Review Article

Evaluating Mechanical Circulatory Support Devices in Cardiogenic Shock: A Systematic Review of Randomized Controlled Trials

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Abstract

Cardiogenic shock is a severe medical condition that bears a high morbidity and mortality. It is most commonly precipitated by myocardial infarctions, which impair the heart's ability to effectively act as a pump and provide perfusion to the body's vital organs. Pathophysiologically, cardiogenic shock is characterized by the heart's inability to maintain its cardiac output (CO), resulting in a compromise of perfusion to the vascular beds. Mechanical circulatory assist devices are at the higher end of the spectrum in terms of treatment modalities for Cardiogenic shock and are both costly and require significant skill and training to operate. This systematic review of randomized control trials aims to delineate between the feasibility and efficacy of the most commonly implemented mechanical heart assist devices, comparing intra-aortic balloon pump devices and ventricular assist devices. A thorough search was conducted using PubMed, Trip database (Turning Research into Practice) and Cochrane Central Register of Controlled Trials (CENTRAL) to identify the relevant manuscripts. A combination of keywords and Boolean operators was used for the data extraction (((percutaneous coronary intervention [Title/Abstract]) OR (impella pump[Title/Abstract])) AND (cardiogenic shock [Title/Abstract])) OR (intra aortic balloon pump [Title/Abstract]). The literature search generated a total of 5656 articles. Non-RCTs, cohort studies, cross-sectional studies, case control studies, case series, case reports, in vitro studies, animal experiments, commentaries, letters to the editor and expert opinions were additionally excluded. Four RCTs were finally assessed regarding the Mechanical circulatory support devices in cardiogenic shock and hence included in the systematic review for quality synthesis. Intra-aortic balloon pump insertion in combination with inotropic support is suggested as a first line intervention for myocardial infarctions complicated by cardiogenic shock, whereas ventricular assist devices with the capability of percutaneous insertion such as "Impella" are proven more useful in patients with triple vessel disease undergoing percutaneous coronary intervention. The selection of which mechanical support device to use in a particular patient is therefore of the utmost importance as the correct device should be selected for the specific underlying pathology in order to improve the patient and outcome and minimize the associated complications therewith.

Introduction

Cardiogenic shock is a severe medical condition which bears a high morbidity and mortality[1]. It is most commonly precipitated by myocardial infarctions which impair the heart's ability to effectively act as a pump and provide perfusion to the body's vital organs, other causes of cardiogenic shock include left ventricular outflow tract obstruction, septic shock, myocarditis, cardiomyopathy, acute chordal rupture with subsequent mitral regurgitation and aortic insufficiency. Pathophysiologically, cardiogenic shock is due to the "failure" of the heart to maintain its cardiac output (CO), resulting in a compromise of perfusion to the vascular beds[2]. Cardiogenic shock is initially and primarily managed pharmacologically with the use of agents such as vasopressors and inotropes, these are however only effective until a point, thereafter a further decompensation may occur and the need for mechanical circulatory assist devices are pertinent[3,4]. Mechanical circulatory assist devices are at the higher end of the spectrum in terms of treatment modalities for Cardiogenic shock and are both costly and require significant skill and training by both medical and paramedical staff in order to surgically implant, operate, and to maintain the patient's cardiac output[5-9]. There are numerous devices on the market with various price points that act on the heart in different manners and thereby have to be instituted at different levels of cardiac output in order to best benefit the recipient. It is noted that mechanical circulatory assist devices are lifesaving, and many patients would succumb to their Cardiogenic

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shock without the implementation thereof[10-12]. This systematic review on randomized controlled trials aims to delineate between the feasibility and efficacy of the most commonly implemented mechanical heart assist devices, comparing intra-aortic balloon pump devices and ventricular assist devices. The need to identify the most feasible and efficacious mechanical heart assist device is vital, as these interventions are costly. If the best device can be identified, healthcare policy and device procurement will be streamlined and thereby improving access to such devices and aiding in health equity, and will ultimately save the lives of patients who are suffering from severe cardiogenic shock.

