Reviewer's report

Title: Patient experience of the informed consent process during acute myocardial infarction: a sub-study of the VALIDATE-SWEDEHEART trial

Version: 0 Date: 24 Nov 2019

Reviewer: Katie Gillies

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Patient experience of the informed consent procedure during acute myocardial infarction: a substudy of the VALIDATE-SWEDEHEART trial

TRLS-D-19-00945

Olsson et al

Thank you for the opportunity to review this manuscript titled 'Patient experience of the informed consent procedure during acute myocardial infarction: a substudy of the VALIDATE-SWEDEHEART trial'. The manuscript reports a study within a trial that uses a telephone administered survey to explore patient experiences of the informed consent process for the parent trial. Overall the study is well written and described and has some interesting learning points. However, I believe there are some aspects that require attention before publication. Specific queries are listed below:

* Throughout the manuscript the authors refer to the consent process as the 'informed consent procedure'. Whilst this is semantics, the implicit meaning of procedure is such that it is something done to a person at one point in time (e.g. surgical procedure) as opposed to a process which suggests a more inclusive activity that has a temporal component - which the informed consent process should represent.

Abstract

* Within the conclusions section the authors state that patients 'comprehended their inclusion in a scientific study'. The way in which the data is presented currently suggests that the patients had knowledge of their inclusion in a scientific study (e.g. Q1 - Do you remember being asked to participate in a study). Assuming that the responses were coded as 'yes/no' then this does not equate to comprehension but represents knowledge and should be reported accordingly here and in the main text.

Introduction

* Page 3, end of paragraph 3 - include 'limited for the IC process for research'
* Page 3, start of paragraph 5 - include 'Knowledge of AMI patient…..IC process for research…'

* Page 4, paragraph 3 - first use of PCI. Explain in full.

Methods

* Page 5, procedure, include - 'patients who had already consented to participate in the main trial..' 

* Within this section it would be helpful to provide the reader with more information on how the questions for inclusion in the telephone survey were decided upon, through both inception and refinement. Was this informed by the literature? Did it involve patient input?

* Page 6, Statistical analysis - please provide further information on the subgroup analysis. Was this pre-planned? What variables were chosen for investigation?

Results

* Page 6, patient characteristics. This paragraph is slightly confusing. The following points require clarification:

  o Are the 414 patients already consented to the main trial? If yes, please state in text.

  o How do the patients included in the sub-study compare to those in the main trial? For example, are the similar across the baseline characteristics presented in Table 1?

  o Second sentence could make it clearer that the 'main study' is the main trial

  o 'Of the randomised cohort' - does the main trial have a randomised and a comprehensive cohort arm? Or is this the patient population who consent to the main trial? It isn't clear which group are being referred to here.

  o Sentence 4 - include 'None of the 414 patients who were contacted'

Discussion

* Page 8 and 9 - there is data presented in the discussion that is not present in results. Specifically the reasoning from patients regarding justification for participation in the trial and their experience of the IC process. It may be helpful to summarise these
findings and present within the results (and appropriate methods in the methods section) before further discussion in discussion section.

* Page 9, Information section, first sentence. To state that this study shows patients had confidence in healthcare professionals seems a bit of a jump from the data presented. This section should be reconsidered and rewritten based on the data collected and reported.

* Page 10, first paragraph - include 'patients with AMI who have capacity at the time of the IC process'

* Page 9, limitations, need to recognise that patients who did not consent to the main trial may have had very different experiences of the IC process but these were not captured.

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