Radial versus femoral vascular access in ST-elevation myocardial infarction: Are the results of femoral operators unfairly represented in observational research?

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Background Recent randomized controlled trials comparing femoral and radial access in primary percutaneous coronary intervention (PPCI) have shown conflicting results regarding the incidence of major adverse cardiovascular events (MACE) and major bleeding.

Methods Using data from the HEAT-PPCI trial, we compared the primary efficacy (all-cause mortality, stroke, new myocardial infarction or unplanned repeat revascularization) and safety (major bleeding BARC 3–5) outcomes at 28 days, by final access site used (radial or femoral) and by default operator type. We then assessed outcomes in femoral cases performed by both operator types.

Results Radial access (RA) was associated with fewer MACE (91/1472 = 6.2% vs. 36/332 = 10.8% $P = .003$) and major bleeding events (38/1472 = 2.6% vs 22/332 = 6.6% $P = .001$) when compared to femoral access (FA). When analyzing outcomes by default operator type, there was a similar incidence of MACE (111/1575 = 7% vs 16/229 = 7% $P = .97$) and major bleeding events (49/1575 = 3.1% vs 11/229 = 4.8% $P = .18$). In cases where FA was performed by default radial operators, there was a higher rate of MACE (22/122 = 18% vs 14/210 = 6.7% $P = .003$) and major bleeding events (11/122 = 9% vs 11/210 = 5.2% $P < .001$), potentially explained by a higher risk profile in these cases.

Conclusion Default femoral operators achieved comparable outcomes when compared to default radial operators. The less favorable outcomes observed in FA cases may result from its selective use by radial operators in high risk cases. (Am Heart J 2019;210:81-87.)

Major bleeding after percutaneous coronary intervention (PCI) is associated with increased mortality and major adverse cardiovascular events (MACE).[1] The choice of access site may influence the rate of complications and adverse events following primary PCI (PPCI). Since the introduction of PPCI as the preferred treatment for reperfusion in the acute management of ST-elevation myocardial infarction (STEMI), there has been a shift in operator preference for radial over femoral access.[2-4] However recent trials comparing the two access sites in PPCI have shown conflicting results regarding the incidence of MACE and major bleeding.[5-8]

Previous trials comparing access sites do not consider the default preference of radial or femoral for each operator. Therefore, randomization of the access site alone does not control for the varying experience of individual operators. The primary aim of this study was to examine associations between default radial and default femoral operator type, irrespective of final access site chosen.

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Despite the increase in RA use, FA is still used in certain circumstances by all operators. It is, therefore, important to establish the safety of the FA when used by both femoral and radial operators. A secondary aim of this study was to analyze all FA cases to establish differences between all operators when performing cases via FA.

Methods

HEAT-PPCI was a single-center, randomized controlled trial comparing unfractionated heparin versus bivalirudin in the treatment of patients with suspected STEMI, for planned management with PPCI (registered at clinicaltrials.gov NCT01519518).[9] The trial recruited from the Liverpool Heart and Chest Hospital, a high-volume PPCI center. For individual operators (defined as participants in the PPCI service, for the duration of the trial) the annual medial PCI case volume was 218 cases (range: 158–283), based on data for the financial year 2013–14. Participants were tracked during their index admission for clinical outcome events and followed up for 28 days following randomization.

The HEAT-PPCI trial was partially funded by unrestricted grants from The Medicines Company and AstraZeneca but these companies had no involvement in any aspect of trial design, conduct or reporting. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the manuscript, and its final contents.

The primary efficacy outcome of the HEAT-PPCI trial was the proportion of patients who had at least one MACE at 28 days. MACE included all-cause mortality, cerebrovascular accident (CVA), reinfarction or additional unplanned target lesion revascularization. The primary safety outcome was the proportion of patients who had a major bleed by 28 days, classified as type 3–5 according to the Bleeding Academic Research Consortium (BARC). All outcomes were adjudicated, blinded to the treatment allocation.

When patients were recruited into the HEAT-PPCI trial, they were treated by the operator who was assigned to PPCI activity by a rota system. Over time, this creates a near-random allocation of patient-types and risk profiles between operators. The route of arterial access was determined by operator preference and recorded in the trial documentation. This allowed analysis of 28-day outcomes by access site. Operators in the study had established practice patterns for vascular access that allowed their categorization as "default femoral" or "default radial" based on the access site used as their natural first preference, accounting for over 90% of all historic and trial-specific activity.

