Author’s response to reviews

Title: Marginal unit costs are falling as numbers of LVADs are growing: Experiences from Oslo University Hospital

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

Thank you for your response dated 30 Mai 2012 regarding our submission of our manuscript RE: 1833073570715796 - Marginal unit costs are falling as numbers of LVADs are growing: Experiences from Oslo University Hospital for Journal of Cardiothoracic surgery.

First we would like to express our gratitude to expert reviewers for their comments to improve our manuscript. According to their objections and suggestion, we have revised the manuscript and provide additional information.

Reviewer #1:  
1) Introductory comments
Is the independent variable “time” binary (VA vs HVAD) or ordinal (implant nr 1 vs 2 vs 3 etc.)?

Page 5 line 22: Initial testing indicated that the best model fit was achieved by linear regression models. Two different specifications were estimated for each of the two dependent variables. Due to few degrees of freedom (few cases) the number of independent variables will be strongly limited. Both specifications included number of patients and days on ECMO. Number of patients worked as a trend variable and was simply described as a variable taking the value of 1 for the first LVAD-procedure and increasing by 1 for each consecutive treatment.

Clarity on hypothesis and conclusion. Please be very clear about the hypothesis, which variables changed over time, and whether the hypothesis was confirmed or not.

Page 4 line 7: The aim of this study was to investigate how total hospital costs per patient developed as the number of LVAD procedures increase and clinical experience was accumulated. The data consisted of information of patients from two subsequent periods where two different 3rd generation LVADs were used; in period 1VentrAssist™ LVAD (removed from the market in 2008) and in period 2 HeartWare™ LVAD (Framingham, MA, USA).
Our hypothesis was that total hospital cost will decrease as we gain experience through introducing new LVAD program.

Statistics. There are no statistics to support the findings. Are the changes statistically significant?

Page 10 line 1: Although the results from the regression analyses should be regarded as indicative as the number of units are low, the gradually declining costs were confirmed.

2) Title and abstract

Title: unit cost? This is not an analysis of unit cost but of total implant cost as numbers of LVAD IMPLANTATIONS are INCREASING

Page 1 line 9 title changed: Hospital costs fell as numbers of LVADs were increasing: Experiences from Oslo University Hospital

Abstract: The abstract is much much too long. Suggest shorter and more clear and concise, e.g.: ... consecutive implantation series of two 3rd generation Left Ventricular Assist Devices (LVADs).

Page 2 line 5-9 changed: The current study was undertaken to examine total hospital costs per patient of a consecutive implantation series of two 3rd generation Left Ventricle Assist Devices (LVAD). Further we analyzed if increased clinical experience would reduce total hospital costs and the gap between costs and the diagnosis related group (DRG)-reimbursement.

Cost data of ... VentrAssist from 2005-2009 and ... HeartWare from 2005-2011. Total cost .. per patient?
Costs: suggest compare e.g. total cost, length of stay and reimbursement for period 1 vs 2, with p-values, and then the regression.
Page 2 line 23- page 3 line 7 changed to comparison of total hospital cost, DRG reimbursement and length of stay.

Clarify regression – readers are clinicians. 14096 USD less cost for each additional patient. Would mean > 300000 USD less cost over the time period of 29 patients? Reasonable?
Regression analysis page 2 line 18-19: We used regression analyses to analyze cost variations over time and between the different devices

Abstract conclusion: sufficient with one or two sentences.
Page 3 line 9-11 Abstract conclusions revised according to suggestions. There were significant reductions in total hospital costs per patient as the numbers of patients were increasing. This can possibly be explained by a learning effect including better logistics, selection and management of patients.

3) Background, method, result and discussion

For consistency: LVAD, not VAD.
Page 4 line 2 and page 8 line 20 is changed from VAD to LVAD.
Cost effective: not true! The cited refs 5-7 suggest that cost effectiveness is WORSE than suggested norms (Western norms around 100,000 Euro per QALY). There is an editorial by Slaughter and Rogers that suggests that LVADs are nevertheless justifiable, and there is an older study by Hutchinson that suggests that cost per QALY is something like 30-80,000 USD, but it cannot be said that LVAD is cost effective. Better to say that cost effectiveness is likely improving with time. This belongs in discussion. Furthermore, this is a study about cost, not cost effectiveness. Therefore background should address previous literature on cost. See e.g. Slaughter J card surg 2011.

Page 4 line 7-8 Cost effectiveness part has been moved to discussion page 10 line 23 .According to suggestion this reference is added in reference list

Page 4 line 13-16: regression analysis is removed for this section and discussed in statistical method page 5 line 22 – page 6 line 5.

State clearly and sequentially aims and hypothesis. What was the hypothesis? That total costs decline over time? The aim of this study was to investigate how total hospital costs per patient developed as the number of LVAD procedures increased. The data consisted of information of patients from two subsequent periods where two different 3rd generation LVADs were used; in period 1 VentrAssist™ LVAD (removed from the market in 2008) and in period 2 HeartWare™ LVAD (Framingham, MA, USA). Costs of the pre-LVAD work-up and treatment, the LVAD implantation phase as well as the post-LVAD care were evaluated in a setting of implementation of a new treatment program.