Methodology

A thorough search was conducted using PubMed, Trip database (Turning Research into Practice) and Cochrane Central Register of Controlled Trials (CENTRAL) to identify the relevant manuscripts. A combination of keywords and Boolean operators was used for the data extraction (((percutaneous coronary intervention[Title/Abstract]) OR (impella pump[Title/Abstract])) AND (cardiogenic shock[Title/Abstract])) OR (intra aortic balloon pump [Title/Abstract]) (Table1).

Table 1: Various databases used

Databases	Boolean Operators and MeSH terms	Total number of manuscripts screened
PubMed database	(((percutaneous coronary intervention [Title/Abstract]) OR (impella pump [Title/Abstract])) AND (cardiogenic shock [Title/Abstract])) OR (intra aortic balloon pump [Title/Abstract])	1406
Cochrane Central Register of Controlled Trials (CENTRAL)	(((percutaneous coronary intervention [Title/Abstract]) OR (impella pump [Title/Abstract])) AND (cardiogenic shock [Title/Abstract])) OR (intra aortic balloon pump [Title/Abstract])	2371
TRIP database	(((percutaneous coronary intervention [Title/Abstract]) OR (impella pump [Title/Abstract])) AND (cardiogenic shock [Title/Abstract])) OR (intra aortic balloon pump [Title/Abstract])	1879
		5656

Inclusion criteria

All randomised controlled trials (RCTs) providing information on impella pump and Intra aortic balloon pumping published between January 2015 and March 2025, were assessed and were included in the study. All of the articles were screened independently by 3 researchers (SN, JR and IB) in all of the relevant fields. Full-text articles were included and accessed for eligibility in this systematic review. All of the randomised controlled trials (RCTs) available in the English were included in the study.

Exclusion criteria

Data resources such as non-randomised controlled trials non-RCTs, cohort studies, case-control studies, cross-sectional studies, case series, case reports, in vitro studies and animal experiments were disregarded. All commentaries, letters to the editor, expert opinion and review articles were omitted from this systematic review.

Methodology Quality Assessment

The quality assessment of the selected randomised controlled trials RCTs was assessed independently by three researchers (SN, JR and IB). The Cochrane risk-of-bias tool for randomized trials (RoB2) was used for quality assessment. The RoB2 tool is best suited and implemented to assess the domains at low, unclear and a high risk of bias. The Risk-of-bias Visualization (ROBVIS) tool is a web-based application program that was used to generate the traffic light plots and the weighted bar plots.

Extracted Data

The data from the final randomised controlled trials (RCTs) included in the analysis were synthesized by the three independent researchers. The data was extracted and placed into a tabular form based on the authors, years of study, study design, sample size and age group of patients, intervention, impella group only, Intra Aortic balloon pump (IABP) group only, Impella + (IABP) intra aortic balloon pump group together, outcome evaluated, measurements, Left ventricular ejection fraction change (LVEF change), haemodynamic change, potential limitations and clinical outcomes.

Results

The literature search generated a total of 5656 articles. A total number of 4440 articles were screened after 1216 duplicate records were removed. Non-RCTs, cohort studies, cross-sectional studies, case control studies, case series, case reports, in vitro studies, animal experiments, commentaries, letters to the editor, and expert opinions (n=4150) were excluded; articles not related to cardiogenic shock and not related to mechanical circulatory support were additionally excluded. All full texts of eligible articles were examined for final selection, and a backward citation chase was carried out. Four RCTs were finally assessed regarding the Mechanical circulatory support devices in cardiogenic shock and hence included in the systematic review for quality synthesis (Figure1).