Statistical analysis

Data are presented as (n/ d = p%) for categorical variables and as means (standard deviations) or medians (interquartile ranges) for continuous variables after testing for normality. Comparisons between groups were made using chi-square test for categorical variables and unpaired t-test or Mann-Whitney *U* test for continuous variables. $P < .05$ (2 sided) was considered statistically significant. SPSS version 22 (SPSS Inc., Chicago, IL, USA) was used for analyses.

Results

Between 7th February 2012 to 20th November 2013, 1829 patients were enrolled into the HEAT-PPCI trial. It was not possible to obtain consent in 17 cases. Brachial artery was chosen as the final access site in 2 patients. Angiography was not attempted in 6 participants. Of the remaining 1804 cases, RA was used as the final access site in 1472/1804 = 81.6% cases and FA was used in 332/1804 = 18.4% cases (Figure 1). In patients where FA access was used, the access site was closed using an internal vascular closure device in 215/332 = 64.8% of cases, manual pressure was used in 105/332 = 31.6% of cases and 12/332 = 3.6% were not closed because the patient died during or shortly after the procedure. Table I details the baseline characteristics and demographics of the participants categorized by final access site. There were significant differences between the two groups, with RA cases having a better risk profile in term of age, systolic blood pressure, renal function and previous MI/PCI/CABG. RA cases were also significantly less likely to have an intra-aortic balloon pump (IABP) used during the procedure, require venous access or receive glycoprotein IIb/IIIa inhibitors.

Relationship between final access site and clinical outcomes

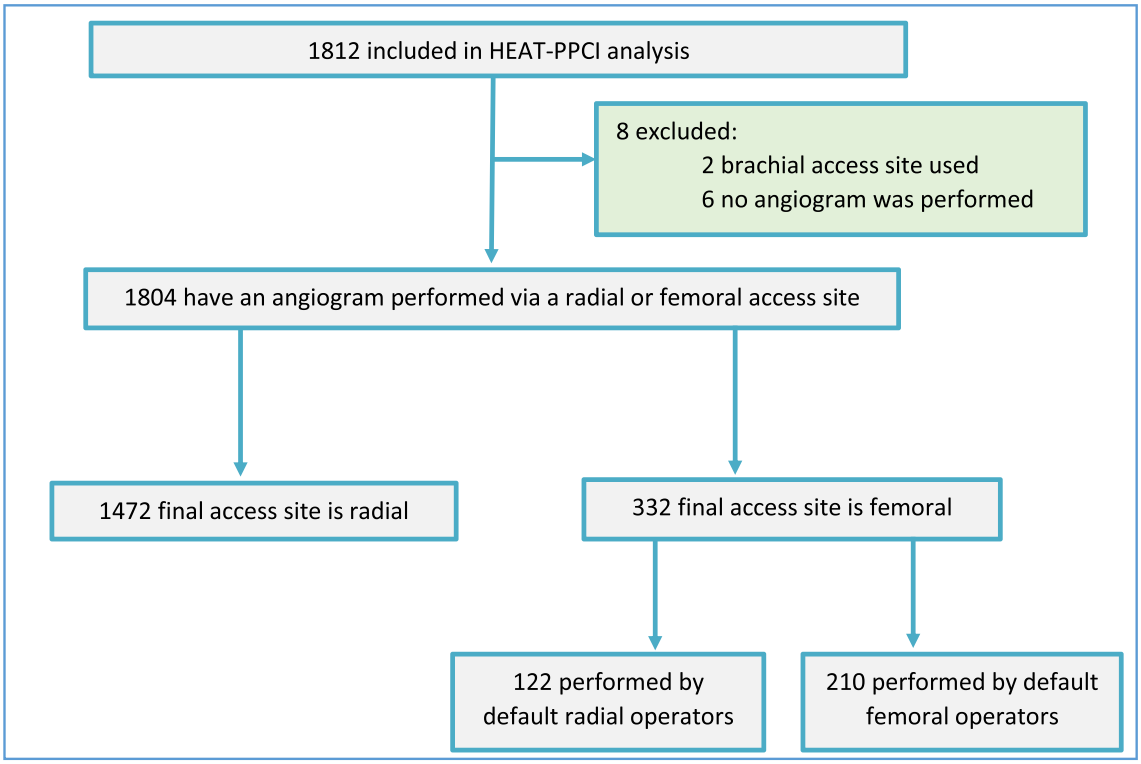
Table II illustrates the clinical outcomes by final access site. The primary efficacy outcome of MACE occurred in a significantly higher number of FA cases vs. RA cases (36/332 = 10.8% vs. 91/1472 = 6.2% $P = .003$). The 28-day mortality was higher in the FA cases (27/332 = 8.1% vs. 55/1472 = 3.7% $P = .001$). The number of major bleeding events was also significantly higher in the FA cases (22/332 = 6.6% vs. 38/1472 = 2.6% $P = .001$).

