Author's response to reviews

Title: Comparing Radiation Exposure During Percutaneous Vertebroplasty Using One- vs. Two-fluoroscopic Technique

Authors:

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Author's response to reviews: see over
Dear Executive Editor,

I appreciate so much with your efforts to our paper and the reviewer’s valuable critiques and comments. I have read them carefully and would like to reply them accordingly. The text was revised on a point-by-point basis and highlighted them with red color. We fully understand the policy of the Journal, therefore we decide to edit and re-submit our manuscript for further consideration as your recommendation. Enclosed you will find our article entitle “Comparing Radiation Exposure during Percutaneous Vertebroplasty Using One-vs. Two-fluoroscopic Technique”, which had its revision based on the reviewer’s comments as followings:

To the Reviewers:

Thanks a lot for your timely and highly comments. I have made corrections accordingly. You will see the revisions in the text we re-submitted and highlighted with red color.

Referee 1: Thomas Mroz

1) It appears from the pictures that the source of the fluoroscope is closest to the surgeon. Was this true intraoperatively, and if so, why? Standing closest to the source is associated with higher exposure to surgeon.

Answer:

We recognize that increased distance from the source of fluoroscope can decrease radiation exposure to the operator, especially for scatter radiation. The image intensifier, however, is bulky and often set at the same side of the mainframe of the “lateral fluoroscope”, so that it is difficult or inconvenient for the surgeon to stand at the side of the image intensifier away from the source. To decrease the radiation dose, we use the long handle-clump to hold the spinal needle while locating the entry point, therefore the surgeon's hand can put away from the patient body to decrease scatter radiation. Furthermore, while the spinal needle can be
securely held in the bony tissue, it is not necessary to hold the needle with the hand, then the operator can stand away from the source while X-ray checking.

2) Please discuss the power analysis that was done to arrive at your sample size.

Answer:

Thank you for your valuable advice to improve the validity of the manuscript. I have made power analysis at the first paragraph in "method, statistical analysis" section as below.

The power analysis carried out with the computer program G*Power 3.1 software [5]. The power of each Wilcoxon-Mann-Whitney (two groups) unpaired test was determined by use of power analysis. A post hoc power analysis was performed with a sample size of n=13 per group to examine the potential for type II errors in the data analysis. Assuming an alpha level of 0.05 with a two-sided alternative hypothesis, both the comparisons on radiation dose and operative time between using the two-fluoroscopic technique vs. using the one-fluoroscopic technique had at least 80% power to detect the minimum clinically important differences.

3) The paper does a good job in reporting their results, but it leaves the reader without the ability to apply them if they do not know how to interpret the radiation doses reported. Several authors have mentioned this in their studies (e.g. Mroz et al). It would strengthen your paper if you add references and a short discussion on how to minimize exposure. (The paramount concern of this topic is that ionizing radiation is associated with cancer. How do these doses reported in this paper relate to Occupational Exposure Limits? How many procedures can be done before surgeons need to worry about exceeding these limits? What techniques can be employed to minimize radiation exposure?)

Answer:

Thank you for your valuable advice, which would strengthen the manuscript. I would add a brief discussion at the 1st paragraph (from the line 7) in the “discussion” section as below.

The National council in Radiation Protection and Measurements in 1993 suggested that the occupational exposure limits for extremity (eg. Hands) is 500mSv/y, for the eye is 150 mSv/y, and for the total dose (whole body) is 50 mSv/y [10]. In our study, the whole body dose without protection is 0.27 and 0.25 mSv for the one-fluoroscopic technique and two-fluoroscopic technique, respectively. Therefore, if an operator did not wear the lead apron for shielding, the total exposure dose (whole body) will exceed the annual limit after 200 single-level vertebroplasty procedures annually regardless of one or two-fluoroscopic techniques. According to Mroz's study [11], the whole body dose (0.248 mSv/vertebra) to the operator during kyphoplasty is similar to that of our study. They also measured the exposure doses to the hand and concluded that the exposure dose to the hand would exceed the annual limit after 300 levels of kyphoplasty. Therefore they recommend the operator should always consider the appropriate protection (eg. lead gloves) against the radiation exposure to the hands. However, Wagner [12] et al. evaluated 4 different type protective gloves and reported a large variation in radiation attenuation from exposure reduction of 7% to almost 50%. So that, even though wearing protective gloves, the operator should place his or her hand as away from the path of the radiation beam as possible.
Referee 2: George Panayiotakis

1) Methods ("Dosimetry") and figure 1: The use of only one dosimeter to estimate patient dose, significantly decreases the accuracy and validity of the results. The authors should comment on this limitation.

Answer:
Thank you for the advice. I would address the concern at the first paragraph (from the line 3) in the “Method, Dosimetry” section as below.

Use of a thermoluminescent dosimeter (TLD) is potentially the most accurate way of measuring actual skin dose to the patient, however, it is often impossible to know exactly where on the skin the peak dose will be exposed during vertebroplasty. Ideally, using two TLDs in either plane we can measure patient exposure in both planes. However, it was impossible in the current study since the TLD is not sterile, which can not be placed in the surgical field. Generally, lateral radiographs should be taken more times than anteroposterior view to check cement leakage into spinal canal. In the study, so that, we use the TLD placed on the right flank of each patient to be close to the source of lateral fluoroscope.