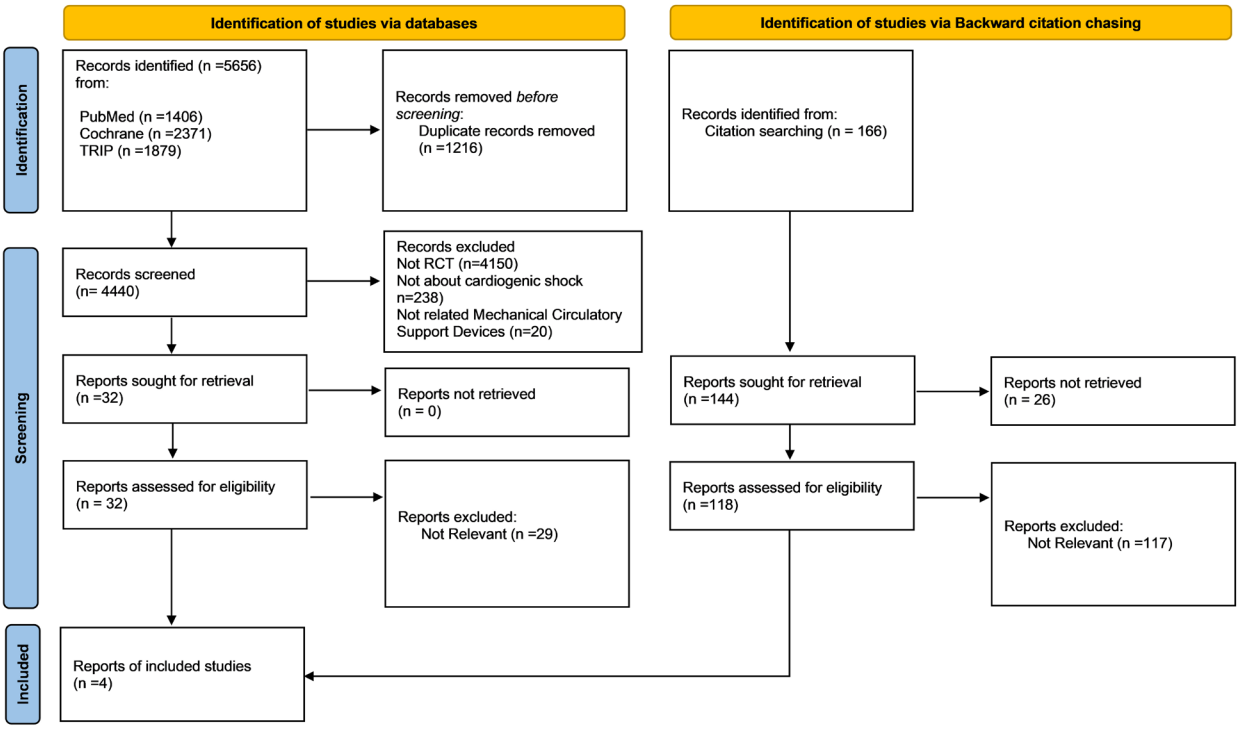

Figure 1: Prisma 2020 flowchart

Risk of bias analysis

Figure 2-3 depicts the risk of bias assessment based on the RoB 2 tool. The Robvis visualization tool, a web-based application program, was used for the development of traffic light plots and weighted bar plots for risk of bias summary and figure. Figure 2 shows the weighted bar plots for the risk of bias summary. Figure 3 shows a traffic light plot. The figure of the risk of bias was generated based on five domains. All the included RCTs underwent a quality assessment by the RoB 2 tool, which showed good overall results of low risk of bias in the randomization process (low risk 100%), deviations from intended interventions (100% low risk), missing outcome data (25% low risk), measurement of the outcome (low risk 100%), and selection of the reported result (low risk 50%), and overall risk of bias for the four RCTs were found to be low risk (50%) and 50%, which signified some concerns.

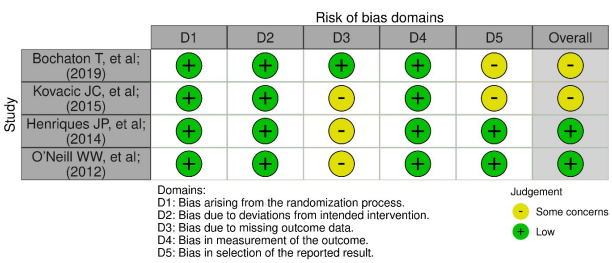

Figure 3: Traffic light plot showing the risk of bias of the RCTs

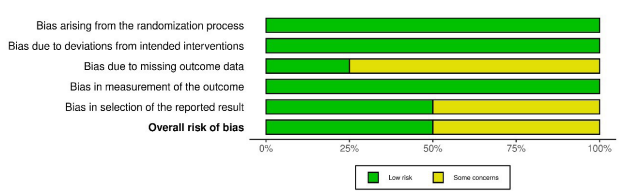

Figure 2: Weighted bar plots showing the summary of risk of bias for the RCTs

Table 2 and 3 depicts the author, year of publication, study design, gender, sample size, intervention and age group of patients, Impella group, IABP group, Impella +IABP group and outcomes evaluated. Table 3 depicts the measurements taken, results at 30 days and 90 days, left ventricular ejection fraction changes (LVEF) and the Haemodynamic changes. Table 4 determines the limitations and clinical outcomes of the included studies.