Relationship between operator default access site and clinical outcomes

Individual default radial operators performed a similar number of procedures to default femoral operators but, as there were fewer femoral operators, in total more radial than femoral procedures were performed, (1575/1804 = 87.3% vs. 229/1804 = 12.7%) (Figure 2). The baseline characteristics of the two groups were comparable and are detailed in Table III.

Table IV illustrates the clinical outcomes by operators' default choice of access site. There was no significant difference in rates of MACE between procedures

Figure 1



Flow diagram outlining the number of participants where radial and femoral access sites were used.

performed by default radial vs. default femoral operators (111/1575 = 7% vs. 16/229 = 7% P = .97). The rate of major bleeding events between the two groups was not significantly different (49/1575 = 3.1% vs. 11/229 = 4.8% P = .18).

Relationship between operator default access site and clinical outcomes in cases where FA was used

A total of 332/1804 cases were performed via FA, with 210/332 = 63.3% performed by default femoral operators and 122/332 = 36.7% performed by default radial operators. Table V illustrates the baseline characteristics of the two groups. Cases where FA was performed by default radial operators had a significantly higher risk profile in terms of age, systolic blood pressure, eGFR, previous MI and PCI. FA cases were significantly more likely to have required venous access or had an IABP used during the procedure.

Table VI illustrates the clinical outcomes for the FA cases by default operator type. FA performed by default radial operators was associated with a significantly higher rate of MACE compared to FA performed by default femoral operators (22/122 = 18% vs. 14/210 = 6.7% P = .003). Mortality rates at 28 days were significantly higher in the FA performed by radial operators. Major bleeding events occurred with more frequency in the FA cases performed by RA operators (11/122 = 9% vs. 11/210 = 5.2% P < .001).

Discussion

The results of this study suggest that there is no difference in outcomes of MACE (111/1575 = 7% vs 16/229 = 7% P = .97) and major bleeding (49/1575 = 3.1% vs. 11/229 = 4.8% P = .18) when comparing cases based on operator default preference.

Recent randomized controlled trials (RCTs) comparing radial and femoral access in PPCI show conflicting results. Three large trials have shown that use of RA in PPCI is associated with lower mortality and fewer bleeding complications.[5,6,10] The largest and most recent trial, MATRIX (Minimizing Adverse Haemorrhagic Events by Transradial Access Site and Systemic Implementation of angioX), randomized 8404 patients with acute coronary syndrome to radial or femoral access and reported a significant difference in all-cause mortality (1.6% vs 2.2%, RR 0.72, 95% CI 0.53–0.99; P = .045) and major bleeding (1.6% vs 2.3%; RR 0.67, 95% CI 0.49–0.92; P = .013).This has reinforced a trend towards increased RA. RA is now recommended as the preferred access site by ESC

Table I. Baseline characteristics and demographics for radial and femoral access sites

