Author's response to reviews

Title: A Cohort Study on the Incidence and Outcome of Pulmonary Embolism in Trauma and Orthopaedic patients.

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Author's response to reviews: see over
Dear Editor,

**Manuscript Title:** A Cohort Study on the Incidence and Outcome of Pulmonary Embolism in Trauma and Orthopaedic patients.

**Authors:** Suribabu Gudipati, Evangelos M. Fragakis, Vincenzo Ciriello, Simon J. Harrison, Petros Z. Stavrou, Nikolaos K. Kanakaris, Robert M. West, Peter V. Giannoudis,

Thank you for sending us the referees’ comments. We have taken into consideration the points raised and have responded as follows:

**1. Major Compulsory Revisions**

1. The calculation of mortality might be misleading.
   1a. Abstract/Results
   What's the denominator of the mortality rate (0.07%)? How many deaths?
   If it is 85 patients with PEs, then 1/85 > 1%.
   If it is the whole study pool (18,151), then 18,151 * 0.07% = 12.7 (13 deaths) -
   This only can be guessed by Table 1.

   **Reply:**

   Thank you for your valuable time taken to review the paper and we appreciate your comments. As this was an abstract we did curtail it but the detail explanation was provided in the results section in the paper. Now this has been clearly explained in the results section of the abstract and highlighted in bold. Secondly, these 85 patients formed the study cohort so we concentrated on the study group and provided the detailed description of their details and this has been shown in the data clean flow chart.

2. Abstract/last sentence
   For the mortality risk factors of morbidities and polytrauma injury, the unadjusted odd ratios and their 95% confidence intervals should also be reported along with the p-values.
It is unclear whether these results were based on univariate or multivariable logistic model and whether they were reported in a corresponding table (Table 7? but the numbers do not match).

Reply

Thank you for your valuable comment. The presence of two or more co-morbidities was significantly associated with the incidence of mortality (Unadjusted OR=3.52, 95%CI (1.34, 18.99), p = 0.034). Although there was also a similar clinical effect size for polytrauma injury on mortality (Unadjusted OR=OR=1.90 (0.38, 9.54), p = 0.218), evidence was not statistically significant for this factor since records revealed fewer details of trauma status for some patients. This has been added to the abstract last in the results section.

3. Statistical analysis (P.9)
Based on the limited study sample and events "There are relatively few events (11) for 3 predictors." - page 14, multivariable logistic model is not recommended statistically.
A univariate analysis and unadjusted observed odd ratio and 95% confidence interval should be reported individually for a factor.

Reply

We thank the referee for his extensive review of our manuscript, which we found most helpful. We have made the changes he has suggested and the manuscript is now much improved as a result. We retain the multivariable logistic modelling providing the unadjusted coefficients that the referee requested. Note that we do not claim that the model provides robust estimates of the coefficients, but have already stated that it is only an exploratory analysis. Neither is the analysis undertaken on the data in isolation. There is good justification for all the terms in the model: specifically that risk of mortality increases with age and with comorbidity and decreases by prophylaxis. Our model shows that the added risk for older patients with comorbidities may be moderated by the use of prophylaxis. Table 7 has been changed accordingly and unadjusted observed odd ratio and 95% confidence interval have been added.

II. Minor Essential Revisions

4. What is the distribution of 85 patients?
Abstract - "(25 underwent elective surgery and 60 sustained acute trauma)."
Table 1- it is 24/61.

Reply
Kindly accept the apologies for the mistake and it has been corrected now. It is 24 elective and 61 trauma patients.
5. Table 3, decimal point (.) was not consistently used to report percentage.

Reply
Kindly accept the apologies for the mistake and it has been corrected now. As correctly pointed out some were decimal points and some were commas. Now we changed them and all have been marked as decimal points

III. Discretionary Revisions

6. Table 8 (Characteristics of PE patients) is usually the Table 1 of an article? Most used comma (,) instead.

Reply
This is the table of patients’ characteristics after 6 months of diagnosis of PE. As we can see from other tables we have divided the characteristics of the whole cohort into smaller and individually characterised table for more detailed description for the reader to make it clear and concise. The idea of table 8 was to give a snap shot of how many were alive or not and their characteristics at the end of 6 months.

All the authors have seen and agree with the contents of the revised manuscript.

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Kind Regards

Yours Sincerely,

Professor PV Giannoudis

* On behalf of all authors.