Bay Labs, Inc. Protocol 1.0



Study for Point-of-Care Echocardiography with Assistance Technology

Table and Figure Mockups

Complete Set

Version 4.0

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Table 1 Patient Enrollment and Accountability by Site

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Study Phase |  |  | Study Site | | All |
|  |  |  | Northwestern | Minneapolis |  |
|  | Patients Enrolled, Neither [STUDY\_ECHO\_PROCEDURE.Study\_Exam\_Date or CONTROL\_ECHO\_PROCEDURE.Control\_Exam\_Date] is non-missing |  | XX | XX | XX |
|  |  |  |  |  |  |
| Nurse Exam | Patients Undergoing Nurse-acquired EchoGPS echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Patients Completing Nurse-acquired EchoGPS echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Patients withdrawing early from Nurse-acquired EchoGPS echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  | Withdrawal reason, n (%) |  |  |  |  |
|  |  | Patient withdrew consent | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Adverse Event | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Equipment Issue | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Other | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
| Sonographer Exam | Patients Undergoing Sonographer-acquired echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Patients Completing Sonographer-acquired echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Patients withdrawing early from Sonographer-acquired echocardiogram, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  | Withdrawal reason, n (%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Patient withdrew consent | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Adverse Event | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Equipment Issue | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | Other | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
| Study Completion | Patients Completing both Nurse exam and Sonographer exam, n(%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Table 2 Patient Enrollment and Accountability by Nurse

[STUDY\_ECHO\_PROCEDURE or CONTROL\_ECHO\_PROCEDURE]

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Acquiring Nurse (Nurse ID) | | | | | | | |  |
| Study Phase |  |  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | All |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | Patients Enrolled, N |  |  |  |  |  |  |  |  |  | XX |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Nurse Exam | Patients Undergoing Nurse-acquired EchoGPS echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  | Patients Completing Nurse-acquired EchoGPS echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  | Patients withdrawing early from Nurse-acquired EchoGPS echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | Withdrawal reason, n (%) |  |  |  |  |  |  |  |  |  |  |
|  |  | Patient withdrew consent |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Adverse Event |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Equipment Issue |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Other |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Sonographer Exam | Patients Undergoing Sonographer-acquired echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  | Patients Completing Sonographer-acquired echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  | Patients withdrawing early from Sonographer-acquired echocardiogram, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | Withdrawal reason, n (%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Patient withdrew consent |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Adverse Event |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Equipment Issue |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  | Other |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Study Completion | Patients Completing both Nurse exam and Sonographer exam, n(%) |  |  |  |  |  |  |  |  |  | XX (XX.X%) |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

Table 3 Demographics of Enrolled Patients

[DEMOG]

|  |  |
| --- | --- |
|  |  |
|  | Total |
| Total Enrolled Y if either [STUDY\_ECHO\_PROCEDURE.Study\_Exam\_Date] is non-missing OR  [CONTROL\_ECHO\_PROCEDURE.Control\_Exam\_Date] is non-missing | XX |
|  |  |
| Sex, n (% of enrolled) |  |
| Female | XX(X.X%) |
| Male | XX(X.X%) |
|  |  |
| Ethnicity, n (% of enrolled) |  |
| Hispanic or Latino | XX(X.X%) |
| Not Hispanic or Latino | XX(X.X%) |
| Unknown/Not Reported | XX(X.X%) |
|  |  |
| Race, n(% of enrolled) |  |
| White | XX(X.X%) |
| Black/ African American | XX(X.X%) |
| Asian | XX(X.X%) |
| American Indian / Alaska Native |  |
| Native Hawaiian or other Pacific Islander | XX(X.X%) |
| Unknown/ Not Reported | XX(X.X%) |
| Other | XX(X.X%) |
|  |  |
| Age on day of protocol-required scan  , years |  |
| n | XX |
| mean (SD) | XX.X(XX.XX) |
| median | XX.X |
| min, max | XX.X, XX.X |

Table 4 Nurse User Training and Qualification for User Readiness by Site

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | ~~Study Site~~ | | ~~All~~ |
|  |  | ~~Northwestern~~ | ~~Minneapolis~~ |  |
| ~~Nurses undergoing didactic training, guided EchoGPS training and hands-on practice, N~~ |  | ~~XX~~ | ~~XX~~ | ~~XX~~ |
|  |  |  |  |  |
| ~~Nurses approved as a User, n (%)~~ |  | ~~XX (XX.X%)~~ | ~~XX (XX.X%)~~ | ~~XX (XX.X%)~~ |
|  |  |  |  |  |
| ~~Nurses failed as a User, n (%)~~ |  | ~~XX (XX.X%)~~ | ~~XX (XX.X%)~~ | ~~XX (XX.X%)~~ |
|  |  |  |  |  |
| ~~Number of independent, hands-on practice scans necessary before User qualified, per nurse\*~~ |  |  |  |  |
|  | ~~mean (SD)~~ |  |  |  |
|  | ~~median~~ |  |  |  |
|  | ~~min, max~~ |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Table 5 Summary of Patients with Known Cardiac Abnormalities at Time of Enrollment by Study Site

[CARDIAC\_ABNORM\_ENROLL]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
| Patients with any Known Cardiac Abnormality per protocol, n(%) |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
|  |  |  |  |  |
| Category of Abnormality |  |  |  |  |
|  |  |  |  |  |
| Abnormal left ventricular size  [ABCAT=LVS] | TOTAL | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Dilated LV | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Abnormal LV size or wall thickness | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Abnormal left ventricular function  [ABCAT=LVF] | TOTAL | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Hyperdynamic LV | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Reduced LV function +/- regional wall  abnormalities | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severely reduced LV function +/- regional  wall abnormalities | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Abnormal right ventricular size  [ABCAT=RVS] | TOTAL | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Dilated RV | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Pericardial effusion  [ABCAT=PE] | TOTAL | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Presence of more-than-trivial/physiologic  pericardial effusion | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Inferior vena cava size  [ABCAT=IVCS] | TOTAL | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Dilated | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Lack of size change on inspiration | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Right ventricular function  [ABCAT=RVF] | TOTAL | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Decreased RV function | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Left atrial size  [ABCAT=LAS] | TOTAL | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Enlargement | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Valvular abnormalities  [ABCAT=VA] | TOTAL | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mitral valve calcification/stenosis | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mitral valve prolapse | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mitral annular calcification | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Aortic valve calcification/stenosis | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Valvular/leaflet thickening | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Bicuspid aortic valve | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Tricuspid valve calcification/stenosis | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Implanted Medical Devices  [ABCAT=IMD] | TOTAL | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Pacemaker/ICD | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Leadless pacemaker | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Prosthetic heart valve | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | LAA closure device | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Atrial septal defect closure device | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Ventricular septal defect closure device | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Patent foramen ovale closure device | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Valve repair device | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |

Table 6 Summary of Patients with Cardiac Abnormalities Identified through Scheduled Standard-of-Care Echocardiogram by Study Site

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
| Patients with any Cardiac Abnormality Identified through Scheduled Echocardiogram, n(%) | [cardiac\_abnormality=TRUE] | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
|  |  |  |  |  |
| Category of Abnormality, n(%) |  |  |  |  |
|  |  |  |  |  |
| SPECIFY\_ABNORMALITY\_\_\_ABNORMA | Abnormal left ventricular size or function | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
| SPECIFY\_ABNORMALIT\_1\_\_\_\_ABNORMA | Abnormal right ventricular size or function | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
| SPECIFY\_ABNORMALIT\_1\_\_\_\_ABNORMA | Abnormal left atrial size | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Abnormal right atrial size | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Septal defect | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Abnormal mitral valve | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Abnormal tricuspid valve | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Abnormal aortic valve | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Pericardial effusion | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Inferior vena cava size | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Patent foramen ovale | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Other abnormality | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |

Table 7 Summary of Cardiac Pathology Findings from Standard-of-Care Echocardiogram: Abnormal Left Ventricular Size

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
|  |  |  |  |  |
| Left Ventricular Size |  |  |  |  |
|  | Small | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Normal | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Dilated | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Dilation |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Presence of Left Ventricular Hypertrophy |  |  |  |  |
|  | Yes | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | No | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Left Ventricular Hypertrophy |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Systolic function |  |  |  |  |
|  | Normal | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Borderline (Low normal) | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mildly decreased | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderately decreased | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severely decreased | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Diastolic function |  |  |  |  |
|  | Normal | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Grade I: Impaired relaxation | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Grade II: Pseudonormal | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Grade III: Reversible restricted | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Grade IV: Fixed restricted | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mildly decreased | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderately decreased | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderately decreased | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderately to severely decreased | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severely decreased | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Abnormal LV wall motion |  |  |  |  |
|  | Yes | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | No | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Type of abnormal wall motion |  |  |  |  |
|  | Hyperkinetic | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Hypokinetic | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Akinetic | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Dyskinetic | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Regional or global |  |  |  |  |
|  | Regional | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Global | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |

Table 8 Summary of Cardiac Pathology Findings from Standard-of-Care Echocardiogram: Abnormal Right Ventricular Size

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
|  |  |  |  |  |
| Right Ventricular Size |  |  |  |  |
|  | Small | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Normal | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Dilated | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Dilation |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Systolic function |  |  |  |  |
|  | Normal | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Borderline (Low normal) | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mildly decreased | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderately decreased | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severely decreased | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |

Table 9 Summary of Cardiac Pathology Findings from Standard-of-Care Echocardiogram: Abnormal Left Atrial Size

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
|  |  |  |  |  |
| Left Atrial Size |  |  |  |  |
|  | Small | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Normal | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Dilated | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Dilation |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |

Table 10 Summary of Cardiac Pathology Findings from Standard-of-Care Echocardiogram: Abnormal Right Atrial Size

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
|  |  |  |  |  |
| Right Atrial Size |  |  |  |  |
|  | Small | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Normal | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Dilated | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Dilation |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |

Table 11 Summary of Cardiac Pathology Findings from Standard-of-Care Echocardiogram: Septal Defect

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
|  |  |  |  |  |
| Septal Defect |  |  |  |  |
|  | Atrial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Ventricular | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |

Table 12 Summary of Cardiac Pathology Findings from Standard-of-Care Echocardiogram: Abnormal Mitral Valve

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
|  |  |  |  |  |
| Mitral Valve Abnormality |  |  |  |  |
|  | Stenosis | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Regurgitation | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Leaflet calcification | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Annular calcification | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Leaflet thickening | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Prolapse | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Flail | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Tethering | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Other | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
|  |  |  |  |  |
| Severity of Stenosis |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Regurgitation |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Leaflet Calcification |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Annular Calcification |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Leaflet Thickening |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Prolapse Leaflet |  |  |  |  |
|  | Anterior | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Posterior | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Bi-leaflet (anterior and posterior) | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Flail Leaflet |  |  |  |  |
|  | Anterior | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Posterior | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Bi-leaflet (anterior and posterior) | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |

Table 13 Summary of Cardiac Pathology Findings from Standard-of-Care Echocardiogram: Abnormal Tricuspid Valve

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
|  |  |  |  |  |
| Tricuspid Valve Abnormality |  |  |  |  |
|  | Stenosis | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Regurgitation | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Leaflet calcification | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Annular calcification | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Leaflet thickening | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Prolapse | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Flail | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Tethering | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Other | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
|  |  |  |  |  |
| Severity of Stenosis |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Regurgitation |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Leaflet Calcification |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Annular Calcification |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Leaflet Thickening |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |

Table 14 Summary of Cardiac Pathology Findings from Standard-of-Care Echocardiogram: Abnormal Aortic Valve

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
|  |  |  |  |  |
| Aortic Valve Abnormality |  |  |  |  |
|  | Stenosis | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Regurgitation | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Leaflet calcification | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Annular calcification | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Leaflet thickening | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Prolapse | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Flail | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Tethering | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Bicuspid aortic valve | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Other | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
|  |  |  |  |  |
| Severity of Stenosis |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Regurgitation |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Leaflet Calcification |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Annular Calcification |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Severity of Leaflet Thickening |  |  |  |  |
|  | None/Trivial | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mild to moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Moderate to severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Severe | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Indeterminate | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not Reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |

Table 15 Summary of Cardiac Pathology Findings from Standard-of-Care Echocardiogram: Pericardial Effusion

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
|  |  |  |  |  |
| Presence of more-than-trivial/physiologic pericardial effusion |  |  |  |  |
|  | Yes | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | No | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |

Table 16 Summary of Cardiac Pathology Findings from Standard-of-Care Echocardiogram: Inferior Vena Cava Size

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
|  |  |  |  |  |
| IVC Size |  |  |  |  |
|  | Dilated | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Lack of Size Change on Inspiration | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |

Table 17 Medical History: Cardiac History

[MEDHIST]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
| Patients who reported the following prior conditions, n(%) |  |  |  |  |
|  |  |  |  |  |
|  | Hypertension | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Hyperlipidemia | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Diabetes | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Heart Failure | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Atrial Fibrillation | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Other Arrythmias | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Coronary Artery Disease | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Prior Heart Attack | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Valvular Disease | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Pulmonary Hypertension | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Heart Transplant | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Cardiomyopathies | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Congenital heart disease | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Other | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | None | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| If Valvular Stenosis, n(%) that were: |  |  |  |  |
|  |  |  |  |  |
|  | Aortic | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mitral | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Tricuspid | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Pulmonary | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | None | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| If Valvular Regurgitation, n(%) that were |  |  |  |  |
|  | Aortic | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Mitral | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Tricuspid | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Pulmonary | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | None | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| If Valvular Disease, n(%) patients who underwent |  |  |  |  |
|  | Valve replacement: mechanical or bioprosthetic | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Valve repair | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | None | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| If Cardio Myopathies, n(%) that were |  |  |  |  |
|  | Dilated | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Hypertrophic | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Infiltrative/Amyloidosis | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| If Congenital Heart Disease, n(%) that were |  |  |  |  |
|  | Ventricular Septal Defect (VSD) | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Atrial Septal Defect (ASD) | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Patent Ductus Arteriosus (PDA) | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Pulmonary Stenosis (PS) | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Bicuspid Aortic Valve (BiAV) | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Tetralogy of Fallot (TET) | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Ebstein's Anomaly | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Coarctation of the Aorta | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Other | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |

Table 18 Medical History: Non-Cardiac History

[MEDHIST]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
| Patients who reported the following prior conditions, n(%) |  |  |  |  |
|  |  |  |  |  |
|  | Renal disease | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | COPD/Emphysema | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Pulmonary Embolus | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Systemic infiltrative disease like amyloid or  hemachromatosis | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Cancer | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Other | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | None | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| If Renal Disease, n(%) that were |  |  |  |  |
|  |  |  |  |  |
|  | Chronic renal failure | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Chronic renal disease | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| If Cancer, n(%) patients who underwent chemotherapy |  |  |  |  |
|  | Yes | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | No | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
| If Cancer, n(%) patients who underwent radiation |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Yes | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | No |  |  |  |
|  | Not reported |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Table 19 Smoking History

[MEDHIST]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
| History of Smoking, n(%) |  |  |  |  |
|  |  |  |  |  |
|  | Yes | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | No | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| If Yes, Smoking Status |  |  |  |  |
|  | Current | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Past | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Number of Pack Years |  |  |  |  |
|  | n | XX | XX | XX |
|  | mean(SD) | XX.X (XX.XX) | XX.X (XX.XX) | XX.X (XX.XX) |
|  | median | XX.X | XX.X | XX.X |
|  | min, max | XX.X, XX.X | XX.X, XX.X | XX.X, XX.X |
|  |  |  |  |  |
| Years since stopped smoking | n | XX | XX | XX |
|  | mean(SD) | XX.X (XX.XX) | XX.X (XX.XX) | XX.X (XX.XX) |
|  | median | XX.X | XX.X | XX.X |
|  | min, max | XX.X, XX.X | XX.X, XX.X | XX.X, XX.X |
|  |  |  |  |  |
| Used Smokeless tobacco, n(%) | Yes | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | No | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Table 20 Medical History: Implantables

[MEDHIST]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Study Site | | All |
|  |  | Northwestern | Minneapolis |  |
| Patients Enrolled, N |  | XX | XX | XX |
|  |  |  |  |  |
| Patients who reported any implantable, n(%) |  |  |  |  |
|  |  |  |  |  |
|  | Yes | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | No | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  | Not reported | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |
| Type of Implantable |  |  |  |  |
|  | ICD |  |  |  |
|  | Pacemaker |  |  |  |
|  | Leadless pacemaker |  |  |  |
|  | Prosthetic heart valve |  |  |  |
|  | Heart valve repair device |  |  |  |
|  | LAA closure device |  |  |  |
|  | Atrial septal defect closure device |  |  |  |
|  | Ventricular septal defect closure device |  |  |  |
|  | Patent foramen ovale closure device |  |  |  |
|  | Breast implants |  |  |  |
|  | Other |  |  |  |
|  |  |  |  |  |

Table 21 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by BMI category

[STUDY\_ECHO\_CLINPARM]

Derivation rule for Image is acceptable:

1. For each of CARDIO1, CARDIO2, …CARDIO5, create a companion variable CARDIO1YN, CARDIO2YN, ….CARDIO5YN that is 0 if “Image quality inadequate for visual assessment” and 1 otherwise.

2. Summarize across CARDIO1YN, CARDIO2YN, ….CARDIO5YN by taking the majority vote.

3. If majority vote=1 then image is acceptable, otherwise image is unacceptable.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | BMI category of Patient | | | All | MRMC  conf. int. | Acceptance  Criterion | p-value | PASS or  FAIL­­ |
|  | Clinical Parameter |  | < 25 | 25- <30 | ≥30 |  |  |  |  |  |
| 1 | Qualitative Visual Assessment Left Ventricular Size, Yes or no |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  | 80.0% |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment Left Ventricular Global Function, Yes or no |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  | 80.0% |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment Right Ventricular Size, Yes or no |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  | 80.0% |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivialPericardial Effusion, Yes or no |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  | 80.0% |  |  |

Table 22 Side-by-Side Comparison of Acceptability of Nurse-Acquired vs. Sonographer-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment-Primary Endpoints

[STUDY\_ECHO\_CLINPARM] [CONTROL\_ECHO\_CLINPARM]

**{Difference is Pct Acceptable= % Acceptable in Nurse-Acquired Scan - % Acceptable in Sonographer-Acquired Scan}**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Nurse-Acquired Scan | |  | Sonographer-Acquired Scan | |  |
|  |  |  | Acceptability | MRMC  conf. int. |  | Acceptability | MRMC  conf. int. | Diff in Pct. Acceptable |
|  | Clinical Parameter |  |  |  |  |  |  |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers | X |  |  | X |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned | XXX |  |  | XXX |  |  |
|  |  | n (%) acceptable | XXX (XX.X%) | XX.X%, XX.X% |  | XXX (XX.X%) | XX.X%, XX.X% | XX.X% |
|  |  |  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivialPericardial Effusion, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |

Table 23 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Presence of Known Cardiac Abnormality

[STUDY\_ECHO\_CLINPARM]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Presence of Known Cardiac Abnormality | | All |
|  | Clinical Parameter |  | Present | Absent |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivialPericardial Effusion, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table 24 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Study Site

[STUDY\_ECHO\_CLINPARM]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Study Site | | All |
|  | Clinical Parameter |  | Northwestern | Minneapolis |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivialPericardial Effusion, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table 25 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Sex of Patient

[STUDY\_ECHO\_CLINPARM]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Sex | | All |
|  | Clinical Parameter |  | Male | Female |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivialPericardial Effusion, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table 26 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Age of Patient

[STUDY\_ECHO\_CLINPARM]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Age of Patient at Time of Scan | | All |
|  | Clinical Parameter |  | < 65 | ≥ 65 |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivialPericardial Effusion, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table 27 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Sequence Number of Scan Within Nurse

[STUDY\_ECHO\_CLINPARM]

{Within nurse, sort scans by date and time. The earliest is sequence number 1, the next earliest is sequence number 2, etc.}

