ORIGINAL ARTICLE



Utility of a standardized postcardiopulmonary bypass epicardial echocardiography protocol for stage I Norwood palliation

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Abstract

Objective: Stage 1 Norwood palliation is one of the highest risk procedures in congenital cardiac surgery. Patients with superior technical performance scores have more favorable outcomes. Intraoperative epicardial echocardiography may allow the surgeon to address residual lesions prior to leaving the operating room, resulting in improved technical performance. The ability of intraoperative epicardial echocardiography to visualize the relevant anatomy and its association with outcomes is not known.

Design: A standardized intraoperative epicardial echocardiography protocol was developed and performed at the conclusion of Stage 1 Norwood palliation. Data pertaining to visualization of relevant anatomy, and comparison of intraoperative echocardiogram findings with other postoperative investigations was performed. Clinical outcomes, including technical performance, were collected. A historical cohort who received either no echocardiogram or a nonstandardized examination was used as a comparison group.

Results: Thirty on-protocol and 30 preprotocol patients, 22 of whom had a nonstandardized intraoperative epicardial echocardiogram, were studied. Compared with preprotocol, visualization of the relevant anatomy was significantly increased for the Damus-Kaye-Stansel anastomosis (93% vs. 68% P = .03) and branch pulmonary arteries (70% vs. 36%, P = .02). One residual lesion requiring immediate operative reintervention was diagnosed in the preprotocol group. There were 5 patients in each cohort with residual lesions during the postoperative hospitalization that were not appreciated on the intraoperative echocardiogram. Technical performance, rates of reintervention and clinical outcomes were not significantly different between the two groups.

Conclusions: Intraoperative epicardial echocardiography is technically feasible and increases visualization of the relevant anatomy. Larger investigations may be warranted to determine if there is clinical benefit to such an approach.

KEYWORDS

Epicardial echocardiography, intraoperative echocardiography, protocol, stage I Norwood procedure

1 | INTRODUCTION

Intraoperative postcardiopulmonary bypass echocardiography (echo) is routinely performed to assess the surgical repair of congenital heart defects.¹ Benefits include the detection of residual lesions and the provision of information regarding ventricular function and hemodynamics that may aid in postoperative management.²⁻⁴ Intraoperative imaging was originally performed via the epicardial approach,^{5,6} but with the development of transesophageal transducers,^{7,8} that modality has gained popularity. However, epicardial echo (e-echo) is often preferred over the transesophageal approach for evaluation of certain anatomy, and in small infants and neonates.⁹⁻¹²

Stage 1 Norwood palliation (S1NP) for single ventricle heart disease remains one of the highest risk procedures in congenital heart surgery.^{13,14} A surgical technical performance score has been developed that is based predominantly on imaging findings.¹⁵ Patient with superior technical performance scores have been demonstrated to have improved clinical outcomes.^{16,17} In addition, reinterventions after S1NP are often related to recurrent or residual lesions that were addressed at the time of surgery, primarily aortic arch obstruction and shunt or pulmonary artery obstruction.^{13,18,19} Recent data suggests that immediate reintervention on residual lesions is associated with improved outcomes compared to reoperation in the postoperative period.²⁰

While e-echo has been frequently utilized at our institution to assess S1NP, it has not been performed in a standardized fashion. In addition, the success of e-echo in visualizing the relevant anatomy has not been reported. We therefore implemented a standardized e-echo protocol based on assessing the components of the operation that comprise the technical performance score. The aim of our study was to determine the technical feasibility of a standardized e-echo for S1NP, and compare visualization rates with a nonstandardized approach. A secondary aim was to determine any clinical impact of this standardized assessment. An historical cohort was used for comparison.

2 | METHODS

A standardized e-echo protocol (Supporting Information Appendix) was developed. Details of the protocol were reviewed with echocardiographers and surgeons at staff meetings. After a training period to familiarize both the echocardiographers and surgeons with performance of the protocol, the protocol was formally implemented and data collected in a prospective fashion on 30 consecutive infants undergoing S1NP. Intaoperative e-echo was performed at the conclusion of S1NP on an iE33 ultrasound system (Philips, Best, The Netherlands) with an S12-4 sector array transthoracic transducer placed within a sterile plastic sheath filled with approximately 30 mL of normal saline as a standoff medium. Additional saline was instilled within the chest cavity as needed by the surgeon, who manipulated the probe and obtained the images. The echocardiographer was present in the operating room and reviewed the images in real-time while guiding the surgeon, and operating the ultrasound machine controls. Following completion of the surgery, the surgeon completed a questionnaire that sought their opinion on ease and utility of the examination. A separate questionnaire on study findings and image quality was completed by the staff echocardiographer.

