

Levosimendan vs intra-aortic balloon pump in coronary artery bypass grafting: a meta-analysis

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Corresponding author:

Dan Sheng

2671647426@qq.com

Author Affiliation:

Hunan University of Chinese Medicine.

Sheng, D¹; Wang, YJ²; Zhong, LQ³; Wang, YJ⁴; Fu, SY⁵; Sun, X⁶; Llang, H⁷.**ADMINISTRATIVE INFORMATION**

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Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202360092

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 June 2023 and was last updated on 29 June 2023.

INTRODUCTION

Review question / Objective P:adult patients (≥ 18 years) in coronary artery bypass grafting. I:Levosimendan. C:intra-aortic balloon pump. O:atrial fibrillation, postoperative mediastinitis, need for inotropic support, in-hospital mortality, postoperative length of stay, ventilation time. S:randomized controlled trials.

Condition being studied Coronary artery bypass grafting(CABG) is the most effective surgical procedure for the treatment of coronary artery disease, especially in patients with complex lesions and high-risk coronary artery disease, It is based on hemodynamic reconstruction to increase blood supply to the myocardium by diverting blood flow to other arteries, improving blood circulation, and reducing the risk of myocardial infarction. After

coronary artery bypass, recanalization of the distal end of the blocked vessel may improve myocardial ischemia and hypoxia . However, cardiac rehabilitation after CABG is a complex process and it is worth considering how to facilitate cardiac recovery and reduce complications.

Levosimendan is a new positive inotropic drug that differs from traditional positive inotropic drugs in that it increases the sensitivity of cardiac myocytes to calcium by binding to troponin C, and has the dual effect of increasing the sensitivity of cardiac myocytes to calcium ions. Levosimendan can be used in cardiac surgery to protect the heart, reduce ischemia or reperfusion injury, improve postoperative cardiac function, and effectively prevent and treat postoperative heart diseases. Historically, the intra-aortic balloon pump (IABP) has been the most widely available circulatory support method for patients who have undergone cardiac surgery[6]. IABP has the potential to be

used as a first-line therapy and has been associated with improved survival when implanted in high-risk patients in the preoperative phase. The IABP is the most commonly used mechanical assist device in China. The balloon inflates when the heart is in diastole to increase perfusion of the brain, coronary arteries, and peripheral circulation and deflates during cardiac systole to reduce cardiac afterload, increase cardiac output, and improve circulation.

The prognosis of CABG patients has been reported to be improved by the prophylactic use of IABP. But the main disadvantage of IABP is the emergence of problems related to balloon fitting, such as limb ischaemia and vascular damage, particularly in patients with systemic atherosclerosis. Levosimendan, a novel medication for the treatment of high-risk cardiac patients, has been shown in the majority of earlier studies to enhance intraoperative hemodynamic parameters and lessen the occurrence of postoperative low cardiac output syndrome, which in turn lowers the incidence of postoperative mortality and improves prognosis and has fewer side effects. To ascertain the difference in complication rates between these two therapies.

METHODS

Search strategy

1. PubMed:

1 # (((simendan[MeSH Terms]))OR (levosimendan)) OR (intravenous levosimendan);

2 # (intra-aortic balloon pump[MeSH Terms]) OR (Intra Aortic Balloon Pumping OR Intraaortic Balloon Pumping OR Balloon Pumping, Intraaortic OR Pumping, Intraaortic Balloon OR Pumping, Intra-Aortic Balloon OR Balloon Pumping, Intra-Aortic OR Pumping, Intra Aortic Balloon);

3 # (coronary artery bypass[MeSH Terms]) OR (Artery Bypass, Coronary OR Artery Bypasses, Coronary OR Bypasses, Coronary Artery OR Coronary Artery Bypasses OR Coronary Artery Bypass Surgery OR Bypass, Coronary Artery OR Aortocoronary Bypass OR Aortocoronary Bypasses OR Bypass, Aortocoronary OR Bypasses, Aortocoronary OR Bypass Surgery, Coronary Artery OR Coronary Artery Bypass Grafting);

4 # 1 and # 2 and # 3

2. EMBASE:

1# 'levosimendan'/exp OR levosimendan OR (intravenous AND levosimendan)

2# 'intraaortic balloon pump'/exp OR 'intraaortic balloon pump' OR (balloon AND pumping, AND intraaortic) OR (pumping, AND intraaortic AND balloon) OR (pumping, AND 'intra aortic' AND

balloon) OR (balloon AND pumping, AND 'intra aortic') OR (pumping, AND intra AND aortic AND balloon)

3# 'coronary artery bypass graft'/exp OR (artery AND bypass, AND coronary) OR (artery AND bypasses, AND coronary) OR (bypasses, AND coronary AND artery) OR (coronary AND artery AND bypasses) OR 'coronary artery bypass surgery' OR (bypass, AND coronary AND artery) OR (aortocoronary AND bypasses) OR (bypass, AND aortocoronary) OR (bypasses, AND aortocoronary) OR (bypass AND surgery, AND coronary AND artery) OR 'coronary artery bypass graft'

