Archives of Neuroscience
Volume 10 · Issue 3 · e135297

OPEN PEER REVIEW

Adopting and Adapting Clinical Practice Guidelines for the Use of Baseline MRI in Acute Spinal Cord Injury in a Developing Country

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SUBMITTED	REVISED	ACCEPTED	DOI
29 Jan 2023	15 Jul 2023	8 Aug 2023	10.5812/ans-135297

About this report

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1 Original submission

2 comments · 24 Mar 2023 – 24 Mar 2023

Associate Editor

MAJOR REVISION 24 Mar 2023

Dear EIC,
Thanks to the authors, and appreciation to the researchers. The manuscript presents valuable research. But some revisions are needed. The authors should revise it based on the comments. Also, minor changes should be made to the abstract:
1- The study design should be mentioned in the first line of the Introduction.
2- A summary of the statistical analysis results should be mentioned in the results section.

Editor-in-Chief

MAJOR REVISION 24 Mar 2023

Dear Author,
Thank you for submitting the article. It needs some revision. Please revise it based on the reviewers' and AE's comments.

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Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear Reviewers,

The authors would like to thank you for the precious and insightful comments you provided on this submission. Below, you can find the point-by-point response to the raised queries.

> Reviewers' Comments:

Reviewer 1:

The title is incomprehensible. Please correct the title.

Response: With many thanks for this comment. We edited the study title to represent a comprehensive one for this study, as below:

“Adopting and Adapting Clinical Practice Guidelines for the Use of Baseline MRI in Acute Spinal Cord Injury for a Developing Country”

The goal should also be modified according to the title.

Response: We thank the reviewer for this insightful comment. We revised the study aim for a better presentation of the goals of this submission, as brought below:

“We aimed to adopt and adapt suitable recommendations for guideline development in Iran based on the available international guidelines on the utilization of MRI in management of acute SCI patients through a systematic review of literature followed by guideline development based on the Delphi technique.”

What is the type of study?

If it is a systematic review, please do it according to the checklists of systematic review articles.

Response: Thanks for this constructive comment. The current investigation was an original effort to develop a guideline for MRI use in acute spinal cord injury in Iran. Through the first steps of the study, in order to retrieve the relevant studies and guidelines on this topic we did a comprehensive search and review of literature. This stage was done through a systematic search and review of literature based on the PRISMA checklist as provided in the methods section (lines 111-112) and the results of literature screening

provided in opening of the results section (lines 156-165). Nevertheless, the main body of this study was based on the Delphi technique through which the expert panel commented on the final concluded comments to amend some changes on recommendations with the aim of adopting and adapting appropriate recommendations to be used as a beneficial tool to develop a guideline on this topic for Iran. Therefore, the design of this study was a primary systematic review followed by the Delphi technique for guideline developement.

Mention statistics and previous studies in the introduction section.

Response: With many thanks for this comment, we majorly revised the introduction section to reflect previous studies and similar research on the topic, as below:

“Traumatic spinal cord injury (SCI) results in the loss of sensory, motor and/or autonomic functions of patients (1). Based on the most recent review of literature and data integration, the national incidence of traumatic SCI varies widely globally in a range of about 5 to 150 cases per million (2), with higher incidence in developing countries (3). Management of SCI patients requires substantial healthcare resources, with its estimated annual costs up to six times more than other chronic diseases (4). The requirement for high-level acute care in the short term, as well as the related long-term secondary consequences, account for the majority of these costs (5).

