Author's response to reviews

Title: Translation and validation of the Korean confusion assessment method for the intensive care unit

Authors:

    Eun Young Heo (eunyoungheo@gmail.com)
    Byoung-Jo Lee (minddoctor@naver.com)
    Bong-Jin Hahm (hahm@snu.ac.kr)
    Eun Hee Song (julie0315@hanmail.net)
    Han-A Lee (hugo0364@hanmail.net)
    Chul-Gyu Yoo (cgyoo@snu.ac.kr)
    Young Whan Kim (ywkim@snu.ac.kr)
    Sung Koo Han (hansk@snu.ac.kr)
    Young-Soo Shim (ysshim@snu.ac.kr)
    Sang-Min Lee (sangmin2@snu.ac.kr)

Version: 2 Date: 25 January 2011

Author's response to reviews:

Sabina Alam, PhD
Senior Executive Editor
BMC series journals

Dear Pf. Sabina Alam,

We wish to thank you and reviewers for kind comments on our manuscript entitled, “Translation and validation of the Korean confusion assessment method for the intensive care unit (ID : 1020346906460242)”. We have revised the manuscript based on reviewers’ comments, which will strengthen the paper.

Here we summarize the changes to the paper below. These changes are marked with blue color and underlined in the resubmitted manuscript.

Reviewer 1.

Major Compulsory Revisions

1. It is not rational to exclude feature 1 from the CAM-ICU. Without feature 1, how can one distinguish between delirium and preexistent dementia?

Feature 1 is an essential part for delirium diagnosis using the CAM-ICU. Without feature 1, diagnosis of delirium is impossible. We only excluded feature 1 from the analysis during the 1st study period. Because disagreements between raters occurred mainly in feature 1 and through the 1st study period, we found some translation problems of Korean CAM-ICU. After we supplemented a few words which had been uncertain and educated nurses to improve the understanding of
the CAM-ICU, we surely included all of 4 features of the CAM-ICU to produce the results.

2. How many patients received psychoactive medication in between the two assessments? This is vital to know, because a majority of patients received for example haloperidol in between assessments, no good comparison can be accomplished.

During the 1st period, psychoactive medications (mostly midazolam or vecuronium for sedation) were administered to 30 out of 48 patients during their ICU stay. Only one patient was being administered midazolam at the time of delirium assessment. However, if patients were diagnosed with delirium and had been administered any antipsychotics which were known to be effective in treatment of delirium, we excluded these patients for assessment.

3. Methods; line 25 …. We took time to discuss the results with the raters ........ This is a source for bias. If the nurses changed the outcome of the CAM-ICU assessment after a discussion with the authors (who are delirium experts?), what is then the value of the CAM-ICU? The authors should state in how many occasions the nurses changed their opinion, or even better, use the CAM-ICU result before the discussions.

We had discussed several times about disagreements. We just discussed the results and tried to educate nurses and improve their understanding about CAM-ICU. We did not change any results which were already made by the Korean CAM-ICU before discussion. We clarified this point. (3rd paragraph of Methods, line 13) We feel sorry to confuse you.

4. Results and discussion; line 6..... 41% of enrolled.....
What is your explanation for the lower incidence of delirium when compared to the frequencies found by Ely et al, to which you referred?

Those reference studies were performed with only mechanically ventilated patient in medical or coronary ICU. However, we included both ventilated and non-ventilated adult medical ICU patients. Non-ventilated patients are known to be in less severe medical condition compared to ventilated patients. We guess that these different conditions of enrolled patients might cause the lower incidence of delirium.

5. Results and Discussion; line 12.......During the second period ..........I do not understand what the authors mean with this paragraph. Did they look at the entire CAM-ICU (so yes or no delirium) or did they look at the individual features? A disagreement rate of 23% is still very high. Kappa’s of 0.60 and 0.64 are low, indicating a moderate agreement at best. Again, it is logical that, if both nurses were helped by the same person to correct their CAM-ICU scores, the intrarater reliability will go up.
We meant the interrater reliability of all 4 features of the Korean CAM-ICU (# = 0.81, P<0.001).