Preoperative and operative data included patient demographics and procedural variables. Data from the postoperative period included variables pertaining to the hospital course, complications and reinterventions. Intraoperative e-echo findings were compared with results from other imaging modalities (echo and catheterization) performed during the post-S1NP hospitalization. The technical performance score at discharge was determined as per previously developed criteria.¹⁵ Follow-up data after discharge from the S1NP hospitalization was collected until time of bidirectional Glenn, death or subsequent intervention if bidirectional Glenn was not performed. Follow-up data included Congenital Heart Disease WILEY

interstage events, reinterventions and pre-bidirectional Glenn technical performance score.¹⁵ A consecutive cohort of 30 patients undergoing S1NP prior to implementation of the standardized protocol was used as an historical control. The institutional review board of Boston Children's Hospital approved the investigation with waiver of informed consent.

Comparisons between the preprotocol and on-protocol groups were performed using Fisher's exact test for categorical variables and the Wilcoxon rank-sum test for continuous variables. The Kaplan-Meier method was used to estimate survival, and compared between groups using the log-rank test. Statistical analysis was performed using Stata version 13.1 (College Station, TX).

3 | RESULTS

Patients in the preprotocol (n = 30) and on-protocol (n = 30) cohorts were similar with respect to baseline demographics, anatomy, comorbidities, and pre-S1NP interventions (Table 1). Cardiopulmonary bypass times did not differ between the two groups. The majority of patients received a right ventricle to pulmonary artery (RV-PA) conduit in both the preprotocol and on-protocol cohorts. An additional bypass period was required in 3 (10%) preprotocol and 2 (7%) on-protocol patients (P = 1.0).

3.1 | Epicardial echocardiography findings

An e-echo was performed in 22 (73%) preprotocol and 30 (100%) onprotocol patients (P = .005, Table 2). The duration of the e-echo did not differ between the two groups. No complications related to the e-echo were reported in either group. Residual lesions were noted by e-echo in 3 (10%) of preprotocol and 4 (13%) of on-protocol patients. These residual lesions prompted a return to bypass in one preprotocol patient and none of the on-protocol patients.

The one preprotocol patient who returned to bypass for intraoperative revision had severe right ventricular dysfunction with sluggish bidirectional flow noted in the right coronary artery. A clot was subsequently removed from the right coronary artery with improvement in flow and right ventricular function. Another preprotocol patient had narrowing at the Damus-Kaye-Stansel anastomosis (DKS) noted on e-echo. The patient had cardiac arrest in the operating room and was placed on extracorporeal membrane oxygenator support, but did not undergo immediate reintervention. After a postoperative catheterization noted neo-ascending aorta obstruction, the patient was taken for surgical revision of the DKS. The obstruction was considered mild, however, and other patient comorbidities were considered more significant in contributing to the patient's eventual death. An additional preprotocol patient who had an intact atrial septum stented in-utero had incomplete resection of the atrial septal stent at S1NP with a residual gradient noted on the e-echo. No reintervention was performed until the bidirectional Glenn.

There were 4 residual lesions noted by e-echo in the on-protocol cohort. A distal aortic arch gradient was noted in one patient. Mild arch narrowing was confirmed on the discharge echo with a cuff blood