	Radial access (n = 1472)	Femoral access (n = 332)	*P*
Baseline characteristics			
Age (years)	62.4+/−12.9	66.0+/−13.7	<.001
Body weight (kg)	80.5+/−17.9	77.7+/−18.4	.016
SBP on admission (mmHg)	137.4+/−27.4	130.1+/−30.3	<.001
eGFR (ml/kg/min)	76.0+/−16.0	69.8+/−20.1	<.001
Hemoglobin (g/dl)	13.6+/−1.6	13.2+/−1.8	<.001
Diabetes	195/1472 (13.2%)	53/332 (16%)	.84
Previous MI	154/1472 (10.5%)	59/332 (17.8%)	<.001
Previous CABG	16/1472 (1.1%)	26/332 (7.8%)	<.001
Previous PCI	98/1472 (6.7%)	31/332 (9.3%)	<.001
GPI Use	201/1471 (13.7%)	61/332 (18.4%)	.03
Venous access use	32/1472 (2.2%)	33/331 (10.0%)	<.001
IABP Use	37/1373 (2.7%)	22/305 (7.2%)	.001

SBP, Systolic BP; eGFR, estimated glomerular filtration rate; CABG, coronary artery bypass grafting; MI, myocardial infarction; PCI, percutaneous coronary intervention; GPI, glycoprotein inhibitors; IABP, intra-aortic balloon pump.

Table II. 28-day clinical outcomes by final site access

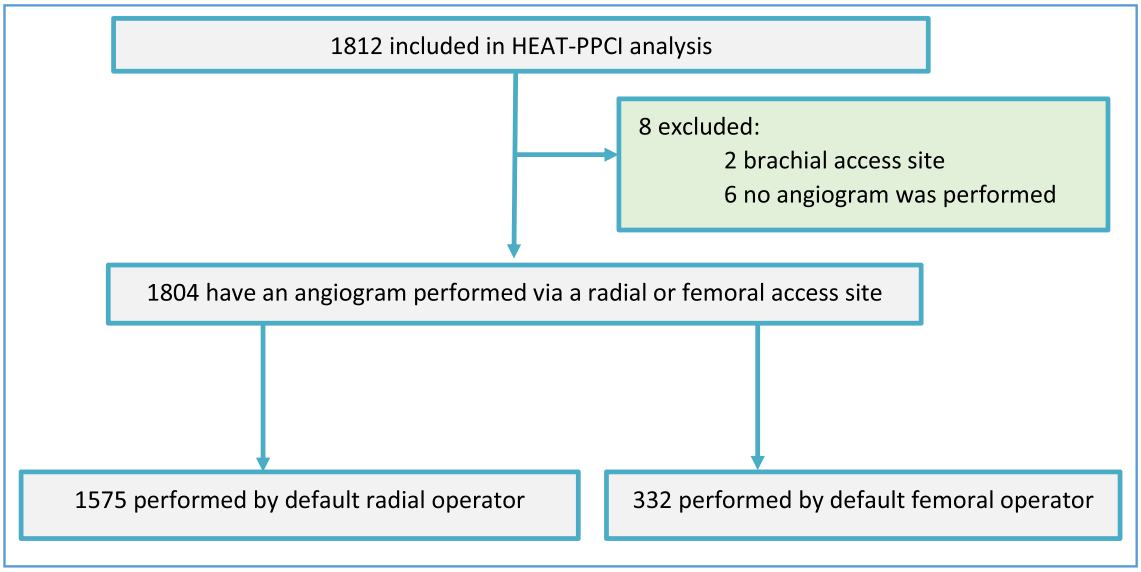
	All radial (n = 1472)	All femoral (n = 332)	*P*
MACE	91/1472 (6.2%)	36/332 (10.8%)	.003
Mortality	55/1472 (3.7%)	27/332 (8.1%)	.001
Major bleed	38/1472 (2.6%)	22/332 (6.6%)	.001
Access site related	5/1472 (0.3%)	7/332 (2.1%)	<.001
Minor bleed	118/1472 (8%)	62/332 (18.7%)	<.001
Access site related	59/1472 (4.0%)	55/332 (16.6%)	<.001
Any bleed	153/1472 (10.4%)	81/332 (24.4%)	<.001

MACE, Major adverse cardiovascular events.

