Format for ANSWERING REVIEWERS

July 22, 2013

Dear Editor,

Please find enclosed the edited manuscript in Word format (file Revised-subcutaneous ICD-akerstrom 2013-wjc-invited-review.doc).

Title: Subcutaneous implantable defibrillator: state-of-the art 2013

Author: Finn Akerström, Miguel A. Arias, Marta Pachón, Alberto Puchol, Jesús Jiménez-López

Name of Journal: *World Journal of Cardiology*

ESPS Manuscript NO: 4315

The manuscript has been improved according to the suggestions of reviewers:

1 Format has been updated

2 Revision has been made according to the suggestions of the reviewers

Reviewer 00214291

1. Page 8: One limitation of the START trial is the fact that ICDs from three different manufacturers were used, because their detection algorithms are at least slightly different. Therefore, it is problematic to compare the performance of the subcutaneous defibrillator to a cohort of ICDs provided by 3 different manufacturers (e.g. when calculating the sensitivity and specificity). This limitation should be acknowledged. Furthermore, the study does only comprise 64 patients.

We agree with the reviewer that the limited number of patients and use of 3 different transvenous ICDs (TV-ICDs) with different arrhythmia detection algorithms constitute significant study limitations. However, we also believe that it was important to include different TV-ICDs in the analysis in order to make the results more applicable to routine clinical practice. Furthermore, separate analyses for each TV-ICD vs. S-ICD were made (significantly superior specificity for the S-ICD when compared to 2 of the 3 TV-ICDs). The following sentence has been modified and now reads (page 6; line 22): "*It should be noted however, that the START study included a limited number of patients, only evaluated induced arrhythmias and that most of the atrial tachyarrhythmias were atrial fibrillation.*" Another sentence has been added (page 6; line 24): "*Furthermore, given that 3 different TV-ICD systems were included, comparison of the composite performance of these systems vs. ICD-S should be interpreted with caution since their arrhythmia detection algorithms are not identical.*"

2. S-ICD System Clinical Investigagtion study: 92 % procedure-related complication-free rate at 180 days. Please provide data about the complications which occurred during follow-up.

Details about the complications during the first 180 days have been added to the manuscript. However, complication data during the whole follow-up are currently not available since the study has not been published and because it was not part of the endpoints. The following section has been modified and now reads (page 6; line 33): "*A total of 321 patients were included in the safety cohort and of those 92% had*

met the procedure-related complication-free rate at 180 days. Complications included (number of patients) system infections (4), suboptimal pulse generator and and/or electrode position (4), lead dislodgement (2), oversensing (3), inappropriate shock (3) and premature battery depletion (2). In 10 patients the device was explanted due to system infection (4), oversensing (2), pre-mature battery depletion (1), CRT indication (1), need for ATP (1), and elective due to patient request (1). The device successfully converted 100% of the induced VF episodes."

3.) Spelling mistakes (e.g. page 5, line 22: manucture__; page 12, line 9: two important studies will are; page 13, line 16: who patients; page 13, line 20: Nevertheless, patient_
The spelling mistakes have been corrected.

Thank you very much for your interesting and proper comments.

Reviewer 00225356
1. The author should add a table in which they list the best and worst candidates for this type of defibrillator. This will allow to simplify the relative paragraph ("What patients should receive a subcutaneous cardiac defibrillator?")
Please refer to Table 3 "S-ICD patient suitability".

2. I would stress even more that the post-implant test should be done in these cases and explain the rationale for this, opposite to what happens with TV-ICD, for which routine post-implant test is no longer mandatory and is frequently avoided, without compromising safety.
The following sentence has been added (page 4; line 7): *"Noteworthy, since the device safety and effectiveness data comes from studies that utilized defibrillation testing this constitutes an obligatory step during implantation of the S-ICD, as opposed to the TV-ICD system where this is no longer considered necessary."*

3.The title should read: "Subcutaneous implantable defibrillator: state-of-the art 2013"
The title has been modified accordingly.

Thank you very much for your interesting and proper comments.

3 References and typesetting were corrected

Thank you again for publishing our manuscript in the *World Journal of Cardiology*.

Sincerely yours,

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