TABLE 1 Baseline patient characteristics

Preprotocol (n = 30) On-pro	rotocol (n = 30)	P value
Male 17 (57%) 22 (73	3%)	.28
Birth weight (g) 3243 (2200 to 3800) 3078 ((1990 to 3920)	.58
Gestational age (wk) 39 (36 to 41) 39 (35	5 to 41)	.22
Cardiac anatomy		.17
HLHS 24 (80%) 19 (63	3%)	
AS/borderline left heart 1 (3%) 6 (20%	%)	
Other 5 (17%) 5 (17%	%)	
Genetic syndrome 5 (17%) 6 (20%)	%)	1.0
Noncardiac structural anomaly 4 (13%) 4 (13%)	%)	1.0
Fetal intervention 2 (7%) 1 (3%)	6)	1.0
Pre-S1NP operative intervention 2 (7%) 0 (0%)	6)	.49
Pre-S1NP catheter intervention4 (13%)5 (17%)	%)	1.0
Age at operation (d) 5 (1 to 60) 4 (2 to	to 20)	.29
Cardiopulmonary bypass time (min) 152 (115 to 287) 158 (9	91 to 243)	.77
Cross-clamp time (min) 110 (60 to 169) 126 (3	36 to 165)	.25
Circulatory arrest time (min) 21 (3 to 88) 19 (2 to 88)	to 76)	.54
Source of pulmonary blood flow		.55
RV-PA conduit 24 (80%) 21 (70	'0%)	
Blalock-Taussig shunt 6 (20%) 9 (30%	%)	
Additional bypass run 3 (10%) 2 (7%)	6)	1.0

Data presented as n (%) or median (range).

AS, aortic stenosis; HLHS, hypoplastic left heart syndrome; RV-PA, right ventricle to pulmonary artery; S1NP, stage 1 Norwood palliation.

pressure gradient between 10 and 20 mm Hg. The patient developed right ventricular dysfunction during the interstage and underwent balloon dilation of the aortic arch for an 11 mm Hg gradient. Branch pulmonary artery stenosis was noted in the other 3 patients, none of which required early reintervention. One patient had pulmonary artery stenosis addressed surgically at the time of the bidirectional Glenn, and the pulmonary artery stenosis was not appreciated to be significant in follow-up examination in the other 2 patients.

Rates of visualization of the relevant anatomy were higher for onprotocol patients, though this only reached statistical significance for the DKS and the branch pulmonary arteries (Figure 1). Within the onprotocol cohort, structures visualized with the greatest frequency, apart from ventricular and valvar function, were the DKS anastomosis (93%) and proximal aortic arch (90%). The Distal aortic arch was imaged in 80% of patients. Structures seen with the least frequency were coronary flow (57%) and the source of pulmonary blood flow (43%). The atrial septum and branch pulmonary arteries were imaged in 77% and 70% of patients, respectively.

There were five patients each from the preprotocol and onprotocol cohorts with residual lesions noted during the S1NP hospitalization that were not appreciated on the e-echo. All 5 of the patients in the preprotocol cohort underwent reintervention during the S1NP

TABLE 2 Epicardial echocardiogram variables

	Preprotocol (n = 30)	On-protocol (n = 30)	P value
Epicardial echo cardiogram performed	22 (73%)	30 (100%)	.005
Study duration (min) ^a	14 (4 to 42)	14 (5 to 42)	.80
Residual lesion identified on echo	3 (10%)	4 (13%)	1.0
Additional bypass run to address residual lesion	1 (3%)	0 (0%)	1.0

Data presented as n (%) or median (range).

^aExcludes 3 preprotocol and 2 on-protocol patient who had additional bypass runs.



FIGURE 1 Rates of visualization of the relevant anatomy. Rates of visualization of the relevant anatomy were higher in on-protocol patients, though this only reached statistical significant for the Damus-Kaye-Stansel (DKS) anastomosis and the branch pulmonary arteries. Within the on-protocol cohort, structures visualized with the greatest frequency were the DKS (93%) and proximal aortic arch (90%). The Distal aortic arch was imaged in 80% of patients. Structures seen with the least frequency were coronary flow (57%) and the source pulmonary blood flow (PBF) (43%). The atrial septum and the branch pulmonary arteries were imaged in 77% and 70% of patients, respectively

hospitalization (all for obstruction of the Blalock-Taussig shunt or RV-PA conduit); whereas 3 of the 5 on-protocol patients underwent predischarge reintervention (2 to address branch pulmonary artery obstruction, and 1 to address proximal arch obstruction)

3.2 | Postoperative and follow-up data

Data pertaining to the postoperative clinical course was not significantly different between groups, nor were discharge technical performance scores (Table 3). In total, 6 (20%) preprotocol patients and 3 (10%) on-protocol patients underwent postoperative reintervention during the S1NP hospitalization (P = 0.47). No patients from either group developed mediastinitis.

