OPEN PEER REVIEW

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Peer Review Report for "A Saline Test Injection Mode Improving the Safety of Using a Power Injector for CT"

Author(s): Shu-Yu Chang, Chia-Hsin Lu, I-Chan Chiang, Wei-Shiuan Chung, Tsyh-Jyi Hsieh

Review Timeline:

Submit Date:	28 Oct 2018
Revised Date:	8 Mar 2019
Accepted Date:	11 Mar 2019

Revision (0)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Associate Editor | **Revision** (0)

4 Nov 2018

Dear EIC,
The manuscript is a novel topic that will be of interest to the readers of the journal. This study evaluated the extravasation rate of contrast medium using a power injector with a saline test injection mode.
- Overall, it is an important study to considering for publication in IJR, once the mentioned issues have been resolved and the manuscript rewrite.
- In fact, Major revision is needed.
- In data analysis, the pain of the patients and other complications of injection should be added.
- Repeated keywords should be omitted.
- The introduction of the paper should be completed and also, more comparison of the results of this method of different patients groups like pediatrics should be added and rewrite the discussion.
- Before resubmission's, check your manuscript with our journal Authors guideline.
Best Regards

REFEREE: Reviewer | **Revision** (0) 5 Nov 2018

Dear AE,
The material and methods section should be explained in more details. how many patients has saline test mode? which groups are compared?
Thanks.

REFEREE: Reviewer | **Revision** (0) 5 Nov 2018

Dear AE,
There are some comments which should be addressed by the author:
- As you mentioned the study was retrospective from 2012-2014.
- It is not mentioned that this method was a routine protocol of your department or it is a new novel method.
- If new, why it is a retrospective study on registered records.
- If it was the routine protocol of your department, you did not clearly state that you have a routine protocol of twice saline injection (from years before this study), once manually by a nurse while placing the venous cannulas (5–10 mL) and again by dual syringe power injector before contrast injection.
Thanks.

REFEREE: Reviewer | **Revision** (0) 23 Nov 2018

Dear AE,
The authors claimed “the saline test injection method can reduce the contrast extravasation rate using an automated IV contrast medium power injector” based on the study design, this claim should be noticed. When we want to assess the effect of an intervention, we should design a clinical trial considering two groups of intervention and no intervention in one setting [RCT for example]. In this case, we should design a trial in which half of the patients are injected without saline test and half are injected after saline test [and when the extravasation occurred, then the authors create new venous access]. [we cannot design a before-after trial here] Then, we compare the rate of extravasation between the two groups at the end. I know that as the extravasation is rare, reaching to a good sample size is hard. [designing a RCT, we had two groups of cases and controls; in the case of the group we have 4 subgroups; (both injections positive for extravasation), (saline test positive and contrast negative), (saline test negative and contrast positive) and (both tests negative). In control, we have two subgroups of extravasation positive and negative. If we want to assess the effect of the saline test, we should compare these groups and subgroups together; especially, comparison of extravasation rate between the control group and saline test positive cases regarding the rate of contrast extravasation seems important as this comparison show if the changing injecting vein after saline extravasation would decrease the rate of contrast extravasation????]. In the current study, even in patients with saline test-positive cases, we cannot claim definitely that if they were not tested by saline, contrast extravasation happened definitely. I ask authors to consider these points and explain. In addition, they should discuss and add appropriate points in this regard in the discussion. [may be in limitations] [the reason for the lower rate of extravasation could be due to different conditions and situations compared to other studies that should be

mentioned and discussed if the data are available]

1- The authors mentioned Extravasations occurred in 12 (0.12%) of 10310 patients, in the abstract. It is better to mention that these 12 were in the saline test or contrast injection. In addition, they mentioned 5 extravasations for saline and 6 for contrast that is a total of 11 while they mentioned 12 cases of extravasation.

2- Please add the objective part before the method section of the paper according to the journal format.

3- What is the protocol in the institution for selecting the patient for injector [not manual injection]? Which patients are considered for manual injection?

4- Please add the approval of the ethics committee was taken in the text.

5-Which vein(s) are selected for injection? Is this identical in all patients before the exam?

6- What were the clinical criteria for diagnosis of extravasation? please add and mention. in addition, what was the clinical protocol for detecting the extravasation? this is important if we consider the study is retrospective and some patients may be missed.

