

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

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| TITLE (PROVISIONAL) | Pulmonary embolism and mortality following total ankle replacement: a data linkage study using the NJR dataset |
| AUTHORS | Zaidi, Razi; MacGregor, Alex; Cro, Suzie; Goldberg, Andrew |

VERSION 1 - REVIEW

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| REVIEWER | Gerard Stansby Newcastle University, UK |
| REVIEW RETURNED | 19-Apr-2016 |

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| GENERAL COMMENTS | <ol style="list-style-type: none">1. This is an interesting and important topic2. There is a major inherent flaw in not using DVT diagnosis - as it means the numbers available result in inadequate power - as there are too few PE's to draw strong conclusions about risk factors etc. They acknowledge this3. Since the majority had VTE prophylaxis it can't tell us about the inherent risk without prophylaxis4. They have not used the approach to BMI that the DoH VTE tools uses - >30 = a risk factor - why not?5. The data linkage technique is not something I know about but is there any validation of its accuracy?6. What were the operation length and was this a factor? I presume they were all > 60 minutes as in the VTE tool?7. There are other papers in the literature which use HES to look at DVT rates so I think they may be wrong about that |
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| REVIEWER | Melih Güven Yeditepe University, Faculty of Medicine, Department of Orthopaedics and Traumatology, Istanbul, Turkey |
| REVIEW RETURNED | 02-May-2016 |

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| GENERAL COMMENTS | The manuscript can be accepted for publication. |
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1

1. This is an interesting and important topic
2. There is a major inherent flaw in not using DVT diagnosis - as it means the numbers available result in inadequate power - as there are too few PE's to draw strong conclusions about risk factors etc. They acknowledge this

3. Since the majority had VTE prophylaxis it can't tell us about the inherent risk without prophylaxis

We agree entirely with this point and stress this throughout. In the literature papers have used such negative findings to make an argument against thromboprophylaxis and we have been clear that this would be inappropriate and we cannot draw such a conclusion from our data.

4. They have not used the approach to BMI that the DoH VTE tools uses - >30 = a risk factor - why not?

We have analysed the data by BMI greater than and less than 30. The findings were no significant difference ($p=0.4$). This is because no PE's occurred in the in the underweight and normal BMI group. We believe that most readers will be more familiar with underweight, normal and overweight than <30 and >30 and we would prefer to keep this in the paper as we feel that this serves as a better descriptive data but we would be happy to amend this at the request of the editor.

5. The data linkage technique is not something I know about but is there any validation of its accuracy?

The linkage technique used in the current project was deterministic linkage, which meant that data fields on NJR had to match the HES exactly in order for us to declare them from the same patient. This method provides a 100% linkage accuracy but because the criteria are stringent the linkage rate is lower. This is opposed to probabilistic linkage that calculates the probability that entries on two datasets are from the same patient, where we would have more links but with less accuracy. We have discussed this in the methods.

6. What were the operation length and was this a factor? I presume they were all > 60 minutes as in the VTE tool?

Operation length is not captured on the NJR dataset therefore we could not reliably analyse this. However the reviewer is correct in that all ankle replacement operations will likely be greater than 60 minutes.

7. There are other papers i the literature which use HES to look at DVT rates so I think they may be wrong about that.

The reviewer is correct that HES has been used to look at DVT rates in the past. However this is entirely flawed because outpatient visits are not recorded in the HES record. We make this point in the paper. Although A&E episodes are coded on the HES, coding is poor and incomplete.

As an example a recent study looked at DVT rates post appendectomy however they used a third dataset for validation including both primary care and hospital data to identify incidences of PE (<http://www.ncbi.nlm.nih.gov/pubmed/26818405>, Humes et al, 2016).

Reviewer 2

The manuscript can be accepted for publication.

We thank the reviewer for his positive comment.