Table 2: Author, year of the study, study design, sample size, mechanical intervention used and the patient age group

Author, year of study	Study design	Gender	Sample size	intervention	Patient age group
Bochaton T, et al; (2019)[7]	RCT	Male	12	Impella LP5.0 pump and IABP	Between 45 and 73 years
Kovacic JC, et al; (2015)[8]	RCT	Male	325	Impella 2.5(IR2.5) and IABP	Between 56 and 78 years
Henriques JP, et al; (2014)[12]	RCT	Male	427	Impella 2.5 and IABP	Between 56 and 79 years
O'Neill WW, et al; (2012)[10]	RCT	Male	452	Impella 2.5 and IABP	Between 56 and 79 years

Table 3: Author, Impella groups, IABP group, Impella and IABP, and outcome evaluated in each study.

Author, year of study	Impella group only	IABP group only	Impella +IABP group	Outcome evaluated
Bochaton T, et al; (2019)[7]	Not available	6	6	CPI and LVEF
Kovacic JC, et al; (2015)[8]	167	158	Not available	MAE, 3VD and LVEF
Henriques JP, et al; (2014)[12]	216	211	Not available	MAE
O'Neill WW, et al; (2012)[10]	226	226	Not available	MAE, CPO, LVEF

Table 4: Measurements, results at 30 days and 90 days, left ventricular ejection fraction (LVEF) and Haemodynamic changes.

Author, year of study	Measurements	At 30 days	At 90 days	LVEF Changes	Haemodynamic changes
Bochaton T, et al; (2019)[7]	CPI was measured by Swan-Ganz catheter. LVEF was measured by echocardiography.	For LVEF: IABP (40.6%±12.5%) Impella LP5.0+IABP (38.6%± 14.4%)	Not evaluated	IABP (30+8 %) and Impella LP5.0+IABP (29+6 %)	Change in CPI at 12 hours for IABP (CPI = 0.08 ± 0.08 W/m2) Impella LP5.0 + IABP group (CPI = —0.02 ± 0.25 W/m2)
Kovacic JC, et al; (2015)[8]	3VD, LVEF and MAE were measured by undergoing high-risk PCI with IR2.5 vs IABP.	After PCI, reduction in incidence of MAE: IR2.5 vs IABP (32.9% vs 42.4%).	After PCI, reduction in incidence of MAE:IR2.5 vs IABP (39.5% vs51.0%)	IABP (23.4± 5.7) and Impella (22.6±5.9)	The duration of hemodynamic support was shorter in the IR2.5 versus IABP group, 35.1% of IABP patient's vs 6.1% in the IR2.5 group.
Henriques JP, et al; (2014)[12]	Kaplan–Meier estimates the incidence of MAE through 30 and 90 days were	MAE rates for Impella 2.5 and IABP were (31.7% versus 40.0%) at 30 days	MAE rates for Impella 2.5 and IABP were (38.0% versus 50.0%) at 90 days	IABP (24.1±6.1) and Impella2.5 (23.2±6.6)	IABP patients experienced a longer duration of hemodynamic support and were most probably to be discharged from the catheterization laboratory on support.
O'Neill WW, et al; (2012)[10]	2 treatment comparison on the primary end point (30-day MAE) and on 90-day MAE were performed by using the 2 tests. As an additional supportive analysis, Kaplan–Meier estimates of the cumulative incidence of MAE through 30 and 90 days were performed	Composite of major adverse events for IABP (40.1%) and Impella 2.5(35.1%) p=0.227	Composite of major adverse events for IABP (49.3%) and Impella2.5(40.6%) P=0.066	IABP (24.1 ±6.3) and Impella 2.5(23.4 ±6.3)	Impella 2.5 provided superior hemodynamic support in comparison with IABP, with maximal decrease in cardiac power output from baseline of (- 0.04± 0.24 W) in comparison with (-0.14 ±0.27 W) for IABP (P 0.001)