Magnetic Resonance Imaging (MRI) provides detailed evaluation of the spinal cord parenchyma and ligaments in a non-invasive manner (6). However, there are barriers including hemodynamic instability, traumatic injuries, respiratory difficulties, difficulty of safe patient transport, and need for close monitoring of acute SCI cases, which limit MRI utilization for traumatic SCI patients in the acute setting (7). The benefits of MRI such as defining the extent and etiology of spinal cord compression, detecting ligamentous instability at spinal level injury, and identifying vertebral artery injury makes this modality an interesting option for evaluation of acute SCI patients (1, 8). On the other hand, MRI has disadvantages for an acute setting like traumatic SCI including its time-consuming nature which may put unstable trauma patients at life-threating risks specially if it brings up delays in vital surgical interventions, and requiring extensive resources and costs to provide its availability for a 24/7 emergency trauma center (1). The later one is a major obstacle of early management of acute traumatic SCI in low- and middle-income countries (LMICs) due to restrictions in medical and instrumental resources like MRI (9, 10), besides lack of guideline-based evaluation and care of acute SCI cases (11, 12).

Variation in patient outcomes is affected by the treatments offered by healthcare providers with more extensive impact in emergency clinical settings like trauma (13). As such, Clinical Practice Guidelines (CPGs) provide recommendations to reduce heterogeneity and variations in the provided care to maximize outcomes (14, 15). There have been several attempts to develop guidelines for the use of MRI in individuals with acute traumatic SCI which provide evidence-based recommendations for SCI management (1). Efforts to develop a guideline for MRI use for acute SCI started by the 2002 AANS/CNS guideline which suggested MRI as an option for evaluation of acute SCI in a couple of clinical scenarios (16). The 2013 update of the same guideline introduced MRI higher than an option and suggested as a level Ⅲ recommendation for the specific scenarios of patients with acute SCI (6, 17). Application of such recommendations provide an opportunity for homogeneous and integrated patient management. However, the developed countries where these guidelines were created have significant infrastructures such as level I, II, III, IV trauma centers (16, 17). However, in developing countries such as those located at the Middle East region, there is less defined and coordinated trauma centers and CPGs for management of acute traumatic SCI (3, 18). Developing new CPGs has many challenges needing high costs and resources (19); therefore, it is rational to adopt/adapt the existing guidelines prepared in developed countries and implement them in LMICs to address the burden of major public health issues like acute SCI (20, 21). Thus, promoting the recommendations by CPGs and facilitating their use by clinical practitioners is critically important to achieve this aim.”

The working method is very unclear. Please write your article according to the valid checklists or modeling other articles.

Response: We thank the reviewer for this constructive comment. In this revision we tried our best to rewrite the methods section to make the presented material clearer for readership and prevent confusion. The revised section could be found in lines 87-154.

The structure of the article has fundamental flaws. For example, the findings have fundamental problems.

Response: Thanks for this comment. The results section is mainly on two topics of the results of the literature search and final recommendations decided by the expert panel. We understand the presentation of the results was somehow confusing. Therefore, we tried to make some revisions on this section to improve the material, as presented in lines 155-193.

Authors are given time to make major corrections. Otherwise, the article will be rejected.

Response: Thanks for the chance provided by journal to revise our submission. In this regard, we tried to address the insightful comments of the reviewers and editors to enhance this manuscript. We hope the changes made in different sections of the manuscript besides the responses to the comments meet the expectations and resolve the shortcomings of the prepared paper. We are looking forward to receiving your feedback on the amendments.

Reviewer 2:

the researchers have done a so called systematic review of the literature to find recommendations regarding preforming MRI after spinal cord injuries. their search ended in only 3 such a recommendation all over. they tried to perform Delphi search including ..... neuro- ortho- spine surgeons and have tried to reach an empowered conclusion in Iranian Context. the methodology looks weak to me so I don't think it can be an ONTIME research with an outstanding practice able output.

