Reviewer's report

Title: Quality of care of patients with acute myocardial infarction in Bulgaria: a cross-sectional study

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Reviewer: Seth W. Glickman

Reviewer's report:

This article addresses an important topic. Recent attention has been focused on the global burden of cardiovascular disease, and this article raises important issues in the quality of care in patients with cardiac disease in Bulgaria. I believe the international scientific community would benefit from a paper such as this one which highlights the unique challenges and barriers to quality cardiovascular care in Bulgaria. I commend the authors for their hard work and efforts to bring these issues to light. However, I believe that the paper requires major revisions before it should be considered for publication. Broadly, the authors need to frame this paper more generally as a descriptive study of quality of cardiovascular care in Bulgaria, with a description of both pre-hospital times to presentation and in-hospital treatment and outcomes (LOS and death).

More specifically, I recommend the authors do one of two things, either 1) Make this paper purely descriptive (including the pre-hospital times, in-hospital treatment patterns, LOS, and outcomes) and remove the regression models, or 2) Include the regression models only if they are substantially modified. The current statistical analyses are not in a form that is acceptable for publication – the models are not well defined, important co-variates are not included, the results are not displayed completely, and regression diagnostics are not reported. If the models are substantially revised and additional information included in them they could add important information.

Detailed suggestions follow:

1. Abstract (Page 2) - Was the data really prospectively collected? The methods describe a retrospective chart review following patient discharge. Please modify accordingly.

2. Background (Page 3) - The second paragraph describing the evidence supporting reperfusion therapy is too long and not necessary. You can summarize the overwhelming evidence for early reperfusion in STEMI in one or two sentences, and cite the American College of Cardiology/American Heart Association treatment guidelines. I would recommend referencing work from NRMI and CRUSADE in the U.S. which has demonstrated gaps in adherence to evidence based guidelines for AMI, and that your work extends theirs by focusing on the quality of MI care in Bulgaria.

3. Methods - Study region (Page 4) - A description of available pre-hospital
services (i.e. ambulances, etc) would be helpful to the international reader. How do most patients in Bulgaria get to the hospital? Do they use an ambulance? Do they take a car? It’s difficult impossible to interpret the time delays without knowing this information (more on this to follow…..)

4. Methods - Study population (Page 4) - How is AMI defined? Is it based on the diagnosis of the treating physician? EKG criteria? Positive cardiac biomarkers? Are biomarkers (i.e. troponin, CK) even checked routinely in patients with suspected MI? Were patients with unstable angina/chest pain (but without positive biomarkers) included? Please clarify.

5. Methods - Pre-hospital time delay (Page 4) - Please expand on the methodology that was used to perform chart reviews. For example, were the research personnel who performed the chart reviews formally trained? Were they blinded to the study objective? Were there multiple independent study personnel that performed chart reviews? If so, you should calculate and report a Kappa-coefficient to report the inter-rater reliability. All of the data and study findings hinge on the reliability of the data collection process - it is critical that you describe this in more detail. The following reference might give some perspective on this issue and provide additional useful references. Also, why did you categorize the time into 6 intervals? Please explain your reasoning.


6. Medical history (Page 5) - I think you need to describe how you abstracted information about medical treatments (i.e. fibrinolytics). For example, please define whether you were able to assess whether patients were eligible or if they were excluded from therapy due to some contraindication. (i.e. bleeding diathesis, previous stroke, severe hypertension, etc).  