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Number of Scans Completed by Sequence Number of Scan Within Nurse | | |  |
|  |  |  |  |  |  | All |
|  |  |  | 1-10 | 11-20 | 21-30 |  |
|  | Clinical Parameter |  |  |  |  |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size, Yes or no |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function, Yes or no |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size, Yes or no |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivialPericardial Effusion, Yes or no |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |

Table 28 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Primary Endpoints, by Acquiring Nurse

[STUDY\_ECHO\_CLINPARM]

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Acquiring Nurse (Nurse ID | | | | | | | | All |
|  |  |  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |  |
|  | Clinical Parameter |  |  |  |  |  |  |  |  |  |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 8 |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivial Pericardial Effusion, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |

Table 29 Side-by-Side Comparison of Acceptability of Nurse-Acquired vs. Sonographer-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment-Secondary Endpoints

[STUDY\_ECHO\_CLINPARM] [CONTROL\_ECHO\_CLINPARM]

**{Difference is Pct Acceptable= % Acceptable in Nurse-Acquired Scan - % Acceptable in Sonographer-Acquired Scan}**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Nurse-Acquired Scan | |  | Sonographer-Acquired Scan | |  |
|  |  |  | Acceptability | MRMC  conf. int. |  | Acceptability | MRMC  conf. int. | Diff in Pct. Acceptable |
|  | Clinical Parameter |  |  |  |  |  |  |  |
| 1 | Qualitative Visual Assessment of Inferior Vena Cava Size, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers | X |  |  | X |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned | XXX |  |  | XXX |  |  |
|  |  | n (%) acceptable | XXX (XX.X%) | XX.X%, XX.X% |  | XXX (XX.X%) | XX.X%, XX.X% | XX.X% |
|  |  |  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Right Ventricular Function, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Left Atrial Size, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Aortic Valve, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Mitral Valve, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Tricuspid Valve, Yes or no |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

Table 30 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by BMI category

[STUDY\_ECHO\_CLINPARM] [DEMOG]

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | BMI category of Patient | | | All | MRMC  conf. int. |
|  | Clinical Parameter |  | < 25 | 25- <30 | ≥30 |  |  |
| 1 | Qualitative Visual Assessment of Inferior Vena Cava Size, Yes or no |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Right Ventricular Function, Yes or no |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Left Atrial Size, Yes or no |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Aortic Valve, Yes or noQualitative |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Mitral Valve, Yes or no |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Tricuspid Valve, Yes or no |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

Table 31 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by Presence of Known Cardiac Abnormalities

[STUDY\_ECHO\_CLINPARM]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Presence of Known Cardiac Abnormality  [DEMOG.CARDIAC\_YN] | | All |
|  | Clinical Parameter |  | Present | Absent |  |
| 1 | Qualitative Visual Assessment of Inferior Vena Cava Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Right Ventricular Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Left Atrial Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Aortic Valve, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Mitral Valve, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Tricuspid Valve, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Table 32 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by Study Site

[STUDY\_ECHO\_CLINPARM]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Study Site | | All |
|  | Clinical Parameter |  | Northwestern | Minneapolis |  |
| 1 | Qualitative Visual Assessment of Inferior Vena Cava Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Right Ventricular Function, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Left Atrial Size, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Aortic Valve, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Mitral Valve, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Tricuspid Valve, Yes or no |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table 33 Acceptability of Nurse-Acquired EchoGPS Echocardiography for Clinical Parameter Assessment- Secondary Endpoints, by Acquiring Nurse

[STUDY\_ECHO\_CLINPARM]

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Acquiring Nurse (lNurse ID) | | | | | | | | All |
|  |  |  | 101 | 102 | 103 | 104 | 105 | 106 | 107 | 108 |  |
|  | Clinical Parameter |  |  |  |  |  |  |  |  |  |  |
| 1 | Qualitative Visual Assessment of Inferior Vena Cava Size, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 8 |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Right Ventricular Function, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Left Atrial Size, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Aortic Valve, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Mitral Valve, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Tricuspid Valve, Yes or no |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |  |  |  |

Table 34 Inter-User Variability of Nurse Performance Using EchoGPS to Acquire Scans of Acceptable Quality- Primary Clinical Parameters

[STUDY\_ECHO\_CLINPARM]

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Clinical Parameter | Number of Nurses Assessing this Parameter | Percent of Scans that were of Acceptable Image Quality  to Assess Clinical Parameter | | | | |
|  |  |  | Worst  Performance  [Among the 8 nurses, what was the worst % acceptable?] | Best  Performance  [Among the 8 nurses, what was the best % acceptable?] | Range  best - worst | Mean  average percent acceptable across the 8 nurse | %CV  100 \*standard deviation of % acceptable / mean of % acceptable |
|  |  |  |  |  |  |  |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivial Pericardial Effusion | 8 |  |  |  |  |  |

Table 35 Inter-User Variability of Nurse Performance Using EchoGPS to Acquire Scans of Acceptable Quality- Secondary Clinical Parameters

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Secondary  Clinical Parameter | Number of Nurses Assessing this Parameter | Percent of Scans that were of Acceptable Image Quality  to Assess Clinical Parameter | | | | |
|  |  |  | Worst  Performance  [Among the 8 nurses, what was the worst % acceptable?] | Best  Performance  [Among the 8 nurses, what was the best % acceptable?] | Range  best - worst | Mean  average percent acceptable across the 8 nurse | %CV  100 \*standard deviation of % acceptable / mean of % acceptable |
|  |  |  |  |  |  |  |  |
| 1 | Qualitative Visual Assessment of Inferior Vena Cava Size | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Right Ventricular Function | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Left Atrial Size | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Aortic Valve | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Mitral Valve | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Tricuspid Valve | 8 |  |  |  |  |  |

Table 36 Inter-User Variability of Nurse Performance Using EchoGPS to Acquire Scans of Sufficient Diagnostic Quality by View

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | View | Number of Nurses Assessing this View | Percent of Views that were of Sufficient Diagnostic Quality | | | | |
|  |  |  | Worst  Performance  [Among the 8 nurses, what was the worst % sufficient diagnostic quality?] | Best  Performance  [Among the 8 nurses, what was the best % sufficient diagnostic quality?] | Range  best - worst | Mean  average percent acceptable across the 8 nurse | %CV  100 \*standard deviation of % sufficient diagnostic quality / mean of % sufficient diagnostic quality |
|  |  |  |  |  |  |  |  |
| 1 | PLAX | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | PSAX-AV | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | PSAX-MV | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | PSAX-PM | 8 |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 10- | SC-IVC |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

Table 37 Acquisition Time- Summary of Time to Acquire 10-view Echocardiogram by Nurse, Total and by View\*

{Time for total scan in [STUDY\_ECHO\_PROCEDURE.Study Endtime- Study\_Starttime]

Time for each view is in [STUDY\_ECHO\_VIEW.Scantime]}

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| View | Acquisition Time (min) | Acquiring Nurse (NurseID) | | | | | | | | All |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |  |  |  |  |  |  |
|  | n |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |  |  |  |
|  | n exams |  |  |  |  |  |  |  |  |  |
|  | mean (SD) |  |  |  |  |  |  |  |  |  |
|  | median |  |  |  |  |  |  |  |  |  |
|  | min, max |  |  |  |  |  |  |  |  |  |

Table 38 Inter-User Variability of Acquisition Time among Nurses, Total and by View \*

Time for total scan in [STUDY\_ECHO\_PROCEDURE.Study Endtime- Study\_Starttime]

Time for each view is in [STUDY\_ECHO\_VIEW.Scantime]

TOTAL= Within each nurse, average the total acquisition time across all patient scans assigned to that patient. Then among the 8 mean acquisition times, compute min, max, range, mean, sd, %cv.

