Title: Respiratory physiotherapy and incidence of pulmonary complications in off-pump coronary artery bypass graft surgery: an observational follow-up study

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Version: 2 Date: 11 May 2009

Author’s response to reviews: see over
Dear Editor:

In relation to your e-mail regarding the paper entitled “Respiratory physiotherapy and incidence of atelectasis in off-pump coronary artery bypass graft surgery: an observational follow-up study”, reference MS: 4227136582569333, we would like to reply to the queries of the reviewers with a point by point response to their concerns:

We have marked the comments of the reviewers in bold text, and have marked in blue the new additions to the “revised paper”.

I look forward to your reply,

Yours sincerely,

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Reviewer Heather M Arthur

1- In relation to the comment: “…The authors state that although the intervention has been examined in CABG surgery that is carried out “on by-pass” they do not explain in detail what makes them think that the off-pump CABG patients are different in some important way. In particular, what differences would be expected, in relation to the outcome of interest, for patients who have off-pump CABG surgery? Are these patients at greater or lesser risk of post-operative atelectasis?”

As we mentioned in the introduction: “Although some of these studies have demonstrated the efficacy of preoperative physical therapy to prevent pulmonary complication after CABG surgery, there is a lack of studies regarding the effect of preoperative physical therapy in off-pump CABG surgery”. (P.5 paragraph 4)

This was the main reason for carrying out this study and to discover the situation in these patients (in off-pump CABG surgery). In addition, all patients underwent grafting the mammary artery. The dissection of this artery could increase the risk of complications, as mentioned in the introduction: “The use of the internal mammary artery for coronary artery bypass graft (CABG) surgery increases the percentage of Pulmonary Complications in comparison with bypasses of the saphenous vein conduit [9-12]” (page 3, paragraph 4).

2 – Are the methods appropriate and well described:

“…a randomized controlled trial design would have been a better approach…..”

This is an observational follow-up study. It is true that randomized clinical trials show the best evidence. As we mentioned in the discussion: “It is clear that ideally, a randomised clinical trial should be carried out in order to prove the efficiency of an intervention. This study describes the efficiency of an intervention in a study carried out within the context of standard medical practice in which the patients of both groups were comparable in several variables of interest including age, BMI, creatinine, ejection fraction, the number of affected vessels and \(O_2\) basal saturation”. (page 11, paragraph 5).

“There were unequal numbers in each group”: The differences in sample size in each group do not invalidate the study, and a size estimation and power calculation has been added to the paper (page 7, paragraph 5).
“There is no mention of whether a sample size calculation was done a priori and the issue of statistical power is not addressed”

Sample Size Justification:
The sample size of n=263 patients made it possible to study the patients’ characteristics with a security of 95% and a precision of ±6.1%. In order to detect a difference of 17% vs. 34% in the incidence of atelectasis between those patients receiving preoperative respiratory physiotherapy and those who did not, with a security of 95% and a statistical power of 80%, a sample size of n=103 patients in each group would be required. We finally included 159 patients who received preoperative respiratory physiotherapy, and 104 who did not.

Following the reviewer’s advice, we have included a statement in the Methods section explaining the justification of the sample size. (page 7, paragraph 5)

“there is no clear sense of the “dose” of the intervention, how standardization was achieved and, most importantly, no assessment of patient compliance with the exercise recommendations”

The number of preoperative sessions is associated with the presence or absence of atelectasis. Patients with atelectasis have a lower number of preoperative sessions than patients without atelectasis (2.0±3.5 vs 2.4±2.7; p=0.014). We have added this information to the results. (page 9, paragraph 4).

“how standardization was achieved”

Physiotherapists are trained to intervene and patients received a supervised session of 20 minutes every day.

In the paper we mention: “all of the patients underwent a daily physiotherapy session, under the supervision of the unit physiotherapist”

It is true that we did not measure assessment of patient compliance with the exercise recommendations. Lack of assessment could result in a bias toward the null hypothesis of ‘no difference’ which, however, implies that the effect could be greater.

