ALTSHOCK-2

CLINICAL TRIAL SUMMARY

Presenters	Niguarda Hospital
Objectives	To demonstrate the superiority of early intra-aortic balloon pump (IABP) implantation at admission over local clinical practice (pharmacological only) in acute decompensated heart failure patients with cardiogenic shock with respect to 60-day survival or successful bridge to heart replacement therapies.

Source: https://clinicaltrials.gov/study/NCT04369573

TRIAL DESIGN

Multicentre Prospective Controlled Randomized National, Open-Label, Parallel Assignment trial

SAMPLE SIZE

787 patients underwent screening and 101 were enrolled at 7 centers

INCLUSION CRITERIA

- Age ≥ 18 and < 75, men and women;
- nNed of vasoactive agents to maintain SBP > 90 mmHg or MAP > 60 mmHg.
- Left ventricle systolic function ≤35%
- SCAI B-D according to CSWG definition (JACC 2022)

METHODOLOGY

•Of the 101 patients included in the final analysis, 53 patients were in the IABP group and 48 in the standard care group.

• The **primary endpoint** was survival or successful bridge to heart replacement therapy (HRT) at 60 days. **Secondary endpoints** included overall survival, maximum inotropic score, and maximum sequential organ failure assessment score.

RESULTS

The study reported 28% of the patients with Society for Cardiovascular Angiography and Interventions stage B, 57% with stage C, and 15% with Stage D. The trial was stopped due to futility.

The primary endpoint was attained in 81% of the patients in the IAPB group and 75% in the control group. Thirty-seven percent had HRT ≤60 day follow-up. Escalation was in four patients in the study group and two in the control group.

Thirteen percent of the patients who were initially assigned to the standard care were crossed over to IABP. No differences in the complications was reported.

CONCLUSION

Routine early placement of an intra-aortic balloon pump (IABP), when added to standard care, did not lead to a significant improvement in survival or successful bridging to heart replacement therapy (HRT) in patients with heart failure-related cardiogenic shock

Morici N, Sacco A, Frea S, et al. Early Intra-Aortic Balloon Support for Heart Failure-Related Cardiogenic Shock: A Randomized Clinical Trial. *J Am Coll Cardiol*. 2025;85(16):1587-1597. doi:10.1016/j.jacc.2025.03.003