Table 5: Limitations and clinical outcomes

Author, year of study	Potential limitations	Clinical outcomes
Bochaton T, et al; (2019)[7]	Major bleeding by impella LP5.0 +IABP group. Small sample size.	Patients with CS-AMI stabilized by initial treatment with inotropes and an IABP, no additional haemodynamic support is provided by Impella LP5.0.
Kovacic JC, et al; (2015)[8]	Primary study was stopping prematurely & statistical power was limited.	The Patients with 3VD and reduced LVEF show improved outcomes at 90 days when PCI is performed with IR2.5 hemodynamic support.
Henriques JP, et al; (2014)[12]	The study did not meet the primary end point. Analysis of the Kaplan-Meier event curves suggests that evaluating the end-point at 30 days is not sufficient and a minimum of 90 days follow-up as an efficacy endpoint should be taken	Significantly lower 90-day MAE rates were observed with the use of Impella 2.5 compared to the use of IABP after excluding the first patient per group at each site. This prespecified analysis suggests a learning curve associated with initial introduction of the Impella 2.5
O'Neill WW, et al; (2012)[10]	Only 69% of the planned enrolment occurred, the primary endpoints were speculative. Half of the trial showed marked improvements in the safety for impella-support patients.	The trends for improved outcomes were observed for Impella 2.5–supported patients at 90 days and the 30-day incidence of major adverse events was not different for patients with IABP or Impella 2.5 for the hemodynamic support.

Discussion

Improving perfusion to vital organs, decreasing the workload of the heart and augmenting the cardiac output is the primary goal of Mechanical Circulatory Support devices. Moreover, providing time for recovery, serving as a long-term solution for patients not suitable for heart transplant as well as to assist or replace the function of the heart[10]. The systematic review clearly delineated the advantages of the use of these mechanical circulatory support devices in situations of severe cardiovascular compromise.

Bochaton T, et al. conducted a randomised control trial (RCT) on patients with Cardiogenic shock complicating acute myocardial infarction (CS-AMI) and were stabilized with inotropes and an intra-aortic balloon pump (IABP). The study proved that the addition of the Impella LP5.0 pump did not increase the Cardiac Power Index (CPI), as most of the pump's output substitutes itself for the native heart output. Change in CPI after 12 hours was not significantly different between the two groups (IABP group: ΔCPI = 0.08 ± 0.08 W/m^2; Impella LP5.0 + IABP group: ΔCPI = −0.02 ± 0.25 W/m^2; P = 0.4). For the Impella LP5.0 + IABP group, the native heart rate reduced from 0.37 ± 0.10 to 0.10 ± 0.20 (P = 0.01) for the CPI. However, this finding should be further verified by studies with an appropriate sample size. Major bleeding was observed in the Impella LP5.0 + IABP groups[7].

A similar study conducted by Burkhoff D, et al. found that the Impella LP5.0, substitutes itself for the output of the native heart and that as the flow of the pump increases, the native cardiac output decreases. For an Impella LP5.0, with a 4.7 L/min output, most of the flow is from the pump as the native heart output is overcome and therefore the addition of an Impella LP5.0 pump does not improve the CPI and the IABP alone is sufficient.[11]

A randomised control trial conducted by O'Neill WW et al . on patients being supported with an intra-aortic balloon pump (IABP) or the impella 2.5 system suffering from complex 3-vessel disease or unprotected left main coronary artery disease and severely depressed left ventricular function, during none-mergent high-risk percutaneous coronary intervention (PCI). It was found that those patients who received an IABP in comparison to those who received the Impella 2.5 had better outcomes with a significant 25% relative risk reduction in the MAE incidence at 90 days (36.5% (impella) versus 48.7% (IABP), P=0.014) as well as at 30-day MAE rate was also lower in the Impella 2.5 arm in comparison with the IABP arm (30.6% versus 39.6%, P=0.060). Moreover, with maximal decrease in cardiac power output from baseline of (-0.04 ± 0.24 W) in comparison with (- 0.14 ± 0.27 W) for IABP (P= 0.001), Impella 2.5 provided superior hemodynamic support in comparison with IABP. The limitation in this study was that the trial was terminated from the first 50% of patients enrolled[10].