As a result we have added a paragraph to the discussion concerning the limitations of the study regarding the lack of assessment of patient compliance. Non-compliance could result in a bias toward the null hypothesis of ‘no difference’ which could decrease the effect of the intervention physiotherapy. (page 12, paragraph 2).
“It is not clear which time point was used as the outcome assessment date”

The presence of atelectasis was studied as an event throughout the follow-up, and most patients presented atelectasis 48 hours after surgery. Atelectasis reported at any time throughout the follow-up was counted as an “event”

We have added this information to the text. (page 7, paragraph 4 and page 9, paragraph 4).

“IT is obvious that some patients had more than one outcome: atelectasis, pleural effusion, diaphragm elevation, etc. It would have been helpful to identify this in the paper and also to discuss its meaning for both the analysis and the results”

In some patients it was not possible to determine the incidence of pulmonary complications and, in particular, of atelectasis. As a result, the denominators for calculating the incidence of atelectasis in both groups of patients were 156 and 102 instead of 159 and 104 patients, respectively. We have indicated this in the tables, where we have included the number of patients with data available in each one of the variables studied. As can be seen from the tables, the percentage of missing values is very low in all cases.

“I am a bit confused by Table 5 since this is not the format in which I am used to seeing the results of a logistic regression”

In Table 5 we present the logistic regression model to predict the variables associated with the presence of atelectasis. The first column contains the input variables in the regression model. These variables were selected after checking the univariate analysis in relation to the presence of atelectasis. The second column shows the value of the regression coefficient (b). The third column (p) shows the value of the p-value to test if this coefficient is different from zero. The fourth column refers to the odds ratio for atelectasis and the last column shows the 95% confidence interval of OR

5 - “it would be very helpful to know exactly what post-operative time point the atelectasis was most frequently found”

The presence of atelectasis was studied as an event throughout the follow-up, and most patients presented atelectasis 48 hours after surgery

“since patient compliance to the instructions for preoperative respiratory exercises was no reported we can not be certain about what the magnitude of the effect is or, in particular, the dose response. “

As previously indicated, the degree of compliance was not measured, but in order to improve it, a physiotherapist performed a supervised session each day from the admission of a patient, as indicated in the Material and Methods section. We also found that the number of preoperative sessions is associated with the presence or absence of atelectasis. Patients with atelectasis have a lower number of preoperative sessions than...
patients without atelectasis (2.0±3.5 vs 2.4±2.7; p=0.014). We have added this information to the paper.

“the reviewer disagrees with the authors that it would have been unethical to conduct a RCT”

We would like to point out that this study measured the effectiveness of an intervention in routine clinical practice conditions, in which some patients received physiotherapy and others did not. In the literature there is controversy about their effectiveness. Many authors find that it is effective, and none of them say it is harmful. From our point of view, maintaining a control group without any intervention does not seem very appropriate. In any case, following the comments of the reviewer, we have deleted from the text the paragraph in which we said: “it would not appear ethical for randomized patients to ….conduct a RCT”

6 – “other limitations could have been acknowledged”

In the discussion we refer to the constraints arising from the type of study, measurement of non-compliance, and failure to complete the computerized axial tomography for the diagnosis of atelectasis (page 12, paragraph 2-5)

9 – There are errors in English grammar and spelling

We have sent the text back to a translator in order to correct the grammar and style
Reviewer Paulo Roberto Evora

1 - “...since atelectasis is only one of the possible respiratory complications, title....”

Based on the reviewer’s comment, we have changed the title of the paper, and instead of atelectasis we have now used “respiratory complications”. We had used atelectasis as this was the complication that we actually analyzed.