Response: With many thanks for this wise comment. We agree the presentation of the study methods in the initial submission might be confusing to some extent. The current investigation was an original effort to develop a guideline for MRI use in acute spinal cord injury in Iran. This effort was done in two steps of a primary systematic review followed by guideline adaptation through the Delphi technique. Through the first steps of the study, in order to retrieve the relevant studies and guidelines on this topic we did a comprehensive search and review of literature. This stage was done through a systematic search and review of literature based on the PRISMA checklist as provided in the methods section (lines 111-112) and the results of literature screening provided briefly in opening of the results section (lines 156-165). Nevertheless, the main body of this study was based on the expert panel commenting on final concluded comments to amend some changes on recommendations with the aim of adopting and adapting appropriate recommendations to be used as a beneficial tool to develop a guideline on this topic for Iran.

actually, every case of spine injury undergoes MR imaging right upon admission in our community whether right or wrong. it is just the same as every patient with the complaint of low back pain undergoes MRI whether right or wrong. who is going to manage this kind of practice in our community????????

Response: We could not agree more with the precious comment of the reviewer on the current state of MRI use in Iran and other countries. However, in the case of trauma and acute SCI, the use of MRI might be challenging and associated with some risks. Besides, although MRI availability and use is growing in Iran and other developing countries, it still faces major limitations in many areas of country as transferring the patients to highly resourced trauma centers might be time consuming and may lead to delays in necessary surgical intervention. Therefore, we believe efforts like the current study are essential to guide the clinical staff involved in the management of the patients with acute SCI to improve the final outcomes of

patients. We tried to reflect these facts in introduction section to highlight the gaps in the field and the importance of the current investigation to adopt and adapt guidelines on the use of MRI for acute SCI, as below:

“Magnetic Resonance Imaging (MRI) provides detailed evaluation of the spinal cord parenchyma and ligaments in a non-invasive manner (6). However, there are barriers including hemodynamic instability, traumatic injuries, respiratory difficulties, difficulty of safe patient transport, and need for close monitoring of acute SCI cases, which limit MRI utilization for traumatic SCI patients in the acute setting (7). The benefits of MRI such as defining the extent and etiology of spinal cord compression, detecting ligamentous instability at spinal level injury, and identifying vertebral artery injury makes this modality an interesting option for evaluation of acute SCI patients (1, 8). On the other hand, MRI has disadvantages for an acute setting like traumatic SCI including its time-consuming nature which may put unstable trauma patients at life-threating risks specially if it brings up delays in vital surgical interventions, and requiring extensive resources and costs to provide its availability for a 24/7 emergency trauma center (1). The later one is a major obstacle of early management of acute traumatic SCI in low- and middle-income countries (LMICs) due to restrictions in medical and instrumental resources like MRI (9, 10), besides lack of guideline-based evaluation and care of acute SCI cases (11, 12).

Variation in patient outcomes is affected by the treatments offered by healthcare providers with more extensive impact in emergency clinical settings like trauma (13). As such, Clinical Practice Guidelines (CPGs) provide recommendations to reduce heterogeneity and variations in the provided care to maximize outcomes (14, 15). There have been several attempts to develop guidelines for the use of MRI in individuals with acute traumatic SCI which provide evidence-based recommendations for SCI management (1). Efforts to develop a guideline for MRI use for acute SCI started by the 2002 AANS/CNS guideline which suggested MRI as an option for evaluation of acute SCI in a couple of clinical scenarios (16). The 2013 update of the same guideline introduced MRI higher than an option and suggested as a level Ⅲ recommendation for the specific scenarios of patients with acute SCI (6, 17). Application of such recommendations provide an opportunity for homogeneous and integrated patient management. However, the developed countries where these guidelines were created have significant infrastructures such as level I, II, III, IV trauma centers (16, 17). However, in developing countries such as those located at the Middle East region, there is less defined and coordinated trauma centers and CPGs for management of acute traumatic SCI (3, 18). Developing new CPGs has many challenges needing high costs and resources (19); therefore, it is rational to adopt/adapt

the existing guidelines prepared in developed countries and implement them in LMICs to address the burden of major public health issues like acute SCI (20, 21). Thus, promoting the recommendations by CPGs and facilitating their use by clinical practitioners is critically important to achieve this aim.”