Median follow-up duration was 174 days in the preprotocol cohort and 151 in the on-protocol cohort (P = 0.14, Table 3). Patients did not differ between groups with respect to interstage extracorporeal membrane oxygenator use, reinterventions, or survival (Figure 2). While technical performance scores were not significantly different between the groups at discharge, they did decrease between discharge and follow-up. This seemed to be driven primarily by patients moving from optimal to adequate scores. In the preprotocol cohort, 10 patients moved from optimal to adequate, 8 of whom had either stenosis or distortion of the pulmonary arteries or RV-PA conduit. For the other 2 preprotocol patients moving from optimal to adequate scores, 1 underwent interstage balloon dilation of the aortic arch (and had pulmonary artery distortion noted at the pre-bidirectional Glenn catheterization) and the other underwent arch dilation and had pulmonary artery distortion at the pre-bidirectional Glenn catheterization. There were 2 patients in the preprotocol cohort who moved from an optimal to an inadequate score. Both were admitted with cyanosis in the interstage and underwent intervention for RV-PA conduit or pulmonary artery stenosis.

There were 14 patients in the on-protocol cohort who moved from optimal to adequate scores; 7 had either stenosis or distortion of the pulmonary arteries or RV-PA conduit in isolation, 2 had mild gradients across the atrial septum (one of whom also had pulmonary artery stenosis), 4 underwent balloon dilation of the arch (2 of whom also had pulmonary artery stenosis/distortion), and 1 underwent balloon dilation of the DKS (and also had the RV-PA conduit stented). There were 2 patients who moved from optimal to inadequate scores, both of whom required interstage catheter reintervention for atrial septal restriction.

Echocardiographers were surveyed regarding the quality of images of the e-echo. The largest proportion of examinations (50%) were rated as having good image quality, 23% were very good, and an equal proportion (13%) were either excellent or fair. Echocardiographers were somewhat confident that the e-echo findings represented the patient's true anatomic result in 30%, confident on 50% and very confident in 20%.

As for surgeons, they reported the e-echo would influence plans for postoperative care in 47%. The images were very easy or easy to obtain in 57% and somewhat difficult or difficult in 40%. The majority of studies (80%) were reported to take an acceptable amount of time, with 7% taking too little time and 7% too much. Surgeons had higher confidence that the e-echo results represented the patient's true anatomic result than the echocardiographers (27% somewhat confident, 13% confident and 57% very confident, P = 0.003). The e-echo was reported to be at least somewhat useful by all of the responding surgeons.

4 | DISCUSSION

We found that a standardized e-echo protocol was technically feasible, did not add a significant amount of imaging time to the operation over a nonstandardized approach, and was associated with increased rates

TABLE 3 Stage I Norwood palliation hospital course and follow-up

	Preprotocol	On-protocol	P value
S1NP hospitalization			
Negative fluid balance (d) Chest closure (d) Extubation (d) Transfer out of ICU (d) Discharge (d) Cardiac arrest (d) ECMO (d) Urgent chest washout/evaluation for bleeding Urgent evaluation for patency of source of PBF Death Any reintervention Discharge technical performance score Optimal Adequate Inadequate	2 (0 to 3) 2 (0 to 14) 6 (3 to 56) 10 (6 to 31) 30 (13 to 71) 5 (17%) 5 (17%) 6 (20%) 2 (7%) 3 (10%) 6 (20%) 23 (77%) 1 (3%) 6 (20%)	2 (0 to 4) 3 (0 to 11) 7 (2 to 36) 12 (3 to 39) 24 (9 to 81) 2 (7%) 5 (17%) 4 (13%) 0 (0%) 1 (3%) 3 (10%) 3 (10%)	.20 .77 .68 .77 .23 .42 1.0 .73 .49 .61 .47 .40
Follow-up Age (d) Weight (g) Interstage ECMO Death Interstage surgical reintervention Interstage catheter reintervention Technical performance score ^a Optimal Adequate Inadequate	174 (92 to 249) 6305 (4420 to 9500) 1 (3%) 2 (7%) 1 (3%) 6 (20%) 9 (36%) 13 (52%) 3 (12%)	151 (83 to 190) 5920 (3950 to 7800) 2 (7%) 1 (3%) 0 (0%) 6 (20%) 9 (32%) 16 (57%) 3 (11%)	.14 .07 .70 .51 1.0 1.0 .92

Data presented as n (%) or median (range).