4# #1 AND #2 AND #3

3. Cochrane Database of Clinical Trials:

#1 MeSH descriptor:[Simendan] explode all trees

#2 ("levosimendan" or "intravenous levosimendan" or "intravenous levosimendan"):ti,ab,kw

#3 #1 or #2

#4 MeSH descriptor:[intraaortic balloon pump] explode all trees

#5 ("intra-aortic balloon pump or Intra Aortic Balloon Pumping or Intraaortic Balloon Pumping or Balloon Pumping, Intraaortic or Pumping, Intraaortic Balloon or Pumping, Intra-Aortic Balloon or Balloon Pumping, Intra-Aortic or Pumping, Intra Aortic Balloon"):ti,ab,kw

#6 #4 or #5

#7 MeSH descriptor:[coronary artery bypass graft] explode all trees

#8 ("coronary artery bypass graft or Artery Bypass, Coronary or Artery Bypasses, Coronary or Bypasses, Coronary Artery or Coronary Artery Bypasses or Coronary Artery Bypass Surgery or Bypass, Coronary Artery or Aortocoronary Bypass or Aortocoronary Bypasses or Bypass, Aortocoronary or Bypass, Aortocoronary or Bypass, Aortocoronary or Bypass Surgery, Coronary Artery or Coronary Artery Bypass Grafting"):ti,ab,kw

#9 #7 or #8

#10 #3 and #6 and #9

4. Google scholar:

(levosimendan OR intravenous levosimendan) AND (intra-aortic balloon pump OR Intra Aortic Balloon Pumping OR Intraaortic Balloon Pumping OR Ballon Pumping, Intraaortic OR Pumping, Intraaortic Balloon OR Pumping, Intra-Aortic Ballon OR Balloon Pumping, Intra-Aortic OR Pumping, Intra Aortic Balloon) AND (coronary artery bypass OR Artery Bypass, Coronary OR Artery Bypasses, Coronary OR Bypasses, Coronary Artery OR Coronary Artery Bypasses OR Coronary Artery Bypass Surgery OR Bypass, Coronary Artery OR Aortocoronary Bypass OR Aortocoronary Bypasses OR Bypass, Aortocoronary OR Bypasses, Aortocoronary OR

Bypass Surgery, Coronary Artery OR Coronary ArteryBypass Grafting).

Participant or population Adult patients (≥ 18 years) undergoing Coronary artery bypass grafting CABG(on-pump or off-pump).

Intervention Levosimendan.

Comparator Intra-aortic balloon pump.

Study designs to be included RCT.

Eligibility criteria Articles that evaluated at least one of these indicators were included in this study. The exclusion criteria included non-human experimental studies, non-rigorous control group design or study design, data errors, duplicate reporting, subject data, and incomplete data. Duplicate published studies were excluded and the most recent updated data were included in the final analysis.

Information sources PubMed, Embase, Cochrane Database of Clinical Trials and Google Scholar were systematically searched for randomized controlled trials on the use of Levosimendan and IABP support in adult patients undergoing CABG from database inception to January 2023.

Main outcome(s) A total of 543 records were retrieved from the above 4 databases. After title, abstract, and full-text screening, five articles met the eligibility criteria and were included in the final analysis.

Quality assessment / Risk of bias analysis The internal validity and risk of bias were assessed independently by two reviewers, using standardized criteria according to Cochrane Methods. Six domains were assessed: adequate sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting, and no other biases. We prespecified that trials with a high or unclear risk of bias in no more than two domains were considered high quality.

Strategy of data synthesis RevMan 5.4 software was used to analyze each observation. Cochrane Q was used to test the heterogeneity of the included literature, and $P \geq 0.1$ and $I^2 \leq 50\%$ indicated low heterogeneity between studies, and a fixed effects model was used. If $I^2 > 50\%$, the reason for heterogeneity was analyzed first; if the reason could not be analyzed, a meta-analysis was not performed, and descriptive analysis was used. In this meta-analysis, variables included

dichotomous and continuous variables, and dichotomous variables were statistically analysed by relative risk ratio (RR); continuous variables were statistically analysed by standardised mean squared deviation (SMD), and all analyses were expressed with 95% confidence intervals (95% CI). Publication bias was presented as a funnel plot.

Subgroup analysis This meta-analysis includes five studies with a total sample size of 487 cases, 239 in the Levosimendan group and 248 in the IABP group.

Sensitivity analysis One document was excluded in turn, and the remaining documents (n-1) were combined for meta-analysis, and whether the results of the original meta-analysis were significantly changed by observing the changes in the combined results were assessed by the influence of certain studies.

Language restriction None.

Country(ies) involved China.

Keywords Levosimendan; intra-aortic balloon pump; IABP; coronary artery bypass grafting; CABG; meta-analysis.

Contributions of each author

Author 1 - Dan Sheng.
Email: 2671647426@qq.com
Author 2 - Wang,YJ.
Author 3 - Zhong,LQ.
Author 4 - Wang,YJ.
Author 5 - Fu,SY.
Author 6 - Sun,X.
Author 7 - Llang,H.