PLAX= Within each nurse, average the acquisition time for the PLAX view across all patient scans assigned to that patient. Then among the 8 mean PLAX acquisition times, compute min, max, range, mean, sd, %cv.

and so on…

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Mean Per-Nurse Acquisition Time | | | | | |
| View |  | Number of Nurses  Attempting this View | Shortest  Mean  Time | Longest  Mean  Time | Range | Mean  across  Nurses | SD  across  Nurses | %CV  across Nurses |
|  |  |  |  |  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |  |

Table 39 Percent of Views that were Autocaptured by BMI category

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | BMI Category of Patient | | |  |
| View |  | < 25 | 25- <30 | ≥30 | All |
|  |  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |

Table 40 Percent of Views that were Autocaptured by Presence of Known Cardiac Abnormalities

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Presence of Known Cardiac Abnormalities  [DEMOG.CARDIAC\_YN] | |  |
| View |  | Present | Absent | All |
|  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 1 | PLAX |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 5 | AP4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 6 | AP5 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 7 | AP3 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 8 | AP2 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 9 | SubC4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 10 | SC-IVC |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |

Table 41 Percent of Views that were Autocaptured by Age of Patient

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Age of Patient | |  |
| View |  | < 65 | ≥ 65 | All |
|  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 1 | PLAX |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 5 | AP4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 6 | AP5 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 7 | AP3 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 8 | AP2 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 9 | SubC4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 10 | SC-IVC |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |

Table 42 Percent of Views that were Autocaptured by Sex of Patient

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Sex of Patient | |  |
| View |  | Male | Female | All |
|  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 1 | PLAX |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 5 | AP4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 6 | AP5 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 7 | AP3 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 8 | AP2 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 9 | SubC4 |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |
|  |  |  |  |  |
| 10 | SC-IVC |  |  |  |
|  | N of Scans |  |  |  |
|  | n (%) Autocaptured |  |  |  |

Table 43 Percent of Views that were Autocaptured by Sequence Number of Scan within Nurse

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Sequence Number of Scan within Nurse | | |  |
| View |  | 1-10 | 11-20 | 21-30 | All |
|  |  |  |  |  |  |
| 10-View Total | TOTAL |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  | N of Scans |  |  |  |  |
|  | n (%) Autocaptured |  |  |  |  |

Table 44 Inter-User Variability of Percent of Scans Autocaptured among Nurses, Total and by View

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Percent of Scans Autocaptured | | | | | |
| View |  | Number of Nurses  Attempting this View | Lowest  Pct . Autocaptured among Nurses | Highest  Pct. Autocaptured among Nurses | Range | Mean  Pct. Autocaptured  among Nurses | SD  Pct. Autocaptured  among Nurses | %CV  Pct. Autocaptured  among Nurses |
|  |  |  |  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |  |

Table 45 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and BMI category

[STUDY\_ECHO\_VIEW]

[To compute Diagnostic Quality (1,0), compute the median of CARDIO1, CARDIO2, CARDIO3, CARDIO4, CARDIO5. If the median >= 3.0, then Diagnostic Quality=1, else Diagnostic Quality=0. ]

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | View |  | BMI category of Patient | | | All | MRMC  conf. int. |
|  |  |  | < 25 | 25- < 30 | ≥30 |  |  |
| 1 | PLAX |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table 46 Side-by-Side Comparison of Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography vs. Sonographer –Acquired Echocardiography by 2-D View

[STUDY\_ECHO\_VIEW]

[CONTROL\_ECHO\_VIEW]

**{Difference in Pct Acceptable= % Acceptable in Nurse-Acquired Scan - % Acceptable in Sonographer-Acquired Scan}**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Nurse-Acquired Scans | |  | Sonographer-Acquired Scans | |  |
|  | View |  | Diagnostic  Quality  (ACEP ≥ 3) | MRMC  conf. int. |  | Diagnostic  Quality  (ACEP ≥ 3) | MRMC  conf. int. | Diff in Pct. Acceptable |
|  |  |  |  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |  |
|  |  | n of Acquirers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |

Table 47 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Presence of Known Cardiac Abnormalities

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Presence of Known Cardiac Abnormalities | | All |
|  |  |  | Present | Absent |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table 48 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Study Site

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Study Site | | All |
|  |  |  | Northwestern | Minneapolis |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table 49 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Sex of Patient

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Sex | | All |
|  |  |  | Male | Female |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table 50 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Age of Patient

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Age of Patient at Time of Scan | | All |
|  |  |  | < 65 | ≥ 65 |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Nurses |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table 51 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Sequence Number of Scan Within Nurse

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | View |  | Sequence Number of Scan Within Nurse | | | All |
|  |  |  | 1-10 | 11-20 | 21-30 |  |
| 1 | PLAX |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |
|  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table 52 Diagnostic Quality of Nurse-Acquired EchoGPS Echocardiography, by 2-D View and Acquiring Nurse

[STUDY\_ECHO\_VIEW]

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | View |  | Acquiring Nurse (Nurse ID) | | | | | | | |  |
|  |  |  |  |  |  |  |  |  |  |  | All |
| 1 | PLAX |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |  |  |  |  |
|  |  | n of Nurses |  |  |  |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table 53 Acceptability of Trained-Sonographer-Acquired Transthoracic Echocardiogram for Clinical Parameter Assessment by BMI category

[CONTROL\_ECHO\_CLINPARM]

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Clinical Parameter |  | BMI category of Patient | | | All | MRMC  conf. int. |
|  |  |  | < 25 | 25- <30 | ≥30 |  |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivial Pericardial Effusion |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Inferior Vena Cava Size |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Right Ventricular Function |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 7 | Qualitative Visual Assessment of Left Atrial Size |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 8 | Qualitative Visual Assessment of Aortic Valve |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |

Table 54 Acceptability of Trained-Sonographer-Acquired Transthoracic Echocardiogram for Clinical Parameter Assessment by Presence of Known Cardiac Abnormalities

[CONTROL\_ECHO\_CLINPARM]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Presence of Known Cardiac Abnormality | | All |
|  |  |  | Present | Absent |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivial Pericardial Effusion |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Inferior Vena Cava Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Right Ventricular Function |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 7 | Qualitative Visual Assessment of Left Atrial Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 8 | Qualitative Visual Assessment of Aortic Valve |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table 55 Acceptability of Trained-Sonographer-Acquired Transthoracic Echocardiogram for Clinical Parameter Assessment by Study Site

[CONTROL\_ECHO\_CLINPARM]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Study Site | | All |
|  |  |  | Northwestern | Minneapolis |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivial Pericardial Effusion |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Inferior Vena Cava Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Right Ventricular Function |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 7 | Qualitative Visual Assessment of Left Atrial Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 8 | Qualitative Visual Assessment of Aortic Valve |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table 56 Acceptability of Trained-Sonographer-Acquired Transthoracic Echocardiogram for Clinical Parameter Assessment by Sex of Patient

[CONTROL\_ECHO\_CLINPARM]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Sex | | All |
|  |  |  | Male | Female |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivial Pericardial Effusion |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Inferior Vena Cava Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Right Ventricular Function |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 7 | Qualitative Visual Assessment of Left Atrial Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 8 | Qualitative Visual Assessment of Aortic Valve |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table 57 Acceptability of Trained-Sonographer-Acquired Transthoracic Echocardiogram for Clinical Parameter Assessment by Age of Patient

[CONTROL\_ECHO\_CLINPARM]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Age of Patient | | All |
|  |  |  | < 65 | ≥ 65 |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivial Pericardial Effusion |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Inferior Vena Cava Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Right Ventricular Function |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 7 | Qualitative Visual Assessment of Left Atrial Size |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |
|  |  |  |  |  |  |
| 8 | Qualitative Visual Assessment of Aortic Valve |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) acceptable |  |  |  |

Table 58 Acceptability of Trained-Sonographer-Acquired Transthoracic Echocardiogram for Clinical Parameter Assessment by Sequence Number of Scan Within Sonographer

[CONTROL\_ECHO\_CLINPARM]

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Sequence Number of Scan within Sonographer | | | All |
|  |  |  | 1-10 | 11-20 | 21+ |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivial Pericardial Effusion |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Inferior Vena Cava Size |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Right Ventricular Function |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 7 | Qualitative Visual Assessment of Left Atrial Size |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |
|  |  |  |  |  |  |  |
| 8 | Qualitative Visual Assessment of Aortic Valve |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |

Table 59 Acceptability of Trained-Sonographer-Acquired Transthoracic Echocardiogram for Clinical Parameter Assessment by Acquiring Sonographer

[CONTROL\_ECHO\_CLINPARM]

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Sonographer ID | | | | | All |
|  |  |  | 101 | 102 | 103 | 104 | 105 |  |
| 1 | Qualitative Visual Assessment of Left Ventricular Size |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 2 | Qualitative Visual Assessment of Left Ventricular Global Function |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | Qualitative Visual Assessment of Right Ventricular Size |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | Qualitative Visual Assessment of Non-trivial Pericardial Effusion |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 | Qualitative Visual Assessment of Inferior Vena Cava Size |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 6 | Qualitative Visual Assessment of Right Ventricular Function |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 7 | Qualitative Visual Assessment of Left Atrial Size |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 8 | Qualitative Visual Assessment of Aortic Valve |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) acceptable |  |  |  |  |  |  |

Table 60 Diagnostic Quality of Trained-Sonographer-Acquired Transthoracic Echocardiogram by 2-D View and BMI category

[CONTROL\_ECHO\_VIEW]

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | View |  | BMI category of Patient | | | All | MRMC  conf. int. |
|  |  |  | < 25 | 25- < 30 | ≥30 |  |  |
| 1 | PLAX |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table 61 Diagnostic Quality of Trained-Sonographer-Acquired Transthoracic Echocardiogram by 2-D View and Presence of Known Cardiac Abnormalities

[CONTROL\_ECHO\_VIEW]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Presence of Known Cardiac Abnormalities | | All |
|  |  |  | Present | Absent |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

\*diagnostic quality=image has median ACEP score ≥ 3 as rated by 5 independent expert cardiologists.

Table 62 Diagnostic Quality of Trained-Sonographer-Acquired Transthoracic Echocardiogram by 2-D View and Study Site

[CONTROL\_ECHO\_VIEW]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Study Site | | All |
|  |  |  | Northwestern | Minneapolis |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

Table 63 Diagnostic Quality of Trained-Sonographer-Acquired Transthoracic Echocardiogram by 2-D View and Sex of Patient

[CONTROL\_ECHO\_VIEW]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Sex | | All |
|  |  |  | Male | Female |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

Table 64 Diagnostic Quality of Trained-Sonographer-Acquired Transthoracic Echocardiogram by 2-D View and Age of Patient

[CONTROL\_ECHO\_VIEW]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | View |  | Age | | All |
|  |  |  | < 65 | ≥ 65 |  |
| 1 | PLAX |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |
|  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |
|  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |
|  |  | n of Sonographers |  |  |  |
|  |  | N of Patients Scanned |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |

Table 65 Diagnostic Quality of Trained-Sonographer-Acquired Transthoracic Echocardiogram by 2-D View and Sequence Number of Scan within Sonographer

[CONTROL\_ECHO\_VIEW]

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Sequence Number of Scan within Sonographer | | |  |
|  | View |  | 1-10 | 11-20 | 21+ | All |
|  |  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |
|  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |
|  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |

Table 66 Diagnostic Quality of Trained-Sonographer-Acquired Transthoracic Echocardiogram by 2-D View and Sonographer

[CONTROL\_ECHO\_VIEW]

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Sonographer ID | | | | |  |
|  | View |  | 101 | 102 | 103 | 104 | 105 | All |
|  |  |  |  |  |  |  |  |  |
| 1 | PLAX |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality \* |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 2 | PSAX-AV |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3 | PSAX-MV |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4 | PSAX-PM |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 5 | AP4 |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 6 | AP5 |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 7 | AP3 |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 8 | AP2 |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 9 | SubC4 |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 10 | SC-IVC |  |  |  |  |  |  |  |
|  |  | n of Sonographers |  |  |  |  |  |  |
|  |  | N of Patients Scanned |  |  |  |  |  |  |
|  |  | n (%) of diagnostic quality |  |  |  |  |  |  |

Table 67 Cross-Classification of Cardiologists’ Rating of Image Quality for Clinical Assessment of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by Clinical Parameter

[STUDY\_ECHO\_CLINPARM] [CONTROL\_ECHO\_CLINPARM]