ECMO, extracorporeal membrane oxygenator; ICU, intensive care unit; PBF, pulmonary blood flow.

^aExcludes 5 preprotocol and 2 on-protocol patients that had died.

of visualization of the DKS and the branch pulmonary arteries. In this cohort we were not able to demonstrate an improvement in technical performance scores or clinical outcomes over an historical cohort.

Little data on intraoperative echo for S1NP has been published. Balmer et al.¹² reported their experience with intraoperative echo for a variety of operations, including e-echo for S1NP. They report at least



FIGURE 2 Postoperative survival. Follow-up was until time of bidirectional Glenn, death or subsequent intervention if bidirectional Glenn was not performed. Median follow-up duration was 174 days in the preprotocol cohort and 151 in the on-protocol cohort. Survival was not significantly different between the groups by Kaplan–Meier estimate

one patient returned to bypass for relief of residual arch obstruction based on findings on intraoperative echo; however, the total number of S1NP operations performed is not available. Smallhorn²¹ also described intraoperative transesophageal echo for a variety of lesions and mentioned the importance of assessing tricuspid regurgitation, the aortic anastomosis, and coronary arteries in S1NP for hypoplastic left heart syndrome. He described the difficulty in imaging the aortic arch, though noted it could be done from a high esophageal approach. A case report discusses the use of an intracardiac echo catheter inserted transnasally into the esophagus in a small infant undergoing S1NP.²² To our knowledge ours is the first investigation to focus solely on intraoperative imaging for S1NP.

Visualization of the DKS anastomosis and branch pulmonary arteries was significantly higher in the on-protocol cohort. While differences in rates of visualization of other structures did not reach statistical significance, they tended to be higher in the on-protocol cohort. These data suggest a standardized approach to the intraoperative eecho can result in successful visualization of the majority of the relevant anatomy. This observation is expected given that following a checklist of key images makes it less likely that assessment of important anatomic information is skipped or rushed through. An obvious concern is that following such a protocol would lead to significantly longer studies, however, the e-echo duration was similar in the onprotocol cohort. Further, only 7% of surgeons' responses on the survey rated the e-echo as taking too long to complete.

A significant potential benefit of intraoperative e-echo is the identification of residual lesions that may lead to either immediate intraoperative reintervention or heightened awareness in the postoperative period for potential residual lesions that may change the monitoring of the patient, or the threshold for reintervention. In this investigation, residual lesions were noted by e-echo in 3 (10%) of preprotocol and 4 (13%) of on-protocol patients. However, immediate reintervention was performed in only one preprotocol patient. Of the other residual lesions noted by intraoperative e-echo that were not immediately intervened on, 1 in the preprotocol (DKS obstruction) and 1 in the onprotocol cohorts (arch obstruction) eventually underwent reintervention either in the post S1NP hospitalization or interstage period. Conversely, 2 patients in the on-protocol cohort who had pulmonary artery stenosis identified on the e-echo were not found to have significant pulmonary artery stenosis on follow-up examination. These can be considered "false positives" of e-echo. Therefore, care must be taken not to undertake operative reintervention for lesions that may not be clinically significant.

There were 5 patients each from both the preprotocol and onprotocol cohorts who could be considered to have had "false negatives"—lesions that were detected during the post-S1NP hospitalization that were not present on the e-echo. These lesions were predominantly related to the source of pulmonary blood flow and/or branch pulmonary arteries, though some also involved the DKS or aortic arch. While some of the e-echos noted the anatomy was not well seen, some also noted optimal repair. These data suggest that even if the repair is judged to be optimal on the intraoperative e-echo, undiagnosed residual lesions may still be present. It is not known whether those studies noting optimal repair missed the residual lesions, or if these lesions developed over time, as this is known to happen, particularly for aortic arch, and pulmonary artery obstruction.^{18,19} This relatively high "false negative" rate raises the question whether a more sensitive method of assessment of vascular anatomy, such as intraprocedural angiography, would improve the detection of residual lesions.