7- What was the method of EEV determination?

8- Please add the abbreviation of NIL in table 1.

9- Please compare the rate of total extravasations [12] and only contrast extravasations [6 patients] with other reported studies and mention the P-values [and discuss if it is needed]

Thanks.

REFEREE: Associate Editor | **Revision** (0) 26 Nov 2018

Dear EIC,

Major revision considering the suggestions of the reviewers.

Thanks.

REFEREE: EIC | **Revision** (0) 26 Nov 2018

Dear Author,

Your article is reviewed by the reviewers carefully. According to their comments, this document needs minor revision. Please follow their comments as requested.

Thanks.

OPEN PEER REVIEW

Revision (1)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Dear editor:

Thank you for your nice and detailed review. We have provided a point-by-point revision or response to all of your comments and tried our best to revise our manuscript using a most balanced approach. The reasons and revisions are provided in the following table. In the revised manuscript, all the changes are highlighted on red color. We deeply appreciate your valuable opinions, which stimulated a more thorough consideration of the essay. Thank you.

Sincerely,

First and corresponding authors

January 6, 2019

No.	Recommendations and questions	Responses to Reviewer
Reviewer 1		
1	As you mentioned the study was retrospective from 2012-2014. It is not mentioned that this method was a routine protocol of your department or it is a new novel method. If new, why it is a retrospective study on registered records. If it was the routine protocol of your department, you did not clearly stated that you have a routine protocol of twice saline injection (from years before this study), once manually by a nurse while placing the venous cannulas (5–10 mL) and again by dual syringe power injector before contrast injection.	Thank you for reviewer's comments. Our hospital was re-organized in 2011 and all machines and staffs were also organized in 2011. In previous hospital and old machine, the saline test by dual syringe power injector was performed only in CT angiography with high injection rate (>4ml/sec) because the procedure was complicated in old power injector without program. Because the new power injector with program makes the multiple injection in one setting, the saline test by power injector could be easily performed. When we built up the new CT machine and new power injector with program, saline test with power injector became a routine procedure in using the

		power injector.
Reviewer 2		
1	the material and methods section should be explained in more details. how many patients has saline test mode?	Thank you for reviewer's comments. The changes according to the recommendation have been made in the "3.1 Patients" of "Materials and methods" section as below: "Totally, 10,310 CT examinations using a power injector with a saline test mode were enrolled in this study."
2	which groups are compared?	Thank you for reviewer's comments. Because the saline test mode by power injector is the SOP of contrast-enhanced CT in our hospital, we collected these data retrospectively from database of our hospital. Because the incidence of contrast extravasation is extremely rare, it is difficult to perform an RCT in one institute because of long study time, maybe many years. So, we just share our experience in the saline test mode by power injector. We have made the change in the limitation section.
Reviewer 3		
	The authors claimed "the saline test injection method can reduce the contrast extravasation rate using an automated IV contrast medium power injector" based on the study design, this claim should be noticed. When we want to assess the effect of an intervention, we should design a clinical trial considering two groups of intervention	Thank you for reviewer's comments. Because the saline test mode by power injector is the SOP of contrast-enhanced CT in our hospital, we collected these data retrospectively from database of our hospital. Because the incidence of contrast extravasation is extremely rare, it is difficult to perform an

	and no intervention in one setting [RCT for example]. In this case, we should design a trial in which half of patients are injected without saline test and half are injected after saline test [and when the extravasation occurred, then the authors create a new venous access]. [we cannot design a before-after trial here] Then, we compare the rate of extravasation between the two groups at the end. I know that as the extravasation is rare, reaching to a good sample size is hard. [designing a RCT, we had two groups of cases and controls; in case group we have 4 subgroups; (both injections positive for extravasation), (saline test positive and contrast negative), (saline test negative and contrast positive) and (both tests negative). In control, we have two subgroups of extravasation positive and negative. If we want to assess the effect of saline test, we should compare these groups and subgroups together; especially, comparison of extravasation rate between control group and saline test positive cases regarding the rate of contrast extravasation seems important as this comparison show if the changing injecting vein after saline extravasation would decrease the rate of contrast extravasation????]. In the current study, even in patients with saline test positive cases, we cannot claim definitely that if they were not	RCT in one institute because of long study time, maybe many years. So, we just share our experience in the saline test mode by power injector. We have made the change in the limitation section.

