Author's response to reviews

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

In relation to your e-mail regarding the manuscript entitled “Respiratory physiotherapy and incidence of pulmonary complications 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 reviewer 1 (Heather M. Arthur) providing a point by point response to her concerns.

In this letter, we have marked the comments of the reviewer in bold text. In the manuscript, we have marked in blue the new additions to the “revised paper”.

Following your indications, we have also revised the format of the manuscript according with the journal guidelines.

We are researchers from the University Hospital Complex of A Coruña (CHUAC) (Spain), which belongs to the Galician Health Service (Servizo Galego de Saúde), a member of BioMed Central.

I look forward to your reply.

Yours sincerely,

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Reviewer's report

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

Version: 2 Date: 24 May 2009

Reviewer: Heather M Arthur

Reviewer's report:

Although the authors have responded to most of the questions raised in the previous review, I remain dissatisfied with aspects of the question and the methods. Justification for the importance of this study in "off pump" CABG patients (other than it has not been reported before) is necessary. This group of patients is probably lower risk than other CABG patients and the uniqueness of the question in this study is not clear. My concern about compliance was also related to clearly documenting the compliance of the physical therapists in providing the intervention. We are simply asked to take the authors' word on this. Finally, the sample size justification needs a better explanation, describing the formula or methods used to arrive at the sample size.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.
Answers to the review
Referee 1: Heather M Arthur

1 - “Justification for the importance of this study in “off pump” CABG patients (other than it has not been reported before) is necessary”

The reasons for the importance of this study in off-pump CABG surgery that we previously mentioned in the manuscript were:

a) “There is a lack of studies regarding the effect of preoperative physical therapy in off-pump CABG surgery” (Page 4, last paragraph).

b) In addition, all patients underwent grafting using 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” (page 3, paragraph 6).

We also consider that:

c) There is uncertainty in relation with the incidence of respiratory complications following this surgery technique. As it is shown in the following references, the studies published to date have been, as a whole, unable to conclusively demonstrate advantages of off-pump CABG:


These references have been added in the Introduction section in the paper with the numbers [8], [9] and [10].

d) During the study period, 326 patients were submitted to CABG surgery in the A Coruña Hospital (previously named Juan Canalejo Hospital). Three hundred and eight (94.5%) of these patients were submitted to off-pump CABG surgery (263 met the inclusion criteria for this study). In this Hospital centre, this surgery technique is increasingly used to minimize the incidence of cardiovascular events such as post-pump encephalopathy and systemic inflammatory response syndrome. Therefore, we think it is justified to study what happens to the majority of these patients.

As we mention in the text, “The philosophy of the Juan Canalejo University Hospital in A Coruña is to carry out CABG surgery without manipulating the ascending aorta and without the need for on-pump, systematically resorting to the use of double mammary

2 - “This group of patients is probably lower risk than other CAGB patients and the uniqueness of the question in this study is not clear”

As we mentioned before, 94.5% of the cases with CABG surgery in A Coruña Hospital were submitted to off-pump CABG surgery. Initially, all of the patients are candidates for off-pump CABG surgery. The main reason for doing on-pump CABG surgery is that during the surgery small caliber of the arteries is detected, so the anastomosis is not possible and a saphenous vein graft must be used. This happened only in 18 of the 326 patients submitted to CABG surgery during the study period.

3 - “My concern about compliance was also related to clearly documenting the compliance of the physical therapist in providing the intervention”

Every day, each patient received one physiotherapy session, with each session lasting 15-20 minutes. All the physiotherapists were trained by a supervisor before the start of the study. This supervisor was the one in charge of assigning patients to physiotherapists and of controlling the time spent with each patient. On a daily basis, patients were discussed within the group of physiotherapists.

These comments were added to the manuscript (page 7)

4 – “The sample size justification needs a better explanation, describing the formula or methods use to arrive at the sample size”

The sample size calculation was performed with the R statistical package [1] (version 2.8.1, 2008; The R Foundation for Statistical Computing) and EPIDAT statistical software [2] (version 3.1, 2006; Dirección Xeral de Saude Pública, Organización Panamericana de la Salud).


Our group has also a web of methodological issues in: http://www.fisterra.com/mbi/investiga/index.asp and the aspects of sample size can be seen in the same web in: http://www.fisterra.com/mbi/investiga/9muestras/9muestras.asp

One objective of the study was to determine the characteristics of the patients who were submitted to off-pump CAGB surgery. For our previous experience with these patients, we have an idea of the prevalence of the incidence of pulmonary complications in off-pump coronary artery bypass graft surgery:

Vázquez, FJ; Juffé, A; Pita, S; Cuenca, J; Tarrió, R; Herrera, JM; Campos, V; Portela, F; Rodríguez, F; Valle, JV; Zavanela, C. Preoperative risk factors to predict greater morbidity in coronary artery bypass grafting surgery without extracorporeal circulation. The Canalejo score. An Cir Card Cir Vasc 2006, 12 (4): 182-190

Vázquez Roque, FJ; Juffé, A; Pita, S; Tarrió, R; Cuenca, J; Herrera, JM; Campos, V; Portela, F; Rodríguez, F; Valle, JV; Zavanela, C. Value of a six risk stratification models in cardiac surgery to predict mortality in coronary artery bypass grafting surgery without extracorporeal circulation. An Cir Card Cir Vasc 2005, 11 (3): 129-135, 135

So, first we estimate the sample size needed for the study (n=263) by using the formula:

\[ n = \frac{Z_a^2 \times p \times q}{d^2} \]

where

- \( Z_a = 1.96^2 (\alpha=0.05) \)
- \( p = \text{expected proportion (we choose } p=0.5) \)
- \( q = 1 - p (q=1 - 0.5 = 0.5) \)
- \( d = \text{precision (in this case } d=6.1\%) \)

For the second objective, to detect a difference between proportions of 17% versus 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 used the following formula:

\[ n = \frac{Z_a \times \sqrt{2p(1-p)} + Z_\beta \times \sqrt{p_1(1-p_1) + p_2(1-p_2)}}{(p_1 - p_2)^2} \]

where

- \( n = \text{sample size in each group} \)
- \( Z_a = 1.96 (\alpha=0.05) \)
- \( Z_\beta = 0.84 (\beta=0.20) \)
- \( p_1 = \text{expected proportion in Group 1.} \)
- \( p_2 = \text{expected proportion in Group 2.} \)
- \( p = \text{average of proportions in both groups} \)
In the paper the sample size justification is described as follow: “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 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”.

Even though we initially estimated that 103 patients would be needed in each group, we finally included 104 and 159 patients, respectively, because we included the patients consecutively. We continued including patients until the minimum sample size was achieved in both groups. This comment has been included in the manuscript.

We consider that the formulas used to calculate the sample size are very well known and therefore they would not provide additional relevant information in the text. However, following the reviewer’s recommendation, we include in the manuscript the following references, where these equations can be consulted:

Daniel DW. Biostatistics. A foundation for analysis in the health sciences. New York, John Wiley & Sons, 2005 (pp. 189-190)


5 – “Quality of written English”

We have sent the manuscript again to a professional English translator.