Author's response to reviews

Title: A clinical decision support tool to screen health records for contraindications to stroke thrombolysis—a pilot study

Authors:

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Author's response to reviews: see over
Point-to-Point Response to Reviewers’ Comments

Reviewer: Damian Borbolla

Reviewer's report:

This is an interesting study, where the authors assessed the efficacy of a CDS tool to detect tPA contraindication in stroke patients’ EHRs. The paper is well written, easy to follow and to understand, but some improvement are recommended.

Comment #1:
The research question is clearly stated in the objectives of the study. As the authors are proposing perform an evaluation in a lab environment, using mock patients’ medical records. I think this could be considered a pilot or feasibility study, and I think this fact should be clear in the title, or in the study objectives (or in both parts).

Response:
We thank Reviewer for this comment on our manuscript. The “Background” and “Conclusion” have been revised as recommended by Reviewer.

Text in the Background section:
The aim of this study was to investigate the efficiency of this tool.

Revised text in the Background section:
The aim of this pilot study was to investigate the efficiency of this tool.

Text in the Conclusion section:
Our results demonstrate that the CCH iStroke may be an efficient tool to support decision making for when to initiate intravenous thrombolysis for patients with acute ischemic stroke.

Revised text in the Conclusion section:
Our results of this pilot study demonstrate that the CCH iStroke may be an efficient tool to support decision making for when to initiate intravenous thrombolysis for patients with acute ischemic stroke. Further studies in real world practice are required.
to investigate its clinical efficiency.

**Comment #2:**

Methods section should be improved; more information about how the intervention was developed and integrated to the EHR should be added to the methodology. I suggest adding graphics of the stool, with one or two screenshots showing the intervention in the paper.

**Response:**

We thank Reviewer for pointing out a shortcoming in our manuscript. Text and figure have been added to the Methods section, as thoughtfully recommended by Reviewer.

Text added in the Methods section:
The app includes forms for National Institute of Health Stroke Scale score assessment, treating criteria assessment, physician visit time record, informed consent, tPA dose calculator, relevant laboratory results, computed tomography images of the brain, and a visual aid for risk communication. The result of contraindication item search is presented below the checkboxes of the item when the physician assesses for treating criteria (Figure 2).

**Figure 2.** A screenshot of Changhua Christian Healthcare System iStroke.
Comment #3:

Authors should also include how the sample was calculated and how participants were recruited in the study. And for the analysis they should also include how timing difference was evaluated, because only contraindications detection was mentioned there.

Response:

We thank Reviewer for another comment about the Methods section. The description of four mock patient records has been moved from the Results section to the Methods section as thoughtfully recommended by Reviewer (Next Comment). The text regarding sample calculation, participant recruiting, and time calculation are attached below for the convenience of Reviewer:

Text in the Methods section:
1) The four cases had six different and a total of nine contraindications.
2) The test patients were preset and balanced between groups with and without the CDS tool appearing six times in each group before recruiting the participating
Physicians who were responsible for thrombolytic therapy at CCH and were willing to perform the test of the CCHS iStroke during off-duty hours and to sign informed consent were recruited.

3) The time taken for the test and the number of missed contraindications were recorded for each group.

Comment #4:

Results should be reorganized, for example the cases could be described in methods, explaining how they were developed. Results should focus on the mail finding related to research questions. How results are presented should be improved, adding counts information, SD and other dispersion important metadates, not only the percentages.

Response:
The description of four mock patient records has been moved from the Results section to the Methods section as thoughtfully recommended by Reviewer. The text in the Methods Analysis and Results section and Table 4 have also been revised according to the reviewer’s suggestion.

Revised text in the Methods Analysis section:
Univariate analysis was carried out using unpaired t, Mann–Whitney, and $\chi^2$ tests, whenever applicable.

Revised text in the Results section and Table 4:
The total number of missed contraindications count also reduced significantly from 23 in the control group to seven in the iStroke group ($P=0.001$). The difference of missed contraindication count between the two groups was statistically significant either per physician or per contraindication item.

Table 4. Test results of control and iStroke groups

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>iStroke</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time, minutes, mean±SD</td>
<td>14.6±7.4</td>
<td>7.3±5.2</td>
<td>0.010</td>
</tr>
<tr>
<td>Total missed contraindication counts, n (%)*</td>
<td>23 (42.6)</td>
<td>7 (13.0)</td>
<td>0.001</td>
</tr>
<tr>
<td>Missed contraindication counts per physician</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean±SD</td>
<td>Median</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>----------</td>
<td>--------</td>
<td>-----</td>
</tr>
<tr>
<td>Missed contraindication counts per item</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean±SD</td>
<td>1.9±0.7</td>
<td>2.0</td>
<td>0.6±1.0</td>
</tr>
<tr>
<td>Median</td>
<td></td>
<td></td>
<td>2.0</td>
</tr>
</tbody>
</table>

SD: standard deviation.

