Author’s response to reviews

Title: PRESERVATION OF RENAL FUNCTION IN CARDIAC SURGERY PATIENTS WITH LOW CARDIAC OUTPUT SYNDROME: LEVOSIMENDAN VS BETA AGONISTS

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Version: 5 Date: 10 Aug 2019

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Abstract

I would suggest the statistical test be included in the results section with the appropriate statistics (more than simply reporting the p-value).

We have changed it, now:
Methods: It is a quasi-experimental study. A total of 100 patients with LCOS received either beta-agonists or levosimendan. We assessed the incidence of postoperative kidney failure in cardiac surgery patients. In patients who had kidney failure at diagnosis of LCOS, we examined whether differences existed in the evolution of kidney failure based on the treatment administered for LCOS. The parameters measured included haemodynamics, oxygen supply, and renal function as assessed by the AKI scale.

Introduction

The introduction requires a paragraph and statement that explains the research gap. It currently reads as mostly a summary of previous work with no connection to the current objectives of the study.

We have changed it, now:

Our group published recently a series of articles demonstrating the protective effects of levosimendan on renal function in patients with severe ventricular dysfunction at high risk for kidney failure. These effects are partially exerted by drug-induced renal preconditioning via the opening of mitochondrial KATP channels (9).

The need to evaluate the possible nephroprotective effect of the drug in patients with low cardiac output syndrome, independent of its inotropic role is the objective of our study.

We postulated that the use of levosimendan as compared to beta-agonists in cardiac surgery patients with LCOS and kidney failure exerts beneficial preconditioning effects on renal function that are independent from its cardioprotective effects. We collected data from cardiac surgery patients who developed LCOS from the more than 600 patients who underwent cardiac surgery in our unit in the last three years. We investigated the potential protective role of levosimendan against renal dysfunction in these patients

Methods

The authors should explain why they used a quasi-experimental study design.

There should be a statement regarding the simple size calculation. Why did they select 50 patients? The data analysis strategy is confusion and poorly written. It would benefit from English language editing as well. Also, identify the statistical software used.

We have changed it, now:

We estimated that a sample of 100 patients with LCOS was required, assuming a reported incidence of 30% of kidney failure in these patients for a 95% CI and a minimum precision of
10% to compare the effects of levosimendan vs beta-agonists in patients with kidney failure at diagnosis. The team conducting the statistical analysis was blinded to the group analyzed. Epidat 4.0 was the statistical software used.

A descriptive statistical analysis was first conducted. Continuous variables were expressed in a table as means, standard deviations or medians based on normality of distribution. If continuous quantitative variables were normally distributed –as assessed by Shapiro-Wilk test– were measured by the ANOVA test. Differences between baseline values and values at 24 h and 48 hours were assessed by Student's t-test when normally distributed in each group. Normal distribution was tested by the Shapiro-Wilk test; otherwise, Wilcoxon or Friedman tests were used. The Wilcoxon and Friedman test are a non-parametric statistical hypothesis test used to compare two related samples, matched samples, or repeated measurements on a single sample to assess whether their population mean ranks differ (i.e. it is a paired difference test). It can be used as an alternative to the paired Student's t-test (also known as "t-test for matched pairs" or "t-test for dependent samples") when the population cannot be assumed to be normally distributed (Lowry, Richard. "Concepts & Applications of Inferential Statistics")

Results

The structure of the section is unorganized and it makes it difficult to read. Please start off with a description of the sample and refer to Table 1 for details. Then discuss the inferential findings.

We have changed it, now:

In our study we finished the recruitment when 100 patients had a diagnosis of low cardiac output syndrome, these patients had an incidence of kidney failure at diagnosis of 30%. We studied both groups (levosimendan vs beta agonist), with 50 patients in each one. Table 1.

Table 3. The column with 'ns' can be removed.

We have deleted it.

Discussion

The study is well analyzed and situated within the existing literature. I would suggest that the authors explain the clinical implications of the study findings.

We have changed it, now:

The possibilities of a relationship between the effect on potassium channels, as well as the possible properties related to pharmacological post-conditioning, in addition to the improvement
of renal perfusion through the treatment of low cardiac output, should be the starting point again clinical trials that have the ability to confirm our findings.

Moreover, the limitations section should be expanded and included as a separate paragraph to improve its readability

We have changed it:

LIMITATIONS:

The main limitation of this study was that patients were not randomized to treatment groups. The reason is that we preferred that physicians treated their patients with the medications they were more familiar with. This may have caused bias in the interpretation of results, as physicians will probably favor the conventional therapy. A triple-blinded study was not possible due to the type of study. However, the team conducting statistical analysis was blinded to the group analyzed. The use of certain biochemical parameters with greater sensitivity and specificity (N-GAL or Cystatin C), would also be useful to evaluate their action

REQUESTED REVISIONS:

The statistical analysis is appropriate. I would encourage that the authors explain why they selected the inferential tests and consider non-parametric testing.

Wilcoxon and Friedman test are a non-parametric statistical hypothesis test used to compare two related samples, matched samples, or repeated measurements on a single sample to assess whether their population mean ranks differ (i.e. it is a paired difference test). It can be used as an alternative to the paired Student's t-test (also known as "t-test for matched pairs" or "t-test for dependent samples") when the population cannot be assumed to be normally distributed (Lowry, Richard. "Concepts & Applications of Inferential Statistics")