{In this example, Overall % Agreement = 100 \* (200 + 20)/240= 91.6%. For confidence interval, use WILSON option for binomial proportion. To generate Kappa statistic, use the AGREE option on the TABLES statement followed by an EXACT AGREE statement.}

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Clinical Parameter Assessed** |  |  |  | |  |  |  |  |
| 1. Qualitative Left Ventricular Size |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Acceptable image quality | Not acceptable image quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa | p-value |
|  | Nurse-acquired echo w/ EchoGPS platform | Acceptable image quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not acceptable image quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 2. Qualitative Left Ventricular Global Function |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Acceptable image quality | Not acceptable image quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Acceptable image quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not acceptable image quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 3. Qualitative Right Ventricular Size |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Acceptable image quality | Not acceptable image quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Acceptable image quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not acceptable image quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 4. Pericardial Effusion |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Acceptable image quality | Not acceptable image quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Acceptable image quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not acceptable image quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **5.** Qualitative Visual Assessment of Inferior Vena Cava Size |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Acceptable image quality | Not acceptable image quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Acceptable image quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not acceptable image quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 6. Qualitative Visual Assessment of Right Ventricular Function |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Acceptable image quality | Not acceptable image quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Acceptable image quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not acceptable image quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **7.** Qualitative Visual Assessment of Left Atrial Size |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Acceptable image quality | Not acceptable image quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Acceptable image quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not acceptable image quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| 8. Qualitative Visual Assessment of Aortic Valve |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Acceptable image quality | Not acceptable image quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Acceptable image quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not acceptable image quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |

Repeat for subgroups:

* + Results per BMI group (<25, 25-30, ≥30)
  + Sex (female, male)
  + Age (<65, ≥65)
  + Sequence number of scan within Nurse RN User
  + Investigative Site

Table 68 Cross-Classification of Cardiologists’ Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View

[STUDY\_ECHO\_VIEW] [CONTROL\_ECHO\_VIEW]

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa | p-value |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **3. View= PSAX-MV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **4. View= PSAX-PM** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |

Repeat for subgroups:

* + Results per BMI group (<25, 25-30, ≥30)
  + Sex (female, male)
  + Age (<65, ≥65)
  + Sequence number of scan within Nurse RN User
  + Investigative Site
  + Pathology

Table 69 Cross-Classification of Cardiologists’ Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Autocaptured Scans Only

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa | p-value |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **3. View= PSAX-MV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **4. View= PSAX-PM** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |

Table 70 Cross-Classification of Cardiologists’ Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Save-Best Scans Only

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa | p-value |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **3. View= PSAX-MV** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **4. View= PSAX-PM** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Sufficient diagnostic quality | Not sufficient diagnostic quality |  | % Overall Agreement and c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Sufficient diagnostic quality | 200 | 5 | 205 | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Not sufficient diagnostic quality | 15 | 20 | 35 |  |  |  |
|  |  |  | 215 | 25 | 240 |  |  |  |
|  |  |  |  |  |  |  |  |  |

Table 71 Cross-Classification of Cardiologists’ ACEP Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | ACEP Rating of  Sonographer-Acquired Echocardiograms, n(%) | | | | |  | % Overall Agreement and c.i. | Cohen’s  Kappa | p-value |
|  |  |  | 1 | 2 | 3 | 4 | 5 |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  | XX.X % (XX.X, XX.X ) | 0.xxx |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **3. View= PSAX-MV** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **4. View= PSAX-PM** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |

Table 72 Cross-Classification of Cardiologists’ ACEP Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Autocaptured Scans Only

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | ACEP Rating of  Sonographer-Acquired Echocardiograms, n(%) | | | | |  | % Overall Agreement and c.i. | Cohen’s  Kappa | p-value |
|  |  |  | 1 | 2 | 3 | 4 | 5 |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  | XX.X % (XX.X, XX.X ) | 0.xxx |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **3. View= PSAX-MV** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **4. View= PSAX-PM** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |

Table 73 Cross-Classification of Cardiologists’ ACEP Rating of Diagnostic Quality of Nurse-Acquired vs. Sonographer-Acquired Echocardiograms by 2-D View- Nurse’s Save-Best Scans Only

{Programmer note: “Save Best” refers to a view that is NOT autocaptured}

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. View= PLAX** |  |  | ACEP Rating of  Sonographer-Acquired Echocardiograms, n(%) | | | | |  | % Overall Agreement and c.i. | Cohen’s  Kappa | p-value |
|  |  |  | 1 | 2 | 3 | 4 | 5 |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  | XX.X % (XX.X, XX.X ) | 0.xxx |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **2. View= PSAX-AV** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **3. View= PSAX-MV** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **4. View= PSAX-PM** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **5. View= AP4** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **6. View= AP5** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **7. View= AP3** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **8. View= AP2** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **9. View= Sub C4** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **10. View= SC-IVC** |  |  |  |  |  |  |  |  |  |  |  |
|  | ACEP Rating of Nurse-acquired echo w/ EchoGPS platform | 1 |  |  |  |  |  |  |  |  |  |
|  | 2 |  |  |  |  |  |  |  |  |  |
|  | 3 |  |  |  |  |  |  |  |  |  |
|  | 4 |  |  |  |  |  |  |  |  |  |
|  | 5 |  |  |  |  |  |  |  |  |  |

Table 74 Cross-Classification of Cardiologists’ Clinical Assessment Using Nurse-Acquired vs. Sonographer-Acquired Echocardiograms- Primary Endpoints Qualitative Visual Assessmentamong Patients for whom a Qualitative Visual Assessment could be Made

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Clinical Parameter** |  |  |  | |  |  |  |  |
|  |  |  |  | |  |  |  |  |
| **1. Qualitative Visual Assessment of Left Ventricular Size** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Normal/Borderline | Abnormal/Enlarged |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa | p-value |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Abnormal/Enlarged |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **2. Qualitative Visual Assessment of Global Left Ventricular Function** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Normal/Borderline | Reduced  (EF ≤ 50%) |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Reduced  (EF ≤ 50%) |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **3. Qualitative Visual Assessment of Right Ventricular Size** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Normal/Borderline | Abnormal/Enlarged |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Abnormal/Enlarged |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **4. Qualitative Qualitative Visual Assessment of Non-trivialPericardial Effusion** |  |  |  |  |  |  |  |  |
|  |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Normal/Borderline | Reduced |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Reduced |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

|  |  |
| --- | --- |
|  |  |

Table 75 Cross-Classification of Cardiologists’ Clinical Assessment Using Nurse-Acquired vs. Sonographer-Acquired Echocardiograms- Secondary Endpoints among Patients for whom a Qualitative Visual Assessment could be Made