A similar study conducted by Henriques JP, et al. compared the Impella 2.5 versus the intra-aortic balloon pump (IABP) during high-risk percutaneous coronary interventions. The major adverse effect (MAEs) rate for those receiving the IABP vs the Impella 2.5 device were found to be (44.8% versus 31.7%) and for IABP (40.0%) at 30 days and at 90 days. Therefore, the observed 90-day MAE was lower in the impella 2.5 group, it must however be noted that the study did not fully achieve its primary end points[12].

Kovacic, JC, et al. similarly conducted a randomised control study on the efficacy of hemodynamic support devices comparing both the Impella 2.5 (IR2.5) and the intra-aortic balloon pump (IABP) in patients with 3-vessel coronary artery disease (3VD) and an impaired LVEF undergoing a PCI. A lower than optimum decrease in the MAP of the 3VD was noted in patients receiving hemodynamic support with impella 2.5. It was also noted that the duration of the hemodynamic support was shorter with impella 2.5 system (6.1%) as opposed to the IABP (35.1%). Furthermore, the MAE at 30 days for the impella 2.5 and IABP systems were 32.9% and 42.4% respectively. At 90 days the MAEs were found to be 39.5% and 51.0% respectively. This study therefore concluded that patients who underwent a PCI with superimposed assistance from the impella 2.5 system had an improved 90 day outcome. A limitation noted in this study was that the statistical power was limited in nature[8].

A study performed by Schrage B. et al. similarly evaluated the use of the impella device compared with intra-aortic balloon pump (IABP) but more specifically in patients with acute myocardial infarctions complicated by cardiogenic shock AMI-CS. Besides, the baseline parameters being equally distributed after matching. There was no significant difference in the 30-day all-cause mortality (48.5% versus 46.4%, P=0.64). No significant difference was noted with respect to the primary end point of the 30-day all-cause mortality (48.4% versus 49.2%, P=0.89) of patients with an Impella implantation after PCI versus the matched pairs from the IABP SHOCK II trial and thus showed no statistical significance. The hemodynamic support with the Impella CP device, which delivers up to 4.0 L/min, was associated with a 30-day survival rate similar to that achieved with an IABP. The impella group suffered from peripheral vascular complications as well as severe and or life-threatening bleeds, which are a detractor as compared to the IABP group[13].

A study conducted by Dangas GD, et al. showed an improvement at the 3 month follow up where the endpoints were compared and found to be lower in the Impella group as compared with the IABP group (MAE, 37% vs 49%, p = 0.014 respectively; Major adverse cardiac and cerebrovascular events [MACCE] (22% vs 31%, p = 0.034). The impella group therefore resulted in a better patient outcome in this study[9].

In a study likened to that of Dangas GD, et al. conducted by Syed AI, et al. also similarly demonstrated the superiority of the Impella Recover LP 2.5 device over the IABP device showing a treatment effectiveness of 33.3%. It is, however noted that the prophylactic IABP in comparison to that of an active IABP shows a relatively lower composite MAE rate at 30 days (21.3%)[14].

Conclusion

Intra-aortic balloon pump insertion in combination with inotropic support is suggested as a first line intervention for myocardial infarctions complicated by cardiogenic shock, whereas ventricular assist devices with the capability of percutaneous insertion such as "impella" are proven more useful in patients with triple vessel disease undergoing percutaneous coronary intervention. The selection of which mechanical support device to use in a particular patient is therefore of the utmost importance as the correct device should be selected for the specific underlying pathology in order to improve the patient and outcome and minimize the associated complications therewith.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

Sarvesh Nunkoo: Conceptualization and design; Writing - original draft; Revising and editing the draft critically for important intellectual content, Data collection; Data curation; Investigation; Methods; Resources; Formal analysis; Visualization, Revising the draft, Acquisition, analysis, or interpretation of data. Approved the final version of the manuscript.

Jared Robinson: Conceptualization and design, Writing - original draft; Visualization; Revising and editing the draft critically for important intellectual content, Acquisition, analysis, or interpretation of data, and Co-Supervision. Approved the final version of the manuscript.

Indrajit Banerjee: Conceptualization and design, Writing - original draft; Visualization; Revising and editing the draft critically for important intellectual content, Acquisition, analysis, or interpretation of data, and Supervision. Approved the final version of the manuscript.

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