Author's response to reviews

Title: The impact of a standardised intramuscular sedation protocol for violence and acute behavioural disturbance in the emergency department

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Author's response to reviews:

To the Editor,

Re: The impact of a standardised intramuscular sedation protocol for violence and acute behavioural disturbance in the emergency setting

Thank you for your email 17th March, 2010 regarding the above manuscript. Please find attached our manuscript which has been revised following the recommendations of the reviewers. Additions have been made in ‘bold’. We have responded to the specific issues below.

We have added sections on competing interests, author contributions and acknowledgements.

Reviewer #1:

Major Compulsory Revision - The study design is confusing; The study is either describing the results of using a protocol or comparing the use of certain medications. It would be best to decide on a study design and focus the manuscript on this.

This has been clarified in the first paragraph of the methods.

Reviewer #2:

Major Compulsory Revisions

1. There needs to be a more detailed description of the Department's policy for when IM sedation was appropriate. For a Department with a relatively modest number of presentations per annum this frequency of chemical restraint seems extraordinarily high.

The use of IM sedation was based on specific inclusion criteria in the clinical trial. This is described in the Methods “Selection of Participants” paragraph 2:
“Inclusion criteria for both the historical controls and the intervention were that
the patient required both physical and chemical restraint, the patient did not
consent to IV or oral sedation and they required the presence of the hospital
security.”

A minor change has been made to keep this clear.

The reason for the high frequency of chemical restraint is the large number of
patients seen in this emergency department with acute behavioural disturbance.
The reason for this is that the hospital provides a tertiary toxicology service for a
much larger area and a drug and alcohol unit. This is already explained in the
second paragraph of the methods (setting). In addition we have referenced an
observational paper in the same emergency department providing more detailed
information on these patients (reference 2 – Downes et al 2009).

2. Certainty. The authors state "We have shown shown that a structured
approach to sedating agitated patients in the ED, where all initial doses of
sedation were given IM, was simple, effective and safe for management of
VABD". The data do not support these claims. The data show that duration of
behaviour and repeated doses were reduced compared with historical controls.
The make no measurement of simplicity and cannot claim to show effectiveness
as the study did not seek to compare to a gold standard but to compare to
existing practice.

We agree that the ideal study would be to compare our intervention group with a
gold standard but this is rarely possible and difficult to achieve with any sort of
study design unless existing practice is the gold standard. No information is
published on the gold standard for sedation of acute behavioural disorder. We
have shown that the IM sedation protocol was more effective than IV sedation.
We have clarified our statements at the beginning of the discussion, conclusion
and in the abstract by acknowledging that we compared to an existing group.

But I would particularly take issue with describing this practice as safe. The data
show that it is no more dangerous than existing practice but I would contend that
4 episodes of significant desaturation and one of airway obstruction in such a
small number of patients could not be reasonable described as safe.

The number of adverse effects related to over-sedation in both the historical
controls and the intervention group is in line with all other studies of sedation of
aggressive patients in the emergency department (See references 3,16). This
study demonstrates it is as safe as the existing practice and previous studies with
the same patient group. This is already discussed and referenced in paragraph 4
of the discussion. No change.

Likewise I think the first paragraph of the discussion is too strongly worded. This
paragraph implies a generalisability of these data that I do not think is
appropriate.
3. Statistics
- There is no measure of statistical significance between the two groups in terms of their adverse events

We have now included 95% confidence intervals for the proportions of adverse effects in the historical controls and the intervention group.

Minor Essential Revisions
I think the data relating to need for repeated doses would be better presented as a logistic regression analysis comparing the need for repeat doses in the historical and RCT groups. This would allow the calculation of an odds ratio and p value.

We have already compared the proportion of patients who required repeat doses of sedation and provided the 95% confidence intervals for this. This is essentially a univariate analysis and an odds ratio could be calculated but it is easier from a clinical perspective to simply see the proportions. A p value implies hypothesis testing and since this was a secondary outcome this is not appropriate. Logistic regression is multivariate analysis and is not possible with such a small dataset.

No change.

Thank you for your consideration of the manuscript.

Yours Sincerely

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