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Clinical Parameter** |  |  |  | |  |  |  |  |
|  |  |  |  | |  |  |  |  |
| **1. Qualitative Visual Assessment of Inferior Vena Cava Size** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Normal | Dilated |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa | p-value |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Dilated |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **2. Qualitative Visual Assessment of Right Ventricular Function** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Normal/Borderline | Reduced |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Reduced |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **3. Qualitative Visual Assessment of Left Atrial Size** |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |
|  |  |  | Normal | Enlarged |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Normal/Borderline |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Abnormal/Enlarged |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

Table 76 Cross-Classification of Cardiologists’ Clinical Assessment Using Nurse-Acquired vs. Sonographer-Acquired Echocardiograms- Aortic, Mitral, and Tricuspid Valves among Patients for whom a Qualitative Visual Assessment could be Made

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Clinical Parameter** |  |  |  | |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| **4. Qualitative Visual Assessment of Aortic Valve** |  |  |  |  |  |  |  |  |  |
|  |  |  | Sonographer-acquired echo w/o platform | |  |  |  |  |  |
|  |  |  | Structurally normal | Structurally  abnormal | Suspected  device |  | % Overall Agreement and c.i. | Cohen’s  Kappa | p-value |
|  | Nurse-acquired echo w/ EchoGPS platform | Structurally normal |  |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  | Structurally  abnormal |  |  |  |  |  |  |  |
|  |  | Suspected  device |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| **5. Qualitative Visual Assessment of Mitral Valve** |  |  |  |  |  |  |  |  |  |
|  |  |  | Sonographer-acquired echo w/o platform |  |  |  |  |  |  |
|  |  |  | Structurally normal | Structurally  abnormal | Suspected  device |  | % Overall Agreement andc.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Structurally normal |  |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  |  | Structurally  abnormal |  |  |  |  |  |  |  |
|  |  | Suspected  device |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| **6. Qualitative Visual Assessment of Tricuspid Valve** |  |  |  |  |  |  |  |  |  |
|  |  |  | Sonographer-acquired echo w/o platform |  |  |  |  |  |  |
|  |  |  | Structurally normal | Structurally  abnormal | Suspected  device |  | % Overall Agreement and MRMC c.i. | Cohen’s  Kappa |  |
|  | Nurse-acquired echo w/ EchoGPS platform | Structurally normal |  |  |  |  | XX.X %  (XX.X, XX.X ) | 0.xxx |  |
|  |  | Structurally  abnormal |  |  |  |  |  |  |  |
|  |  | Suspected  device |  |  |  |  |  |  |  |

Table 77 Panel Variability: Extent of Agreement among Cardiologists in Rating Acceptability of Echocardiography for Clinical Parameter Assessment- Primary Endpoints by Image Acquirer

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Image Acquirer |  | Clinical Parameter | %Overall Agreement | *p*-value |
|  |  |  |  |  |
| Nurse using EchoGPS |  |  |  |  |
|  |  |  |  |  |
|  | 1 | Qualitative Left Ventricular Size, Yes or no |  |  |
|  |  |  |  |  |
|  | 2 | Qualitative Left Ventricular Global Function, Yes or no |  |  |
|  |  |  |  |  |
|  | 3 | Qualitative Right Ventricular Size, Yes or no |  |  |
|  |  |  |  |  |
|  | 4 | Pericardial Effusion, Yes or no |  |  |
| Sonographer without EchoGPS |  |  |  |  |
|  |  |  |  |  |
|  | 1 | Qualitative Left Ventricular Size, Yes or no |  |  |
|  |  |  |  |  |
|  | 2 | Qualitative Left Ventricular Global Function, Yes or no |  |  |
|  |  |  |  |  |
|  | 3 | Qualitative Right Ventricular Size, Yes or no |  |  |
|  |  |  |  |  |
|  | 4 | Pericardial Effusion, Yes or no |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Table 78 Panel Variability: Extent of Agreement among Cardiologists in Rating Diagnostic Quality(ACEP 1-5) of Echocardiography by 2D View and Image Acquirer

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Image Acquirer | View |  | % Overall Agreement | *p*-value |
|  |  |  |  |  |
| Nurse using EchoGPS |  |  |  |  |
|  | 10-View Total | TOTAL |  |  |
|  |  |  |  |  |
|  | 1 | PLAX |  |  |
|  |  |  |  |  |
|  | 2 | PSAX-AV |  |  |
|  |  |  |  |  |
|  | 3 | PSAX-PM |  |  |
|  |  |  |  |  |
|  | 4 | PSAX-MV |  |  |
|  |  |  |  |  |
|  | 5 | AP4 |  |  |
|  |  |  |  |  |
|  | 6 | AP5 |  |  |
|  |  |  |  |  |
|  | 7 | AP3 |  |  |
|  |  |  |  |  |
|  | 8 | AP2 |  |  |
|  |  |  |  |  |
|  | 9 | SubC4 |  |  |
|  |  |  |  |  |
|  | 10 | SC-IVC |  |  |
|  |  |  |  |  |
| Sonographer w/o EchoGPS |  |  |  |  |
|  | 10-View Total | TOTAL |  |  |
|  |  |  |  |  |
|  | 1 | PLAX |  |  |
|  |  |  |  |  |
|  | 2 | PSAX-AV |  |  |
|  |  |  |  |  |
|  | 3 | PSAX-PM |  |  |
|  |  |  |  |  |
|  | 4 | PSAX-MV |  |  |
|  |  |  |  |  |
|  | 5 | AP4 |  |  |
|  |  |  |  |  |
|  | 6 | AP5 |  |  |
|  |  |  |  |  |
|  | 7 | AP3 |  |  |
|  |  |  |  |  |
|  | 8 | AP2 |  |  |
|  |  |  |  |  |
|  | 9 | SubC4 |  |  |
|  |  |  |  |  |
|  | 10 | SC-IVC |  |  |

{Repeat for other Quantitative metrics}

Table 79 Summary of Adverse Events by Study Period

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  | Study Period | | |
|  |  |  | Prior to either scan  (post- Informed Consent signature) | Study Exam  (Nurse-performed  echocardiogram) | Control Exam  (Sonographer-performed  echocardiogram) |
|  |  |  |  |  |  |
|  | N patients entering study period |  | XXX | XXX | XXX |
|  |  |  |  |  |  |
|  | n (%) experiencing any AE |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  | n Events |  | XXX | XXX | XXX |
|  |  |  |  |  |  |
|  | n (%) experiencing any procedure-related AE |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  | n (%) experiencing any SAE |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |
|  | n (%) experiencing any AE that caused withdrawal from study |  | XX (XX.X%) | XX (XX.X%) | XX (XX.X%) |
|  |  |  |  |  |  |

Table 80 Listing of Adverse Events

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Patient ID | Site | Nurse | Sonographer | Verbatim  Term | Body System | Study Period of onset | Severity | Relatedness to Procedure | Serious | Outcome | Action Taken |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
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