guidelines on management of STEMI.[2] Other trials have shown no difference in outcomes between RA and FA.[7,8] There are several possible reasons for these differing results. Firstly, recent advances in technology, such as use of vascular closure devices, have improved the safety of FA.[11] Secondly, RCTs often use different exclusion criteria, definitions of clinical outcomes and doses of antithrombotic medications which may affect the external validity of the results. Thirdly, randomizing the access site does not consider the skill level of the operator. A recent observational trial of British Cardiovascular Intervention Society (BCIS) data showed total procedural volume and proportion of procedures undertaken radially by an operator was associated with lower mortality in patients undergoing PPCI via RA.[12] Therefore, the experience and familiarity of the operator is likely to affect the outcomes of the patient. For an RCT to compare the access sites in a useful way, operators would have to be similar in their competence in using both RA and FA. Few operators meet this requirement and most RCTs do not consider operator or center experience. Both MATRIX and RIVAL found that improvements in outcomes in RA cases were only significant when considering centers with high radial volume.[6,10]

Operators usually have a default access preference, in which they are more experienced.[9] This study compared outcomes by default operator type, reflecting real-world practice in a high-volume regional center. Patients, therefore, benefitted from the clinical judgment exercised by the operator in their choice of access site. The results showed no significant difference in clinical outcomes between radial and femoral operators, with comparable baseline characteristics in the two groups. Selection bias is likely to be minimal because patients were allocated to the operator at random, based on a rota system. These results suggest that FA may not be associated with increased MACE when performed by experienced femoral operators. In trials where the access site is randomized, complications in FA cases could be overestimated because the operator may have to perform

Figure 2



Flow diagram outlining the number of cases where access was gained by default femoral and default radial operators.

Table III. Baseline characteristics and demographics for default radial and default femoral operators

	Radial operators (n = 1575)	Femoral operators (n = 229)	*P*
Baseline characteristics			
Age (years)	63.0+/−13.1	63.2+/−13.3	.86
Body weight (kg)	79.9+/−17.9	80.8+/−18.3	.48
SBP on admission (mmHg)	136.0+/−28.1	136.1+/−28.0	.92
eGFR (ml/kg/min)	75.0+/−16.9	73.8+/−17.4	.32
Hemoglobin (g/dl)	13.5+/−1.6	13.6+/−1.5	.59
Diabetes	213/1575 (13.5%)	35/229 (15.3%)	.75
Previous MI	183/1575 (11.6%)	30/229 (13.1%)	.66
Previous CABG	30/1575 (1.9%)	12/229 (5.2%)	.006
Previous PCI	116/1575 (7.4%)	13/229 (5.7%)	.48
GPI use	219/1574 (13.9%)	43/229 (18.8%)	.05
Venous access use	61/1575 (3.9%)	16/228 (7.0%)	.003
IABP use	53/1469 (3.6%)	6/219 (2.7%)	.47

SBP, Systolic BP; eGFR, estimated glomerular filtration rate; CABG, coronary artery bypass grafting; MI, myocardial infarction; PCI, percutaneous coronary intervention; GPI, glycoprotein inhibitors; IABP, intra-aortic balloon pump.

via an access site which they would not have chosen in normal clinical practice. As far as we know, this is the first study analyzing outcomes by default operator type.

There have been multiple observational trials examining potential differences in outcomes when comparing access sites in PCI.[4,13,14] However, the circumstances and conduct of the HEAT-PPCI study afford a, possibly, unique opportunity to perform a comparison of the strategies of default femoral and radial access, free from much of the bias that normally confounds observational research. The data used in this study are from an RCT, with rigorous tracking of events and high-quality data collection. HEAT-PPCI used real-world, consecutive, unselected cases, making participant selection more reflective of routine practice.

A simple observational analysis of our data would suggest that the performance of PPCI cases with RA is associated with reduced incidence of mortality, MACE and major bleeding. However, examination of the baseline characteristics of patients grouped by final access site shows a less favorable risk profile in patients who had FA. Default radial operators only attempt

Table IV. Twenty-eight-day clinical outcomes by default radial and default femoral operators

	Radial operators (n = 1575)	Femoral operators (n = 229)	*P*
Outcomes			
MACE	111/1575 (7%)	16/229 (7%)	.97
Mortality	73/1575 (4.6%)	9/229 (3.9%)	.63
Major bleed	49/1575 (3.1%)	11/229 (4.8%)	.18
Access site related	8/1575 (0.5%)	4/229 (1.7%)	.055
Minor bleed	142/1575 (9%)	38/229 (16.6%)	<.001
Access site related	82/1575 (5.2%)	32/229 (14.0%)	<.001
Any bleed	186/1575 (11.8%)	48/229 (21%)	<.001

MACE, Major adverse cardiovascular events.