> Associate Editor's Comments:

Associate Editor 1:

Dear EIC,

Thanks to the authors and appreciation to the researchers. The manuscript is a valuable research. But some revisions are needed. Authors should revise it based on comments. Also minor changes should be done in abstract:

1- Study design should be mentioned in first line of Introduction.

Response: With many thanks, we revised the abstract and added the study design in the objective of study, in lines 8-12, and also as provided below:

“We aimed to adopt and adapt suitable recommendations for guideline development in Iran based on the available international guidelines on the utilization of MRI in management of acute SCI patients through a systematic review of literature followed by guideline development based on the Delphi technique.”

2-Summary of Statistical analysis results should be mention in result section.

Response: Thank you for this comment. Since this study had no specific statistical analysis, we could not add any results of analysis to the abstract. However, we provided the result of the systematic review and the number of screened and included literature in the opening of the results section of the abstract for a better understanding (lines 21-23).

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2 Revision 1

3 comments · 1 Jul 2023 – 4 Jul 2023

Referee 1 Reviewer

MINOR REVISION 1 Jul 2023

The authors have tried their best in revising their manuscript, and I would like to suggest that it be accepted after the complete list of limitations is added at the end.

Associate Editor

MINOR REVISION 4 Jul 2023

Dear EIC,
I reviewed the manuscript again. The great effort in improving the manuscript is highly appreciated. But some points remain, as mentioned by the reviewer.
Thank you

Editor-in-Chief

MINOR REVISION 4 Jul 2023

Dear Author,
Your manuscript still needs some revision. Please revise it based on the reviewers' and AE's comments.

3

Revision 2

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Dear Reviewers and Editors,

The authors would like to thank you again for the precious time and consideration you devoted to evaluate this submission. Benefitting from the provided comment we enhanced the manuscript in this revision to meet the standards of publication. We hope the changes could address the raised query on the study limitations.

> Reviewers' Comments:

Reviewer 1:

the authors have tried their best in revising their manuscript and I would like to suggest it to be accepted after adding the complete list of limitations at the end.

> Associate Editor's Comments:

Associate Editor 1:

Dear EIC,

I reviewed the manuscript again. The great effort in improving the manuscript is highly appreciated. But some points still exist as mentioned by reviewer.

Thank you

Response: With many thanks for this valuable comment on adding the list of limitations to the end of manuscript, we provided a full list of limitations and strengths to address this point that could be found in lines 206-220 and also as provided below.

“This study had some limitations. The scarcity of national material, guidelines, recommendations, and previous literature, and also the lack of diversity in international guidelines on the study topic were the main limitation in providing a nationally adapted guideline with recommendations in this study. The other limitation could be the expert panel-based commenting on extracted recommendations that could be biased by various factors; however, by including a diverse group of experts and scoring the recommendations in several rounds, we tried to minimize any possible biases in this regard. Adopting and adapting guidelines instead of developing de novo guidelines could have lower strengths and might be the other major limitation of this study; nevertheless, considering the huge logistic and financial resources needed to develop guidelines from ground, adopting/adapting guidelines is a cost-effective approach to address vital gaps in patient management like what presented in this study. Besides all these limitations, this study had several strengths including being the first effort to provide an evidence-based recommendation for use of MRI in patients with acute SCI, conducting a through systematic review and extraction of relevant recommendations on the study notion, and gathering a robust group of experts to evaluate the recommendations and modify them for implementation in clinical setting of Iran.”

3 Revision 2

2 comments · 8 Aug 2023 – 8 Aug 2023

Associate Editor

ACCEPT 8 Aug 2023

Dear EIC,
I reviewed the manuscript again. The great effort in improving the manuscript is highly appreciated.
The authors have addressed all comments.
Thank you

Editor-in-Chief

ACCEPT 8 Aug 2023

Dear Author,
Thank you for paying attention and responding to the reviewer's comments.