion of patients for whom the primary endpoint (mortality) was followed-up at 1-year. The data completion rate is the proportion of patients with complete data for the six clinical endpoints.
7. Methods line 17 'studies' should read 'student'

Thank you. This has been amended

8. Outcomes collected at one year were listed but no justification for these outcomes were apparent in the manuscript. Authors should clarify in the methods section why these outcomes are important.

The 1-year follow-up study focussed on these six clinical endpoints which are felt to be clinically relevant outcomes in assessing impact of acute kidney injury. The following has been added to the Methods section paragraph 4 line 11:

“These clinical endpoints based on a review of the literature on postoperative AKI [16-19].”

9. Line 1 statistical analysis, delete 'were'

This has been amended

10. Statistical analysis; .......... Fisher's exact modification if group sizes were less than five…. Replace 'group sizes' with 'expected cell counts'

This has been amended

11. Under the section follow-up rates, what is the rationale for including patients from 47 centres that were not enrolled in the study? These patients are not part of the denominator and should not be added in the calculation of percentages.

The reason for including patients from the 47 centres who were not enrolled in the study was to present an accurate follow-up rate for this 1-year follow-up collaborative study. Reason for loss to follow-up were also reported in the results section and Figure 1.

12. Last sentence under characteristics of patients followed-up at one-year, '……. there were no significant different…….' Should read '…….there was no significant difference….'

This has been amended

13. Data completeness need to be defined in the methods

We have clarified this in the methods.

14. Investigator feedback survey; how many were contacted and what was the response rate?

All collaborators involved in the study were contacted and the overall response rate was 78%. The following has been added to the results section paragraph 5, line 2:
“Survey responses were received from 285 students and junior doctors, a 78% (285/365) response rate. At least one response was received from 86% (148/173) of centres that participated in initial data collection in 2015.”

15. Discussion line 4; '……….there was no evidence of significant systematic bias in patients being followed-up' delete 'significant. It's either there is evidence or there is no evidence

This has been amended

16. Discussion last line of first paragraph; 'validation' should read 'validating'

This has been amended

17. Discussion (page 14) Locate this sentence 'In the OAKS study, there were no significant differences in the patient-level demographics, operative indications or ASA grades between the group that underwent one-year follow-up and those that did not' What population is referred to here? Does this also include those patients who died during the first 30 days post-surgery?

This refers to the group of patients with and without follow-up after having excluded patients who died within the first 30 days following surgery. This is described in the flowchart for inclusion of patients.

Reviewer 2:

1. This study is well designed and well conducted. Outcomes of interest were clearly described. Study methodology was appropriate. All results from the pre-specified outcomes of interest have been presented. Study results have been interpreted correctly and are adequately discussed.

Thank you for reviewing the manuscript

Thank you very much for considering our revised submission

Yours sincerely,

Sivesh K Kamarajah

on behalf of the STARSurgUK Collaborative