	tested by saline, contrast extravasation happened definitely. I ask authors to consider this point and explain. In addition, they should discuss and add appropriate points in this regard in discussion. [may be in limitations] [the reason for lower rate of extravasation could be due to different conditions and situations compared to other studies that should be mentioned and discussed if the data are available]	
1	the authors mentioned Extravasations occurred in 12 (0.12%) of 10310 patients, in abstract. It is better to mention that these 12 were in saline test or contrast injection. In addition, they mentioned 5 exravasation for saline and 6 for contrast that is totally 11 while they mentioned 12 cases of extravasation.	Thank you for reviewer's comments. Totally, 12 extravasations were noted in all case and included 5 extravasations in saline test, 6 in contrast injection and 1 in saline flush. The details were mentioned in the table 1.
2	please add the objective part before method section of paper according to journal format.	Thank you for reviewer's comments. The changes according to the recommendation have been made in the objective section as below: “Objectives: The purposes of this study were to calculate the extravasation rate in using a power injector and to determine if using a power injection to inject saline prior to contrast administration could reduce the contrast extravasation rate. ”
3	what is the protocol in the institution for selecting the patient for injector [not manual injection]? Which patients are considered for	Thank you for reviewer's comments. In our hospital, the power injector is routinely used, except for those

	manual injection?	patients in whom suitable venous access cannot be achieved. (mentioned in the 2nd paragraph of the “3.1 Patients” section of “Materials and methods” section) The manual injection is performed in patients in whom suitable venous access cannot be achieved. The achieving of a suitable venous access is mentioned in the 2nd paragraph of the “3.2 Acquisition protocol” section of the “Materials and methods” section.
4	please add the approval of the ethics committee was taken in the text.	Thank you for reviewer's comments. The approval of the ethics committee was mentioned in the first paragraph of “3.1 Patients” of “Materials and methods” section. “This study was approved by the Institutional Review Board of our hospital, and because of the retrospective nature the requirement of informed consent was waived.”
5	which vein(s) are selected for injection? Is this identical in all patients before the exam?	Thank you for reviewer's comments. For using a power injector, only veins at antecubital region or forearm were considered to access a venous cannula in our hospital. The changes according to the recommendation have been made in the “3.2 Acquisition protocol” of “Materials and methods” section as below: “Before CT examination, all patients who were to have a contrast-

		enhanced CT were examined by one of the well-trained nurses of the CT team to assure adequate peripheral venous access at antecubital region or forearm. The venous cannulas were checked by administering 5–10 mL of normal saline manually. If the IV catheter could not be flushed adequately, or if the patient experienced pain at the injection site, a new peripheral venous access site was created.”
6	what were the clinical criteria for diagnosis of extravasation? please add and mention. in addition, what was the clinical protocol for detecting the extravasation? this is important if we consider the study is retrospective and some patients may be missed.	Thank you for reviewer's comments. Clinical criteria for diagnosis of extravasation: 1. patient complaint pain or swelling at injection site, 2. abnormal increase or decrease of the injector pressure was noted on the remote monitor of power injector, 3. there was no normal enhancement at the great vessels. The changes according to the recommendation have been made in the “3.4 Contrast administration” of the “Material and methods” section as below: “If extravasation was noted, the injection procedure would be interrupted. The clinical criteria for diagnosis of extravasation are as below: 1. patient complaint pain or swelling at injection site, 2. abnormal increase or decrease of the injector pressure was noted on the remote monitor of power injector,

		3. there was no normal enhancement at the great vessels.”
7	what was the method of EEV determination?	Thank you for reviewer's comments. EEV was estimated according to the injection rate and time interval between episode and stop of injector. The changes according to the recommendation have been made in the3.5 Data collection” of “Materials and methods” section as below: “EEV was estimated according to the injection rate and time interval between episode and stop of injector.”
8	please add the abbreviation of NIL in table 1.	Thank you for reviewer's comments. The changes according to the recommendation have been made in table 1 as below: “Abbreviations: EEV = estimated extravasated volume; NS = normal saline; Nil: nothing.”
9	please compare the rate of total extravasations [12] and only contrast extravasations [6 patients] with other reported studies and mention the P-values [and discuss if it is needed]	Thank you for reviewer's comments. The extravasation rates have been reported to be 0.1-0.9% in the previous studies. However, it is difficult to compare our result with the previous studies because of the low incidence and different SOP and conditions in the previous studies.
Associate Editor 1		
1	The manuscript is a novel topic that will be of interest to the readers of the journal. This study evaluated the extravasation rate of contrast	Thank you for reviewer's comments. We tried our best to revise our manuscript.