Clinical outcomes, as measured by S1NP hospital course, technical performance scores, reintervention rates, and survival were not significantly different between the two cohorts. This is not surprising as the study was not powered to detect differences in clinical outcomes. Also, in order for a clinical difference in technical performance or patient outcomes to be demonstrated, simply performing an e-echo is insufficient. Action, in the form of intraoperative reintervention, must be taken in order to alter a patient's clinical course. In this small investigation, potentially actionable lesions were noted in 3 preprotocol and 4 on-protocol patients, though reintervention was only performed in one of the preprotocol patients. Of the remaining 6 lesions in both cohorts, only 2 turned out to be clinically significant enough to require postoperative or interstage reintervention. This suggests that simply identifying a potential residual lesion on e-echo may not be sufficient to require an immediate return to cardiopulmonary bypass. But rather, such findings should prompt a discussion with the surgeon as to the potential severity of the lesion and risks versus benefits of immediate reintervention. Further refinement of e-echo findings suggesting the

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need for reintervention, and larger studies powered to detect a clinical difference could be the focus of future investigations.

Historically, while epicardial imaging was the initial modality of choice for intraoperative imaging, transesophageal echocardiography has since superseded it. However, we chose to focus on e-echo in this report as it has been our institutional preference to perform e-echo for S1NP. This is primarily because of the limited availability of miniaturized transesophageal transducers for the smallest patients, and difficulties in imaging the extracardiac, or vascular anatomy by the transesophageal approach. This investigation was not intended to compare e-echo to transesophageal echocardiography. Rather, we aimed to convey that it is the standardization of the approach, and following of a protocol, that increases rates of visualization. With the development of the miniaturized transducers,^{23,24} which can be used in small neonates, and further advances in in technology, it may be that transesophageal echocardiography becomes preferable to e-echo. However, demonstration of adequate visualization of the vascular anatomy would need to be shown.

There are several limitations worthy of mention. The standardization of e-echo may not in fact represent a markedly significant change from the nonstandardized approach undertaken in the preprotocol cohort. This may explain the limited difference in visualization rates between the two cohorts. However, certain components of the anatomy were seen more frequently, and it is possible that with a larger cohort, additional measures of visualization would have reached statistical significance. Also, with a much larger cohort, differences in clinical outcomes may be detected. Additionally, although the study duration was not demonstrated to increase between the preprotocol and onprotocol cohorts, e-echo was commonly used at our institution prior to the implementation of this protocol, which may partially account for this. It is possible that at another institution not as experienced with-eecho, implementing such a protocol may add considerable time to the operation, and a more extensive training period may be required. Finally, the first author was personally present at the majority of operations to ensure protocol adherence. This is not a sustainable practice, and other means of ensuring protocol compliance should be "built in" to echo lab operations to ensure consistent application of the protocol.

In conclusion, a standardized intraoperative e-echo to assess S1NP was technically feasible, did not increase study time or complications, and led to slightly higher rates of visualization of the relevant anatomy. A difference in technical performance scores or clinical outcomes was not appreciated in this cohort, though was not expected given the sample size. Given the potential benefits of standardized imaging and limited downside, consideration should be given by surgical centers to make standardized intraoperative e-echo imaging a part of their S1NP palliations. Larger investigations may be warranted to determine if there is clinical benefit to such an approach.

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CONFLICT OF INTEREST

The authors have no relevant conflicts of interest to disclose.

AUTHOR CONTRIBUTIONS

Dr. Stern conceptualized and designed the study, designed and helped implement the echocardiography protocol, collected data, and drafted the manuscript.

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Dr. Gauvreau contributed to study design, performed statistical analysis, and critically revised and approved the final manuscript.

Dr. Emani contributed to study design, participated in echocardiography protocol development, helped implement the protocol, and critically revised and approved the final manuscript.

Dr. Geva contributed to study design, participated in echocardiography protocol development, helped implement the protocol, and critically revised and approved the final manuscript.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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