Methods: Why is the pre-LVAD phase included? Is it relevant? Is there reason to believe? that costs of pre-LVAD care have declined over time. The rationale and hypothesis for the different costs declining should be stated. If the authors hypothesized that all 3 phase costs have declined over time they should state the rationale for this.

Page 8 line 22-page 8 line 8
The mean total cost for the LVAD procedure is largely driven by the pre-LVAD phase where significant personnel resources were used commonly related to ICU
treatments. In the LVAD phase the major part of cost was related to device cost. However, as different LVADs systems in pipeline are offered by different manufacturing companies and indications will be expanded to a more widespread use, it is likely that device costs will be reduced in the future.

It is worthwhile to mention that total cost for all three phases was almost 30% lower (from $ 585,513 to $ 413,185) in the second era using the new device for intrapericardial placement (HeartWare™LVAD) compare to the first pump used (VentrAssist™LVAD) which in most instances also required more extensive surgery. The total mean cost for pre LVAD phase of the first 20 VentrAssist™LVADs to nine HeartWare™LVADs the total mean cost for HeartWare™LVAD was 62% lower (186,467 to 63,963), indicating a more aggressive attitude to LVAD implantation than in the first study period.

Days on ECMO was entered into the regression to control for SELECTION bias? If aim is to control for selection bias, then surely age, renal function, organ failure, etc etc are also important?

Page 6 line 1: Days on ECMO was entered to control for high risk patients. Additionally, we included a variable describing type of LVAD in one of the specifications. Type of LVAD was described by a dummy variable (HeartWare™=1).

If the aim was to facilitate comparison with DRG (which is discussed later in the methods), then this reason should be stated here.

Page 11 line 6: Assuming that our cost estimates are correct, the discrepancy between cost and reimbursement illustrates one of the basic problems by the price setting in the DRG-system

Regression:
The background states that the aim was to ... cost in two subsequent periods. The "periods" is a binary categorical variable. But analyses appear to consider each consecutive implant, in which case the independent variable is an ordinal categorical variable and no distinction is made between early and late period. Statistics:
There is only descriptive data. How does the reader know that the decrease in cost is statistically significant?

Page 10 line 1 Although the results from the regression analyses should be regarded as indicative as the number of units are low, the gradually declining costs were confirmed. The marginal cost reduction was 14 096 US$ or 3.7% per patients calculated on the basis of total hospital costs excluding device costs. Within the range of this analysis there was no indication that the cost reductions were decreasing. The results should be considered in the light of the fact that by the first patients our institution was trying to establish a new treatment program. Costs at this stage were associated with low volume and high use of manpower. The higher cost among the first patients can be explained by longer LOS and more invasive treatment.
Results:
Please be consistent with numbers and punctuation: e.g. 385,941. Not 385 941.
Page 6 line 23 correct punctuation

Total costs excluded device costs? You mean excluding?
Page 7 line 25 Device costs were 121,280$ for VentrAssist™ LVAD and 200,913$ for HeartWare™. Of the two different specifications the ones without a dummy variable describing type of LVAD perform best for both dependent variables (Table 3). Of the analyses of the two dependent variables the one were device costs are excluded have the best performance (Adjusted $R^2=0.34$). The estimates from the regression analysis of total costs excluding device costs indicated that costs were falling as the number of treated patients increased

Table 2: unclear. Why only one column for Cost drivers pre-LVAD and LVAD phase?

Tabel 2 include complete and correct information for pre –LVAd and LVAD phase

Adverse events: How were they related to costs? This analysis seems possible to do.
We did not attempt to calculated separate cost of adverse events, even it is well known that adverse effect results in longer hospital stay. All cost during hospital stay was calculated regardless of reason.
Post LVAD phase considered one year from LVAD implant date so one year hospital cost of revisit /readmission was calculate.

Discussion:
Again, the authors are confusing with regard to cost vs cost effectiveness, which are very different things. There are no trials evaluating cost effectiveness of these two devices, but that is irrelevant, this paper do not do so either. The first paragraph in the discussion should very briefly summarize the findings in the study. Which costs fell over time and which changes were statistically significant? USD 59,000 per QALY. This is the third place in the paper that cost effectiveness appears, each time giving different references. Please unify and be consistent. Cost effectiveness deserves brief mention in discussion but nowhere else because this work has nothing to do with cost effectiveness.

Cost effectiveness issues has been disused briefly as main focus is hospital cost.
4) **Quality of written english**: Needs some language corrections before being published

Added - Appendix: Regression analysis results

*Thank you for comments this article is improved and checked for written English.*

We hope that you will consider our views and give us opportunity to publish in the journal.

Sincerely

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