Although a disagreement rate of feature 1 and Kappa values of feature 3 and 4 were not fully satisfactory, all features showed significant interrater reliability. And, as we showed in this study, more experience and education would improve the reliability of the Korean CAM-ICU in the future.

6. Results and Discussion; line 23...... We analyzed the sensitivity and specificity again after excluding ............

Again, when you excluded feature 1, this study stopped to be a validation study and became a diagnostic test study, with a new type delirium score.

This result only corresponded to the 1st study period. During the 1st study period, we realized translational problems of the Korean CAM-ICU to use in practice. So we performed the 2nd period study after supplementation and education. After that, we confirmed good sensitivity and specificity of the Korean CAM-ICU which included all 4 features. (3rd paragraph of Result and discussion, line 11)

7. Discussion; line 6 ......acute onset or fluctuating course ......

But this is essential for the diagnosis delirium. The disorders develops rapidly over time. Without this feature, how can you identify delirium?

For diagnosis delirium using CAM-ICU, acute onset or fluctuating course is the essential component for diagnosis. So when raters had difficulties to make a judgment about fluctuating mental status, they referred to the medical records which the nurse in charge wrote down their patient’s mental status every 8 hours. If there was any change within 24 hours, we considered the mental status was fluctuating.

8. Discussion; line 11 ......in practice, interviews with ..........

Why are these interviews not easy, and why was the study nurse not able to perform these interviews?

In SNUH, visiting hours of ICU are from 10:00 to 10:30 am in the morning and from 7:00 to 7: 30 pm in the evening. We performed assessment between 3:00pm to 7:00 pm considering working hours of psychiatrist and nurses. Therefore, it was difficult for them to make extra time to interview with patients’ family.

9. Conclusions; line 5 ... .through reducing the incidence ......

How can a screening method (or diagnostic test if you will) reduce the incidence of delirium?

As reviewer’s comment, screening method cannot reduce the incidence of
delirium.
We hope that clinicians can perform proper management for the patients with delirium more quickly through early diagnosis of delirium. Therefore we changed the sentence according to your recommendation. (Conclusions, line 5)

Minor Essential Revisions
1) Background; line 6, ..... delirium occurred in between 81.7% and 87%.......
This of course is correct, but there are other studies showing a much lower incidence, for example Bergeron et al. Intensive Care Med (2001); 27; 859-864. The authors should discus this and give an explanation for the large difference in incidence.

Those reference studies were performed with only mechanically ventilated patient in medical or coronary ICU. However, we included both ventilated and non-ventilated adult medical ICU patients. Non-ventilated patients are known to be in less severe medical condition compared to ventilated patients. We guess that these different conditions of enrolled patients might cause the lower incidence of delirium.

Bergeron et al. used more complex screening method consisting of eight items compared with the CAM-ICU consisting of 4 items. We can assume that the different diagnostic criteria also might affect the incidence of delirium.

2) Methods; line 24, ........ CAM-ICU in which a few words ........
What words, why were they changed and into what were they changed

In feature 1, we changed the words corresponding to “acute” and “fluctuating” from directly translated words to more explanatory words. Also, we changed 10 words in feature 2A from just a meaningless letter to single sound words with certain meaning such as sun, moon, river and so on.

3) Results and discussion; line 26 .... The overall accuracy ..... How was the overall accuracy calculated?
We used the formula as follows;

The overall accuracy = \{\text{number of true positives (positive by both DSM-IV and CAM-ICU)} + \text{number of true negatives (negative by both DSM-IV and CAM-ICU)}\} / \{\text{numbers of true positives (positive by DSM-IV) + false positives (positive by CAM-ICU) + false negatives (negative by CAM-ICU) + false negatives (negative by DSM-IV)}\}

4) Results and discussion; line 26 .... Sensitivities for the Korean...... Is this with or without feature one?
This is with all 4 features including feature 1.
Discretionary Revisions

1) Background; line 17…..for practical use…….
What do the authors mean? For clinical use?

According to the reviewer’s suggestion, we revised the sentence. (Background, line 17)

2) Methods; line 6….psychosis or neurologic disease
Please explain what kind of neurological diseases this were

Neurologic disease : stroke, epilepsy, intracranial tumors, brain trauma
Psychosis : schizophrenia, personality disorder, bipolar disorder, major depression

3) Methods; line 15 …. One research nurse and another experienced nurse ……. How many years of experience did these nurses have? Did they receive any special training for this study? Had the research nurse worked with delirious patients before?

They had more than 5 years experience in their work fields. They had read manual of the CAM-ICU translated into Korean and had been educated once during the 1st study period. Then during the 2nd study period, they had received more detailed explanations and educations several times.

The research nurse had not worked with delirious patients before. She usually meets outpatients participating in other clinical studies.

4) Methods; line 17 …. An experienced psychiatrist…….
How many years of experience did this psychiatrist have? Was he used to work in the ICU?

He had more than 8 years of experience in psychiatrist and his subspecialty is consultation psychiatry. Therefore he had more experience with patients in ICU than any other psychiatrists.

5) Methods; line 19 …. Were done between three and seven …….. What was the median (or mean) time between assessments?

The important component of delirium is fluctuation. So, we admit the evaluation time is important factor for diagnose the delirium and we fixed the assessment time between 3 pm and 7 pm. Unfortunately, we don’t have data of the exact assessment time. We think that the time of 4 hour had little chance to affect the patients’ mental status critically.

6) Results and discussion; line 1 ..
Please state when the study was performed.
This study was conducted during two separate periods, from July 2008 to October 2008 and during March 2009. We mentioned this on first paragraph, line 6 in Methods section.

7) Results and Discussion; line 18 .....Patients who were admitted.......... Why was admittance shorter than 24 hours an exclusion criterion?

To assess feature 1 of CAM-ICU, we should know the mental status or behavior change at least within the past 24 hours. So we enrolled patients who were admitted more than 24 hours to evaluate ICU delirium.

8) Discussion; line 7 ......except the nurse who ........ I don not understand this sentence. A nurse who does not care for the patient can assess baseline mental status?

There was a mistake in that sentence. We apologize for this mistake. According to the reviewer's comment, we revised the sentences. (Discussion, line 7)

Reviewer 2

Major Compulsory Revisions

My major concern about this paper is the reported “first period” of the study. In this first period of the study there was a low inter rater reliability and a low specificity and sensitivity of the CAM-ICU. The reason for that was the lack of previous training among the raters. Thus the authors prove the obvious: that is necessary a previous training to be able to use the CAM-ICU. I think this finding is already well known. My recommendation to authors is to remove this part as this part does not add anything to our knowledge and it makes the paper “weak” and more difficult to read it.

We completely understand the reviewer's concern. However, even in hospitals where the validation study of the CAM-ICU was performed originally, initial kappa scores in real practice were low as 0.2 and 0.03 (Crit Care Med 2005;33:1199). We think that regular educational intervention and training are the important part for using the CAM-ICU in real ICU practice.

Minor Essential Revisions

1. Are the assessed patients consecutive or randomly selected or the sample was a convenient sample?

On every assessment day, we screened all patients in medical ICU and enrolled
patients who were satisfied with inclusion criteria.

2. Also it seems that there are missing data (missing assessments). I think here a flow chart with numbers of eligible, included, excluded, comatose, assessed, etc could help the reader.

   It is unfortunate that we didn’t record any missing data. We feel so sorry about this.

3. In the second period of the study the authors state that they have 96 pairs of assessments in 22 patients. That means that some individuals had more than one assessment. If this happen the authors need to explain some questions e.g. what was the time between the assessments? Why some patients had one assessment and others two or more? Any change to estimate test-retest reliability?

   The time between the assessments was various. While some patients could be evaluated consecutively, other patients were evaluated at admission and then just before leaving the medical ICU due to their medical conditions. And there was no change to estimate test-retest reliability.

Sincerely yours,

Sang-Min Lee
Division of Pulmonary and Critical Care Medicine
Department of Internal Medicine
Seoul National University Hospital
101 Daehangno, Jongno-gu, Seoul, 110-744, Republic of Korea
Phone: +82-2-2072-0833
Fax: +82-2-762-9662