The new title is: “Respiratory physiotherapy and incidence of pulmonary complications in off-pump coronary artery bypass graft surgery: an observational follow-up study”

2.- The study does not report of where the information had been obtained, from patient’s health records or from a 2005-2006 study database

The information was collected from medical records on a daily basis from admission until the time of discharge

“anaesthesia type, anaesthesia and surgery time durations were not reported”

Information on anaesthesia was not collected. We only included the duration of surgery and surgical procedures

The mean time for surgery was 3.36 ±0.85 hours. We have added this information to the text (page 5, paragraph 3)

“correcting error of the tab space of page 5”

This error has been corrected.

“In the third paragraph there are inserted data that are part of the result in my point of view, since it mentions p value, standard error and average”

We believe that these are characteristics of the sample and the patients included. Its reference in the section on Material and Methods clarifies the characteristics of the sample and the patients, and these are not results of the objectives of the study. We have included this information beforehand in order to make it easier to understand the information that appears later on.

“In page 8 new results are mentioned including statistics values”

With this data, our aim is to emphasize the methodological aspects of the validity of the measures and once again, the characteristics of the patients.
In connection with the comment ...”X-ray were used to evaluate the atelctasis and it is well know that it is a poor method when compared to CAT scan. If CT scan was adopted the results could not be different?”

CT scans are not routinely performed after surgery in these patients. In this study within the context of standard medical practice, in which the patients from both groups were comparable in several variables of interest, CAT scans are not carried out routinely on all patients after surgery. If there was an underestimation of the incidence of atelectasis, this underestimation should be present in both groups of patients. This underestimation of the incidence would not affect the differences detected between the two groups.

We have added these comments in the limitations of the study (page 12, paragraph 3)

3.- Are the data sound?

What does HTA mean?

- We have changed HTA, which it is the abbreviation of Hypertension in Spanish, for ‘Hypertension’ (our apologies).

- “64.6% had 3 affected coronary vessels, 16.3% 4 vessels and the remained patients (one, two vessels?). The number of coronary vessels grafted is close related with anesthesia and operative times”

Based on the reviewer’s comment, we have included the number of patients with 1 or 2 affected vessels in the text: “Most patients had 3 (64.6%) or 4 (6.3%) affected vessels, whilst 5.7% had 1 and 13.3% had 2 affected vessels”. (page 9, paragraph 1)

“In P- 11 it is mentioned 17.3% of atelectasis incidences among the patients who received physiotherapy assistance, however in total of 159 patient 27 individuals had had atelectasis (A percentage of 16.98% that is not shown in table 3). The same difference happens with 37 patients in total of 104 (35.57% and not 36.3%). It would be interesting to recalculate the data. Maybe with these new values it would have different statistical significances”.

In some patients it was not possible to determine the incidence of pulmonary complications and, in particular, of atelectasis. As a result, the denominators for calculating the incidence of atelectasis in both groups of patients were 156 and 102 instead of 159 and 104 patients, respectively. We have indicated this in the tables, where we have included the number of patients with data available for each of the variables studied. As may be seen in the tables, the percentage of missing values is very low in all cases.
Which would be the explanation for a bigger incidence of atelectasis in women. As is shown in the results of P.11?

Other authors have also found differences in this variable. When we carried out a logistic regression analysis (Table 5) the sex variable was not statistically significant for the presence of atelectasis

5. “title criticism” We have changed the title

6. Are limitations of the work clearly stated?

“It is important to discuss study limitations”. In the Discussion we have included the limitations connected with the CAT scan, the lack of assessment of patient compliance with the exercise recommendations, and the type of study previously mentioned. (page 12, paragraph 2-5)

8. “The title mentions respiratory physiotherapy and incidence of atelectasis and the study objective is to determine if preoperative respiratory physiotherapy diminishes the incidence of pulmonary complications”

As previously mentioned, we have changed the title of the paper: “Respiratory physiotherapy and incidence of pulmonary complications in off-pump coronary artery bypass graft surgery: an observational follow-up study.

Additional comments

Based on the reviewer’s comments, we have included some of the references they mention:

