Utility of minimum dataset for generation of real-world data in a context with evidence gaps: the left ventricular assist device as a destination therapy

CO262

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INTRODUCTION

Patients with advanced heart failure who are not candidates for cardiac transplant could benefit **from left ventricular assist device (LVAD) implantation** as destination therapy (DT). However, key issues exist regarding the selection of suitable patients.

In order to solve these uncertainties, a Delphi consensus-based minimum dataset (MDS) composed of 18 outcomes and 47 variables/measures divided into 7 domains was developed.

This MDS was included in a **real-world prospective multicenter registry** (Monitoring study of LVAD as DT) in the Spanish National Health System (NHS).

OBJECTIVES

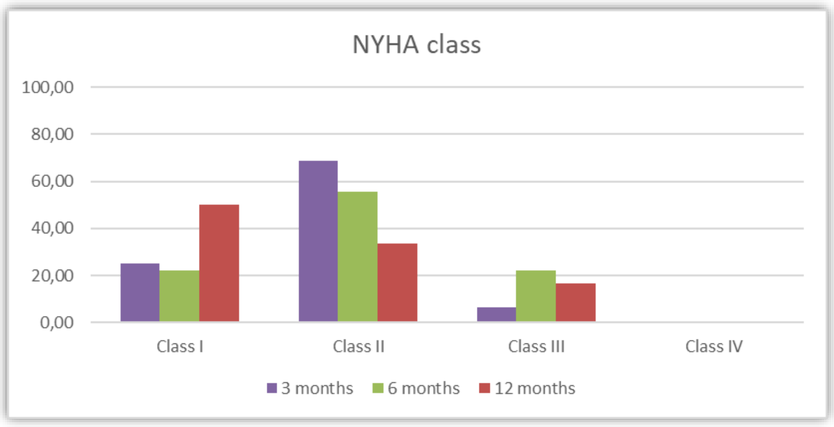
The **aim of this registry** evaluate the implementation and **utility of the proposed MDS** in working out evidence gaps identified previously.

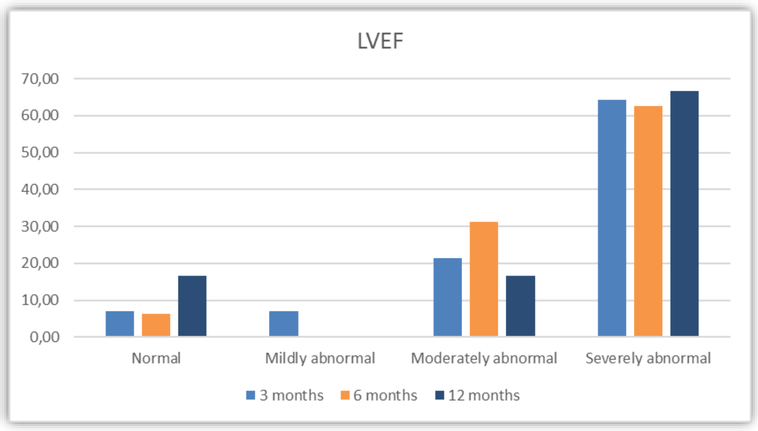
METHODS

- A **registry protocol** was designed including criteria of patient's selection, follow-up intervals (3, 6, 12, 24 months), sample size, quality data assurance plan and the MDS created previously.
- The protocol was approved by all participating hospitals (n=22).
- A **qualitative evaluation addressing the MDS usefulness** solving evidence gaps was done.

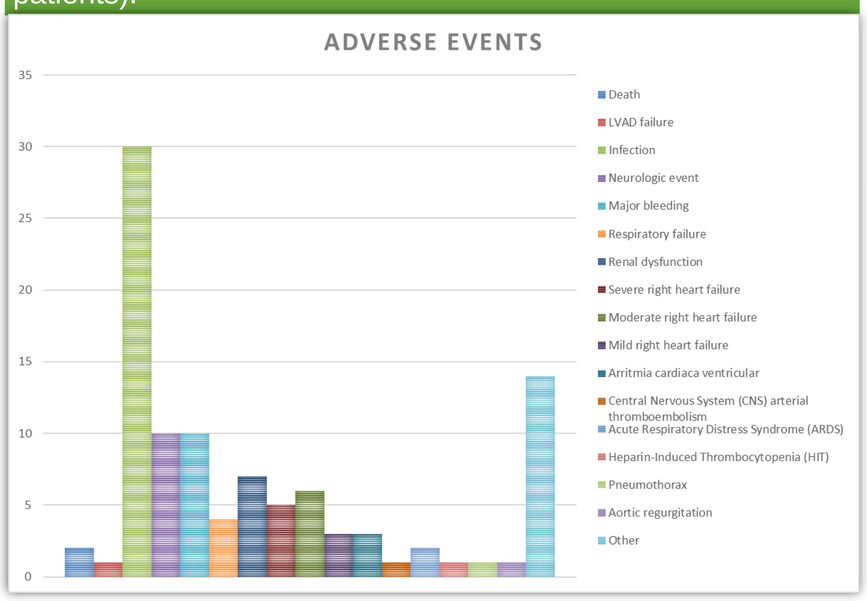
RESULTS

Regarding the effectiveness of LVAD as DT, it was reported an **slightly improvement of clinical/hemodynamic outcomes** (NYHA class and LVEF).





In the first year of follow-up, the main identified challenge was the **high rate of adverse events** (n=101 events in 48 patients).



Outcome	3 months (n=13)	6 months (n=14)	12 months (n=6)
KCCQ-12 scale (mean±SD)	69.19±29.38	77.38±27.06	86.28±36.89
EuroQoL-5D-3L (mean±SD)	0.861±0.154	0.934±0.120	0.928±0.134
Satisfaction[1] (Likert scale)(n/% patients)	n=15		
Very satisfied	3 (20%)	5 (27.8%)	3 (50.0%)
Satisfied	11 (73.0%)	8 (44.4%)	3 (50.0%)
Neither satisfied nor dissatisfied	1 (6.7%)	4 (22.2%)	0 (0%)
Dissatisfied	0 (0%)	1 (5.7%)	0 (0%)
Very dissatisfied	0 (0%)	0 (0%)	0 (0%)
Acceptability[2] (Likert scale)(n/% patients)	n=15		
Absolutely not	0 (0%)	0 (0%)	0 (0%)
Not	0 (0%)	1 (5.7%)	0 (0%)
I don't know	2 (13.3%)	4 (22.2%)	3 (33.3%)
Yes	10 (66.7%)	8 (44.4%)	3 (33.3%)
I am sure	3 (20.0%)	5 (27.8%)	3 (33.3%)

[1]In general, how satisfied are you living with LVAD and [2]Indicate the degree of agreement with the following statement: "If I found myself the same as before, I would have surgery again"

In addition to that, patient-centered outcomes as quality of life (QoL)(EuroQoL and KCCQ) improved both in overall scores and by dimensions. Moreover, patients reported feeling satisfied with intervention and would undergo surgery again.

CONCLUSIONS

- The development of MDS based on identified evidence gaps and its implementation in a real-world registry can be a feasible strategy for generating valuable additional information for better-informed decisions.
- The safety and clinical/hemodynamic results were aligned with previously published results. However, results about QoL and satisfaction/acceptability of patients provided relevant information related to these outcomes considered evidence gaps, as they are not well reported in published literature.
- A long-term follow-up is needed to confirm these initial findings.

REFERENCES

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