	medium using a power injector with a saline test injection mode. Overall, it is an important study to considering for publication in IJR, once the mentioned issues have been resolved and the manuscript rewrite. In fact, Major revision is needed.	
2	In data analysis, like pain of the patients and other complication of injection should be added.	Thank you for associate editor's comments. The changes according to the recommendation have been made in "Results" section as below: "Local tenderness or swelling is noted in all cases. Local pain was noted in 6 cases only. One of the patients with extravasation developed compartment syndrome and received a decompression surgery. There were no complications in the other patients with extravasation."
3	Repeated keywords should be omitted.	Thank you for associate editor's comments. The changes according to the recommendation have been made in "abstract" page as below: "Keywords: Computed Tomography; Contrast Media; Extravasation of Contrast Media; Patient Safety; Power injector."
4	Introduction of the paper should be completed	Thank you for associate editor's comments. The "objectives" section has been added between "background" and materials and methods" sections.

5	more comparison of this methods results of different patients group like pediatrics should be added and rewrite the discussion.	Thank you for associate editor's comments. The pediatrics were not included in this study. Because our hospital is not a medical center or a children hospital, the contrast-enhanced CT with a power injector in the pediatrics are too rare to analyze in our hospital.
6	Before resubmission's, check your manuscript with our journal Authors guideline.	Thank you for associate editor's comments. We have revised and re-checked our manuscript.
Associate Editor 2:		
1	Major revision considering the suggestions of the reviewers	Thank you for associate editor's comments. We tried our best to revise our manuscript.

OPEN PEER REVIEW

Revision (1)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | **Revision** (1) — 30 Jan 2019

Dear AE,
My previous comments are well addressed and clarified in the new revision.
Thanks.

REFEREE: Reviewer | **Revision** (1) — 3 Feb 2019

Dear AE,
The study is reviewed carefully. According to comments and revisions by the author, this manuscript is accepted.
Thanks

REFEREE: Associate Editor | **Revision** (1) — 4 Feb 2019

Dear EIC
Based on the authors' answers to the reviewers' comments, the reviewer(s) have recommended publication.
Kind regards.

REFEREE: Associate Editor | **Revision** (1) — 20 Feb 2019

Dear EIC,
The authors should respond to the mentioned comment.
- In the discussion, “Forth, we did not perform a power statistic calculation because without control group.”
- This sentence is not correct. Do you mean, “Forth, we did not perform a power statistic calculation because we did not have a control group.”
Please clarify.
Thank you.

REFEREE: EIC | **Revision** (1) — 20 Feb 2019

Dear Author,
Your article is reviewed by the reviewers carefully. According to their comments, this document needs minor revision. Please follow their comments as requested.

Thanks.

OPEN PEER REVIEW

Revision (2)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Dear editor:

Thank you for your nice and detailed review. We have provided a point-by-point revision or response to all of your comments and tried our best to revise our manuscript using a most balanced approach. The reasons and revisions are provided in the following table. In the revised manuscript, all the changes are highlighted on red color. We deeply appreciate your valuable opinions, which stimulated a more thorough consideration of the essay. Thank you.

Sincerely,

First and corresponding authors

February 24, 2019

No.	Recommendations and questions	Responses to Reviewer
Associate Editor 2:		
1	In the discussion, “Forth, we did not perform a power statistic calculation because without control group.” This sentence is not correct. Do you mean, “Forth, we did not perform a power statistic calculation because we did not have a control group.”	Thank you for editorial comments. The changes according to the recommendation have been made in the final paragraph of the Introduction section (P. 3).

OPEN PEER REVIEW

Revision (2)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Associate Editor | **Revision** (2) 11 Mar 2019

Dear EIC
Based on the authors' answers to the reviewers' comments, the reviewer(s) have recommended publication.
Kind regards.

REFEREE: EIC | **Revision** (2) 11 Mar 2019

Dear Author,
The document is reviewed carefully by the reviewers. According to their comments and your revisions as requested, this manuscript is accepted.
Thanks.