2) Methods ("PV with two fluoroscopes"): The last sentence referring to 26 patients, should be removed, since it creates a discrepancy with what is mentioned previous paragraphs (13 patients).

Answer:
Thank you for the advice. We readily agree your concern and remove that sentence.

3) Results: Validity of results is significantly limited due to the absence of parameters that are directly connected to the absorbed dose, such as the irradiation time, kV, pulses per second, etc. This limitation has to be clearly stated in the manuscript.

Answer:
Thank you for your suggestion to improve the validity of the results.

The irradiation time was not recorded, and we had already declared it at the last paragraph of the "discussion" section.

I would add a statement at the paragraph (from the line 4) in the “Method, PV with two-fluoroscopic technique” section as below.

In our study, the pulsed fluoroscopy mode was adopted with 15 pulses per second. For all the procedures, the range of the source voltage was 40-110 kV and the current was 0.2-8 mA.

4) Discussion (first paragraph): The derived results should be further compared with relevant dose data corresponding to conventional (single fluoroscope) PV. Important references are missing (Miller et al, Interv. Radiol. 2003, Fitousi et al, Spine 2006, Mehdizade et al, Neuroradiology 2004).

Answer:
Thank you for your valuable advice to make up the integrity of the manuscript. I have made a short discussion at the 2nd paragraph (from the line 7) in the “Discussion” section as below.

Mehdizade et al. used biplane fluoroscopy unit to monitor vertebroplasty, which was similar to two-fluoroscopic technique in our study. They reported that the exposure doses to the operator were 0.022-3.256
mGy with the TLD outside and 0.01-0.47 mGy inside the lead apron. Those data seems to be comparable to our measurements as 0.11-0.39 mSv (0.25 ± 0.14 mSv) with two-fluoroscopic technique. However, we did not know the average dose in their study. Fitousi et al. reported that the occupational exposure to the operator was 0.011 mGy in effective dose, 0.328 mGy in eye dose and 1.861 mGy in hand dose, during vertebroplasty with continuous fluoroscopy (Philips DVIS 3000). By using mobile shielding devices (eg. lead sheet), they found that the effective dose to the operator can be reduced by more than 75%.

5) Discussion (second paragraph): The operative time cannot be linked to radiation exposure. The authors should avoid such statements, since the irradiation time was not measured.

Answer: Thank you for the advice. We readily agree your concern that it is difficult to declare the relation between operative time and radiation exposure. We have removed such statement.

6) Discussion (third and fourth paragraph): The fact that, although the patient dose seems to decrease, the dose to the operator does not change, seems somehow strange. The authors should discuss and if possible justify this fact.

Answer: Thank you for your advice. I have added a brief discussion as the 4th paragraph in the “Discussion” section as below.

In our study, the exposure doses to the patient are significantly different (P=0.031) between using one-fluoroscopic and two-fluoroscopic technique. However, the doses to the operator are not different statistically. The dosimeter on the operator is mainly exposed to the scatter radiation, while that on the patient is partly exposed to primary radiation. Therefore, the dose amount on the operator is less than that on the patient (1.97, 0.95 mSv to patient Vs.0.27, 0.25 mSv to operator). Probably, for the small dose amount to the operator, we need large sample size to prove the dose to the operator significant difference between the two techniques, if any.

7) Figure 3: it is not relevant to any part of the manuscript; neither does it add any additional value to it.

Answer: Thank you for your advice and we would remove the relating sentence in the "Result" section and delete the figure 3.

With my very best regards.

Sincerely,

Yen-Yao Li, MD
The original mail as following:

From: BioMed Central Editorial <editorial@biomedcentral.com>
To: Dr Yen-Yao Li <orthoyao@adm.cgmh.org.tw>
Sent: 5 Oct 2012 02:24:33 +0100
Subject: MS: 1848749063770999 - Comparing Radiation Exposure During Percutaneous Vertebroplasty Using One- vs. Two-fluoroscopic Technique

MS: 1848749063770999
Comparing Radiation Exposure During Percutaneous Vertebroplasty Using One- vs. Two-fluoroscopic Technique
Yen-Yao Li, Tsung-Jen Huang, Chin-Chang Cheng, Meng-Huang Wu and Ching-Yu Lee

Dear Dr Li,

Your manuscript has now been peer reviewed and the comments are accessible in PDF format from the link below. Do let us know if you have any problems opening the file.

Referee 1:
http://www.biomedcentral.com/imedia/6959762080634554_comment.pdf
Referee 2:
http://www.biomedcentral.com/imedia/6632333908150323_comment.pdf

We would be grateful if you could address the comments in a revised manuscript and provide a cover letter giving a point-by-point response to the concerns.

Please also ensure that your revised manuscript conforms to the journal style (http://www.biomedcentral.com/info/ifora/medicine_journals ). It is important that your files are correctly formatted.

We look forward to receiving your revised manuscript by 4 November 2012. If you imagine that it will take longer to prepare please give us some estimate of when we can expect it.

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You will find more detailed instructions at the base of this email.
Please don't hesitate to contact me if you have any problems or questions regarding your manuscript.

With best wishes,

Miss Abigail Quiniquini
on behalf of Dr Frank Roemer

e-mail: editorial@biomedcentral.com  Web: http://www.biomedcentral.com/

To submit your revised manuscript

When you have revised your manuscript in light of the reviewer's comments and made any required changes to the format of your paper, please upload the revised version by following these instructions:

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