7. Statistical analyses (Page 5): The regression models need substantial revision if you wish to include them (it would also be acceptable to remove them if you cannot make the following changes). First, I would recommend using linear regression models with the dependent variable being either LOS or pre-hospital time delay. This seems more appropriate than a logistic regression model with a 4-level outcome. Second, important co-variates are missing – if they cannot be included I’m not sure the results are meaningful. For example, in the model for pre-hospital time delay, you do not include any information about how the patient arrived to the hospital (i.e. walk, car, ambulance, etc). This very well might be the most important factor in describing the time delay between symptom onset and hospital arrival. You also don’t explicitly state that you included distance from primary residence to hospital in the model. It should be included – was it? For the LOS model, the severity of patient illness should be included as a co-variates since it is likely an important predictor of hospital LOS. Do you know anything about the presenting vitals signs (i.e. heart rate, blood pressure) or whether the patient was critically ill (i.e. intubated or in cardiogenic shock?). You also need to account for which hospital the patient was treated at (i.e. hospital 1-6 as a co-variates) since treatment patterns differ at each hospital (different physicians,
nurses, treatment algorithms, etc). What do you mean when you say that “treatment approach” was an independent variable? Third, you must display the results of your regression models in more detail (even if the p values are not statistically significant). All of the You should create tables for pre-hospital delays and LOS that contain odds ratios and confidence intervals for each of the covariates in both the uni-variate and multi-variate models. Fourth, you should include some important diagnostics for the regression model – for example, what is the R2? Did you perform a goodness of fit test to ensure model validity? (i.e. Hosmer-Lemeshow test). Finally, did you test for interaction among the co-variates?

8. Study population (Page 6) - I'm curious about the ratio of STEMI to non STEMI. In the U.S. the ratio of STEMI to non-STEMI is more like 1:4. Is this because cardiac biomarkers are not routinely ordered? Is there another explanation?

9. Pre-hospital time delay (Page 6) - I would eliminate the last two paragraphs (The subgroup....... and A Chi-Square test....). The information is not that helpful in my opinion. You've already described the delays in pre-hospital time in the previous paragraph. The information about distance between hospital location and patient residence could be included in the regression model.

10. Fibrinolytic treatment (page 7) – You state that 17/117 patients (13%) received lytics, but shouldn’t the denominator be 82 (and not 117) since only STEMI patients are candidates to receive thrombolytic therapy? Therefore, the number is 17/82 (21%). Also, were all of these 82 patients eligible for thrombolytic therapy? (i.e. did they have a bleeding diatheses or coagulopathy, etc)? If not, the percentage of eligible patients who received thrombolytic therapy may be higher than 21%. For example, if 10 patients were excluded from thrombolytic therapy due to age or another contraindication, the ratio would be 17/72 or 24%. Did a greater percentage of eligible men versus women receive therapy? (You only mention that 13 men received lytic therapy, but how many men were there total?).

11. Conservative treatment (Page 7) - You should spend more time talking about this section and should highlight it. This will be of great interest to international readers since all of the listed therapies are ACC/AHA recommendations for AMI. Again, please clarify whether the denominator listed for each therapy in table 3 is the total number (n=134) or only eligible patients. Also, I would recommend including additional columns showing the percentage of men that receive therapy versus don't receive therapy and ages of patients that receive therapy versus don't receive therapy for each medication listed. This could be supplemented by logistic regression analyses to look at the likelihood of treatments in men versus women and age <65 versus >65 (after adjusting for other patient characteristics).

12. Prehospital time delay discussion (Page 8-9) - Shorten this up and summarize in one or two paragraphs. I find the information about the lack of public awareness and concerns about the reputation of the Bulgarian health system most interesting.
13. Fibrinolytic treatment (page 10) – There is an important section, but I recommend shortening it into one or two paragraphs.

14. Mortality (Page 12) – With such a small sample size, you should not conclude so strongly that there is a “huge gender problem”. While this is an interesting finding, you can really only say that it needs follow-up research. You don’t have enough information (such as severity of illness of the patients who died) to conclude that there really is a gender difference in mortality if you aren’t adjusting for potentially important confounders.

15. Table 1 Page 18 – Include the information about SES and employment in your description of the patient population.

16. Additional - You need to include a limitations section at the end of the paper that discusses potential limitations of your study (i.e. cross sectional, small sample size, retrospective, inconsistent medical documentation, unable to account for important confounders such as severity of patient illness etc). This would be an opportunity to highlight that future work (including larger more rigorous studies) are needed to address these important limitations of your work.

17. In general, the paper would benefit from additional linguistics review - please review carefully or discuss with colleagues who may be able to help improve the grammar and spelling accuracy. Additional input from a statistical reviewer/colleague might be helpful in refining your methodology and statistical analyses.

Level of interest: An article of importance in its field

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests