Author's response to reviews

Title: The song remains the same although the instruments are changing:
Complications following selective non-operative management of blunt spleen trauma: A retrospective review of patients at a level I trauma centre from 1996 to 2007

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The song remains the same although the instruments are changing:
Complications following selective non-operative management of blunt spleen trauma: A retrospective review of patients at a level I trauma centre from 1996 to 2007
Aisling A Clancy, Corina Tiruta, Dianne Ashman, Chad G Ball and Andrew W Kirkpatrick

Dear Annette Luckmann

Thank you for the opportunity to respond to the reviewers helpful suggestions. We feel they have helped us improve the manuscript greatly and we will hereafter clarify all the revisions and our responses.

Reviewer 1) Julie Mayglothing

Major Compulsory Revisions (JM)

1. I think the authors are trying to do a bit too much in this manuscript, and the useful information they have to present is a bit diluted by some data that is just not helpful. They should truly concentrate on 1. Who failed SNOM and why?

Response: In order to concentrate on this important question we have both expanded upon our discussion of failure of SNOM, as well as moved it forward and emphasized it in the Results section (see below). We have also reported much more detail on the failures of SNOM, including more details on the splenic injuries and timing of SNOM failure.
2. What the usefulness of follow-up imaging is (frequency and timing).
These good questions are being lost in the sea of other data.

Response: We have expanded upon the findings of the 50% of SNOM patients with in-patient follow-up imaging, explaining that no cases of occult hemorrhage or splenic artery pseudoaneurysm were detected out of a subset with an admission CT scan available for grading and comparison. We will agree that we were surprised by this apparently low utility, and have discussed this ion the Discussion. We have also reported that in the 20% rate of follow-up imaging among 179 Calgary patients there were also no cases of occult hemorrhage or splenic artery pseudoaneurysm detected.

It is our belief that in-patient and out-patient follow-up imaging is obtained for different reasons, with the in-patient studies having a goal of detecting bleeding or pseudoaneurysms/hematomas presenting a risk for bleeding, while out-patient imaging is often to document resolution of injury, in order to help guide decisions regarding return to work/activity. As our review did not actually determine usefulness for the first indication, and was not designed to comment upon the second, we are unable to offer a meaningful answer to the question of timing, other than to discuss the issues and to offer our data as a guide to constructing future trials. These points have been added to the Discussion.

We have also supplemented our discussion with two images illustrative images that can be considered optional.

3. There was considerable time and space dedicated to the differences between the OM and SNOM groups. It is well established that patients necessitating OM for splenic injuries are sicker, have higher grades of injury or are hemodynamically unstable. I don’t think the amount of space in the manuscript dedicated to describing these two populations adds anything to the literature that isn’t very well accepted and the section on ED Investigation and Physiologic data doesn’t seem necessary.

In addition, tables 1, 2 and 3 are overrun with extraneous data. I would consolidate this into 2 tables and cut out much of the data.

Response: We have reduced the reported physiological data in the manuscript, emphasizing only the most critical differences between the OM and SNOM patients, which we agree is self-evident. This unnecessary statement of fact has been removed from the Discussion, and we have therefore have deleted Table 1 from the manuscript altogether. We do suggest maintaining the availability of the data however, and thus we have uploaded the file to a supplementary data-site (http://www.traumacanada.org/Default.aspx?pageId=829763) available to all members of the Trauma Association of Canada, where we have previously placed relevant data for
other reports. These extra files could therefore be deleted altogether, hosted by TAC which has guaranteed to do so, or transferred to another website of the JTMO as preferred by the Journal.

2. The biggest question that did not seem to be addressed is why did the patients undergoing SNOM fail? Should they have gotten SAA and SAE from the beginning? We know, by published studies, factors that increase risk of failure of SNOM are higher grade of injury, amount of hemoperitoneum, presence of pseudoaneurysm or contrast blush on CT. The manuscript didn't even mention this. The question that was not answered, and is important to know, is did the people that failed SNOM meet these criteria? Is that possibly why the percentages of SAA and SAE (9 and 7%) are so low? If they did, they weren't really being treated appropriately and therefore, it doesn't add to the knowledge base. More time needs to be dedicated to looking at this patient population. (middle of page 9).

Response: As was reported in Table 3 (Now changed to Table 2), those who failed non-operative management, had a higher mortality, received more blood and crystalloid fluid within the first 4 hours, were slightly older, with higher median ISS scores, lower blood pressure, and stayed twice as long in hospital if they survived. This information has been emphasized in the results.

More importantly as requested by the reviewer we have re-reviewed the 53 patients who failed SNOM, and noted that there were 6 who had evidence of a contrast blush or a suspected acute pseudoaneurysm on the initial CT scan, and that there were five who had contrast extravasation on a subsequent follow up CT scan, meaning that 11/53 (20%) of the failed SNOM group had a lesion that was at least potentially amenable to SAA/SAE. This important fact has been mentioned in the abstract, and further details have been added in the results, and discussed in the discussion.

These 6 patients are telling in that one case was by the a-prior definition of a failed SNOM as being an operation more than 4 hours after admission, but was more likely an inexplicable delay in appropriate OR access. We have made reference to this fact in our Limitations section of the Discussion.

Even more telling, further review of the 5 cases with unaddressed blushes or pseudoaneurysms were apparent earlier in our experience (4 from 2001 and one from 2003). We have added a discussion of how potentially addressing these blushes may have potentially impacted care to our Discussion and re-emphasized the importance of clinicians appreciating the importance of this finding no matter how stable the patient is, to our Discussion.
We have also added a Figure which reflects our increasing use of SAA from 2000 to 2007 which could either be in the manuscript or uploaded on-line.

![Graph showing SAA in NOM population, by year](image)

3. The bottom of page 10 (Inpatient Acute Care Outcomes) states that “Among those selected for NOM, 16% went on to have a splenectomy (9%), splenorrhaphy (2%), or laparotomy…” but then the rest of the section is dedicated to lengths of stays and deaths. The one paragraph is trying to say too much. Put the failures of SNOM in the next section and just delete the ICU data.

Response: We have removed relevant data regarding failure of SNOM within the section previously entitled “Inpatient Acute Care Outcomes”, and placed it within the appropriate section entitled; “Failure of Non-operative Management …”.

We have also clarified the sentence to reflect it’s true intended meaning.

We have also deleted the extraneous ICU data from both the Results section and the remaining Tables.

**Minor Essential Revisions (MJ)**

4. Figure 1 is misleading. If none of the mortalities in the SNOM group were due to splenic injury, this figure doesn’t mean much. Almost all of the causes of death are listed as “multiple blunt injuries” and “massive head injuries”. One could argue that these are patients that are not appropriate for SNOM. Even more reason to take this out.

We have deleted Figure 1.
5. The authors admit that only 50% of patients were from Calgary and they used that database to query for follow-up. Right there, that limits the follow-up data. Can you really make adequate conclusions about late follow up imaging, missed injuries and the usefulness of outpatient CT with maximum 50% follow-up?

We have revised our discussion in the manuscript to emphasize that any of our discussions related to follow-up pertain solely to the 50% of the Calgary population in the study for which we believe we would capture 100% of the outcome events unless they had moved away or were travelling outside of Calgary when an outcome occurred. As the Foothills Medical Centre is the referral centre for all other hospitals in our region which effectively includes parts of two other Provinces, we would follow up many or most patients with serious conditions from this region. This has made the Calgary Health Region with its integrated clinical care, laboratory, and diagnostic imaging systems a natural epidemiological model for many other conditions. However, the long-term population being discussed is the 236 patients that reside within Calgary rather than the 538 total patients to attempt to make the discussion more accurate. Further, the statistics we have quoted for a 2% hospital readmission rate would only be susceptible to a conservative bias.

Reviewer 2 Neil Parry

Major Compulsory Revisions (NP)

1. Data should be updated to 2010

Response: This is the only compulsory revision for which we don’t think we can comply. We respectfully submit that reviewing 216 more charts would constitute a new and distinct study. While we hope to do that in the future to continue our efforts into to describing, understanding and improving the evolution in management of splenic trauma, we are unable to add this data. Our sincere apologies.

2. Data in abstract do not match data in paper (148 early operative intervention vs 150 in the manuscript).

Response: We apologize for this typo which has now been corrected.

3. Would add more strength to paper if the authors could compare readmission rates for both SNOM for blunt splenic injuries to those patients who underwent early splenectomy.

Response: This data was actually presented in Table 4, in which it was reported that among residents of Calgary (who we believe permit the most accurate data to be obtained
as discussed in our response to query 5 from Dr Mayglothing) there were 2 of 57 (4%) operatively managed patients and 3 of 179 (2%) non-operatively managed patients who were readmitted to hospital, which was not statistically different. While the small numbers realistically defy formal statistical comparison, we believe it notable that ALL the NOM patients readmitted required an intervention (surgery or angiography) while NONE of the OM patients did. His data has been summarized in the results, and the concept has thus been emphasized better in the discussion which has been specifically rewritten around this point.

Minor Essential Revisions (NP)

1. Eligibility criteria (p. 5). Please define the exclusion criteria "transferred to the trauma centre for follow-up after receiving acute trauma care at another institution" as a number of your included patients received care greater than 24 hours after their injury.

Response: The difference was that the patients we excluded were transferred for either orthopedic surgeries or rehabilitation or repatriation following management of their trauma care elsewhere. We have reworded this to specifically “transferred to the trauma centre for follow-up of orthopedic or head injuries after receiving their definitive trauma management at another institution”. If this is still unclear we will be happy to rephrase again.

2. P. 8 "Mortality among patients managed operatively was variable over time, ranging from 13% to 40%" Please explain.

When critically analyzed, there was no appreciable trend or finding. We believe this likely relates to the severity of other injuries, or which severe head injuries predominate.

1. **Table 2. Too much data.**

Response: We hope that by deleting Table 1 from the actual manuscript, that this makes Table 2 less burdensome. If still requested however we can either completely place Table 2 on-line and summarize key findings within the Results section.

2. **What were the indications for splenic artery angiography?**

Response: There was no initially no formal protocol during this study to guide decisions regarding SAA and SAE beyond the best judgement of the attending trauma surgeon and radiologist during the time-frame of this study. In 2007, however we introduced
guidelines emphasizing the importance of addressing ongoing extravasation of contrast no matter how stable, but these guidelines did not stipulate whether this should be obtained through SAA/SAE or surgically. The trauma surgeon ultimately decided whether a consultation with the Interventional radiologist was warranted and thereafter the attending Interventional radiologist decided whether an angiogram was warranted and if performed as to whether embolization (and what type) was indicated with occasional discussion with the trauma attending regarding the overall physiological status of the patient. This has been clarified in the Methods. We have noted in the Discussion however, that in response to our noted lack of a standardized approach we have introduced regional recommendations for the Management of splenic injury which are available to the public at:

(http://www.traumacanada.ca/media/blunt_spleen/File%201%20Supplementary%20Files.pdf)

3. **Was there any correlation with SNOM failures and repeat imaging?**

We have addressed this great question in detail in our reply to Dr Mayglothing, especially in regard to vascular blushes seen on the first CT scan obtained.

6. **It appears to me that there were only 11 failures of SNOM (9 splenectomies and 2 splenorrhaphy) not 14. Were the 3 therapeutic laparotomies without splenic intervention included? If so, then you need to include the negative laparotomies which would increase the failure rate.**

Response: In terms of absolute numbers in the 388 patients originally selected for NOM, 7 (2%) required a splenorrhaphy, and 35 (9%) a splenectomy. We would argue, and have now defined this better within the Methods that laparotomies in this group which provided a therapeutic intervention not for splenic pathology would not constitute failure of a non-operative approach to splenic trauma. Upon further consideration we recognize that a non-therapeutic laparotomy in a patient selected for SNOM is likely a failure of management as there was not another reason to operate, and we accept that the additional 8 (2%) patients with exploratory laparotomies only would be included in the failure group for an overall rate of failed SNOM for splenic injuries of 13%. The manuscript has been clarified in the Definitions section of the Methods, Results, and Discussion to reflect this.

7. Inpatient acute care outcomes (p. 10) - would read much easier if actual numbers were used in conjunction with percentages. It is quite confusing as it stands.
This has been revised.

8. What was the median time to failure of SNOM for the inpatient population?

Response: The median time to failure of SNOM was 11.2 hours and overall this data has been reported in much greater detail in the manuscript.

9. It is stated that "we now recommend that repeat imaging is obtained within 72 hours to detect signs of failure in these severely injured patients". Has this decreased your failure rate of SNOM?

We do not currently have the data to answer this question as the protocol was only introduced in 2007. While the current review will serve as an excellent description of our practice in the previous decade and our evolution to the new protocol, on further time and a future critical analysis of the future results will answer this excellent question.

Yours sincerely,

Andy Kirkpatrick
AK/ra