* Missed item number in 54 (9 items x 6) contraindication items in each group.

**Comment #5:**
The conclusion should be reformulated, explaining that this was a pilot study and to support what the authors affirm in the conclusion they should perform an effectiveness study with real patients and in a real environment.

**Response:**
The text in the Conclusion section has been revised as thoughtfully recommended by Reviewer.

Revised text in the Conclusion section:
Our results of this pilot study demonstrate that the CCH iStroke may be an efficient tool to support decision making for when to initiate intravenous thrombolysis for patients with acute ischemic stroke. Further studies in real world practice are required to investigate its clinical efficiency.

**Other minor suggestions:**

**Comment #6:**
In the background, authors mentioned meaningful use and US regulations to justify the study, but the evaluation is performed in a Hospital in Taiwan, so I think this should be reviewed.

**Response:**
We thank Reviewer for this comment. Although the US regulation is mentioned in the Background section, the use of health information technology is reported in other countries as well, including Australia and Taiwan as reviewed in the second cited...
Comment #7:

In the introduction last paragraph the authors mention setting and intervention, which are repeated later in the methods, I suggest deleting or reformulate this paragraph.

Response:
The text in the Methods section has been deleted as thoughtfully recommended by Reviewer.

Deleted text in the Methods section:
CCHS is composed of seven hospitals in an area with a population of about 1.5 million people.

Comment #8:
Keywords should be changed for more representative ones, also respecting NLM-Pubmed MeSH terms, examples could be: Decision Support Systems, Clinical; Decision Making, Computer-Assisted; Hospital Information Systems; Medical Records Systems, Computerized.

Response:
The keywords have been added as thoughtfully recommended by Reviewer.

Revised Keywords:
Biomedical Technology; Brain Infarction; Decision Making, Computer-Assisted; Decision Support Systems, Clinical; Hospital Information Systems; Medical Records Systems, Computerized; Medical Informatics; Stroke; Thrombolytic Therapy.
Reviewer: Farrant Sakaguchi

Reviewer's report:
Overall - Interesting study, reasonable methods, useful results, worthy of report and publication, but writing could be significantly strengthened.
The questions are well defined, methods are appropriate, the data are sound but merit greater analysis, the figures appear genuine, the discussion is balanced, the limitations are clearly stated, the authors clearly acknowledge prior work, and the title and abstract are accurate. However, as the results describe a specific application for a specific clinical setting, without significant innovation or novelty, the writing must be strengthened in order to make it either more easily reproduced, or to emphasize principles that might be generalized by others.

Major Compulsory Revisions:

Comment #1:
The methods should be better described. A little more detail would be appreciated, but more importantly is to clarify the groupings, the number of tests performed, the presentation of the clinical decision-support, and how missing data was analyzed. The data tables should include descriptive statistics and possibly stronger statistical analysis. The writing is free of grammatical errors, but should be clearer, especially in the methods section.

Response
We thank Reviewer for this valid comment on our manuscript. The Methods section and Table 4 have been revised as thoughtfully recommended by Reviewer.

The description of four mock patient records has been moved from the Results section to the Methods section.

Text and figure added in the Methods section:
The app includes forms for National Institute of Health Stroke Scale score assessment, treating criteria assessment, physician visit time record, informed consent, tPA dose calculator, relevant laboratory results, computed tomography images of the brain, and a visual aid for risk communication. The result of contraindication item search is presented below the checkboxes of the item when the physician assesses for treating criteria (Figure 2).
Revised text in the Results section and Table 4:

The total number of missed contraindications count also reduced significantly from 23 in the control group to seven in the iStroke group (P=0.001). The difference of missed contraindication count between the two groups was statistically significant either per physician or per contraindication item.

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<td>0.001</td>
</tr>
<tr>
<td></td>
<td>Median 2.0</td>
<td>0</td>
<td>0.002</td>
</tr>
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Missed contraindication counts per item

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<th>Mean±SD</th>
<th>Median</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>3.8±2.5</td>
<td>3.5</td>
<td>1.0</td>
<td>0.047</td>
</tr>
<tr>
<td>Group 2</td>
<td>1.2±1.5</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
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SD: standard deviation.

**Minor Essential Revisions:**

None

**Discretionary Revisions:**

**Comment #2:**

The impact will be increased as the writing is strengthened.
The figure provides little information. A screenshot or mock-up of the screenshot would be more informative.
The tables would be more useful in a more concise, summarized form, such as by using some descriptive statistics.

**Response:**

We thank Reviewer #1 for another valid comment on our manuscript. A screenshot has been added and Table 4 has been revised (please refer to Response to Comment #1) according to Reviewer’s recommendations.