Table V. Baseline characteristics of participants where FA is used, by default operator type

	Femoral cases by radial operators (n = 122)	Femoral cases by femoral operators (n = 210)	*P*
Baseline characteristics			
Age (years)	70.2+/− 13.8	63.7+/−13.0	<.001
Body weight (kg)	71.9+/−18.2	80.7+/−17.8	<.001
SBP on admission (mmHg)	121.1+/−33.0	135.2+/−27.6	<.001
eGFR (ml/kg/min)	63.6+/−22.8	73.8+/−19.4	<.001
Hemoglobin (g/dl)	12.6+/−2.0	13.5+/−1.5	<.001
Diabetes	22/122 (18%)	31/210 (14.8%)	.19
Previous MI	32/122 (26.2%)	27/210 (12.9%)	.002
Previous CABG	14/122 (11.5%)	12/210 (5.7%)	.06
Previous PCI	19/122 (15.6%)	12/210 (5.7%)	.003
GPI use	21/122 (17.2%)	40/210 (19%)	.68
Venous access use	28/122(23.0%)	15/209 (7.2%)	<.001
IABP use	17/114 (14.9%)	5/191 (2.6%)	<.001

SBP, Systolic BP; eGFR, estimated glomerular filtration rate; CABG, coronary artery bypass grafting; MI, myocardial infarction; PCI, percutaneous coronary intervention; GPI, glycoprotein inhibitors; IABP, intra-aortic balloon pump.

femoral access in specific circumstances, many of which are associated with higher risk. Such reasons include circulatory collapse resulting in an impalpable pulse; radial occlusion associated with previous procedures (a marker of chronic or advanced disease); a requirement to access bypass graft conduits and a need to access the groin for reasons of intra-aortic balloon pump insertion or placement of a temporary wire.

Some studies have suggested that procedures performed through FA by radial operators have higher complication rates.[15,16] This seems logical because increased experience with an access site leads to better outcomes.[12] However, a recent observational study showed that a reduction in the number and proportion of femoral cases is not associated with a loss of femoral proficiency.[17] This may be because although the radial operators are more experienced in RA in uncomplicated cases, in cases where the patient presents in cardiogenic shock or hemodynamically unstable, they perform PCI via FA and therefore maintain competency in the use of FA in complex cases. Our study shows that cases performed via FA had higher rates of MACE and major bleeding when performed by default RA operators, but the risk profile of these patients was less favorable. This suggests that the overall clinical condition of the patient may explain the increased incidence of MACE and major bleeding, rather than the access site used or access skills of the operator.

Limitations

The number of cases performed by the default femoral operators (and the number of associated adverse events) is low and hence it is difficult to characterize results in this group with precision. There was no routine use of radiographic guidance, micropuncture or ultrasound imaging for femoral access during the trial. It is likely use of a more fastidious technique would improve outcomes for patients who have procedures performed via FA. This is an analysis of observational data and therefore cannot be used to infer a causal relationship

Table VI. Twenty-eight-day clinical outcomes in cases where FA was used, by default radial and default femoral operators

	Radial operators (n = 122)	Femoral operators (n = 210)	*P*
Outcomes			
MACE	22/122 (18%)	14/210 (6.7%)	.003
Mortality	20/122 (16.4%)	7/210 (3.3%)	.001
Major bleed	11/122 (9%)	11/210 (5.2%)	<.001
Access site related	3/122 (2.5%)	4/210 (1.9%)	.71
Minor bleed	24/122 (19.7%)	38/210 (18.1%)	.72
Access site related	23/122 (18.9%)	32/210 (15.2%)	.45
Any bleed	33/122 (27%)	48/210 (22.9%)	.39

MACE, Major adverse cardiovascular events.

between access site and outcomes. There may be a risk of unmeasured confounding. HEAT-PPCI was a single center study so the results are not necessarily generalizable to all patient groups or operator experiences.

Conclusion

Default femoral operators achieved comparable outcomes compared to default radial operators. The less favorable outcomes observed in FA cases may result from its selective use by radial operators in high risk cases. Further studies are required to establish the differences between RA and FA since the introduction of vascular closure devices and should compare the default operator type as this would better reflect real-world practice.

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