



PVDOMICS STUDY

Clinical Center Right Heart Catheterization (RHC)

Results Form #280

Instructions: Review PVDOMICS MOP Chapter 100 prior to completing right heart catheterization (RHC).

Healthy volunteers will not undergo a RHC.

Heparin Use:

- If participant received heparin within 30 minutes of this test, then either wait a minimum of 30 minutes or reschedule RHC.
- If the participant received low molecular weight heparin within 8 hours of this test, then the RHC must be rescheduled. The participant must wait 8 hours after receiving low molecular weight heparin before the RHC may be done.
- If either of these situations is true, DO NOT complete this form.

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1. Identification Number

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2. Alphacode

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3. Date of RHC (mm/dd/yyyy)

4. Did this participant undergo a right heart catheterization (RHC)?
(0=No, 1=Yes, 8=N/A - participant is healthy volunteer)

- a. Why was the RHC not done?
 1=Abnormal lab value
 2=Participant could not tolerate procedure (provide explanation at end of form)
 3=Physician judgment (provide explanation at end of form)
 4=Heparin not withheld appropriately
 5=Cannot be off of positive pressure airway device during the procedure
 6=Participant refused
 7=RHC not done per PVDOMICS protocol. [Data of limited value per CP Core review]

5. Was this RHC completed with an invasive CPET? (0=No, 1=Yes, *also complete Form 291*).....

6. Was a left heart catheterization done in conjunction with this RHC? (0=No, 1=Yes)

7. Was participant taking heparin prior to RHC?

0=No, skip to Q8 for other medications taken

1=Yes, taking heparin

2=Yes, taking low molecular weight heparin (e.g. dalteparin, enoxaparin, Lovenox, etc.)

a. Was heparin withheld for the appropriate amount of time?

0=No, **STOP. Reschedule or wait until 30 minutes if heparin was given OR 8 hours if low molecular weight heparin was given before attempting RHC**

1=Yes, withheld for the appropriate amount of time

8. Has participant taken any of the following medications in the last 24 hrs (0=No, 1=Yes)

a. Insulin? (0=No, 1=Yes)

b. Anticoagulant other than heparin? (0=No, 1=Yes).....

9. Date of last meal (mm/dd/yyyy)..... / ____ / ____

10. Time of last meal (use 24-hr clock; hh:mm) :

11. Measured height on day of RHC (cm).....

12. Measured weight on day of RHC (kg).....

Body Surface Area (BSA) (m²)..... *(Note: database will calculate BSA and store in database. Write the measurement in the greyed out box on this paper CRF)*

13. Measured hemoglobin on day of RHC (g/dl), if available.....

a. Where was blood taken for hemoglobin? (1=Peripheral blood, 2=PA blood sample) _____

Procedure Notes14. Is participant using oxygen at the time of this RHC? (0=No, 1=Yes, 8=N/A, never on O₂) _____a. What O₂ flow rate is used during right heart catheterization (L/min)? _____

15. Venous access obtained via (1=Internal jugular vein, 2=Antecubital vein, 3=Femoral vein) _____

16. Swan-Ganz sheath French size used during RHC _____17. Swan-Ganz catheter French size used during RHC _____

18. Name of study site staff physician performing the RHC _____

*(use first 6 letters of staff physician's last name and first initial)***Resting Blood Draw**

19. Venous blood draw time (hh:mm, use 24-hour clock) :

20. Was systemic arterial blood drawn? (0=No, 1=Yes) _____

(Optional, only if arterial line already in place)

a. Systemic Arterial blood draw time (hh:mm, use 24-hour clock) :

MEASUREMENTS: All measurements will be repeated under four different conditions: Resting Right Heart Catheterization, Oxygen Challenge, Vasodilatory Challenge, and either a Fluid Challenge (Saline Loading) or an invasive Cardiopulmonary Exercise Test (iCPET). Some subjects may be excluded from the 100% Oxygen Challenge or Vasodilatory Challenge. Refer to the MOP Chapters 100 for RHC details and Chapter 111 for iCPET details.

Resting Right Heart Catheterization

21. Was a Resting Right Heart Catheterization done? (0=No, 1=Yes)..... _____
- a. Superior Vena Cava Oxygen Saturation (SVC sat) (%) _____
- b. Fraction of Inspired Oxygen (FiO₂) (%) _____
- c. Pulse Oximetry Oxygen Saturation (O₂ sat) (%) _____
- d. Arterial Oxygen Saturation (Art O₂) (%) *if available, if not leave blank*..... _____
- e. Systemic Systolic Blood Pressure (SBP) (mmHg) _____
- f. Systemic Diastolic Blood Pressure (DBP) (mmHg) _____
- g. How was Blood Pressure measured? (1=Noninvasive Cuff, 2=Arterial Line) _____
- h. Heart Rate (bpm) _____
- i. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other)..... _____

Pressure measurements during the resting right heart catheterization will be taken twice, once during spontaneous breathing and once during an end-expiratory breath hold.

Right Atrium Measurements:

Breathing Condition	a. Spontaneous Breathing	b. End-Expiratory Hold
22. Right Atrium (RA) Mean Pressure	_____	_____
23. RA Peak "a wave" Pressure	_____	_____
24. RA Peak "v wave" Pressure	_____	_____
25. RA Oxygen Saturation (RA sat) <i>Draw back 3mL of waste in syringe, then 1mL in second syringe for analysis</i>	_____ %	

Right Ventricle Measurements:

Breathing Condition	a. Spontaneous Breathing	b. End-Expiratory Hold
26. Right Ventricle (RV) Peak Systolic Pressure (SBP) (mmHg)	_____	_____
27. RV End Diastolic Pressure (mmHg)	_____	_____

Resting Right Heart Catheterization, continued**Pulmonary Capillary Wedge Pressure (PCWP) Measurements:**

Breathing Condition	a. Spontaneous Breathing	b. End-Expiratory Hold
28. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave)	____	____
29. PCW Peak "a wave" Pressure	____	____
30. PCW Peak "v wave" Pressure	____	____
31. PCWP Oxygen Saturation (PCWP sat) <i>Draw back 3mL of waste in syringe, then 1mL in second syringe for analysis</i>	____ %	

PCWP OMICS Blood Draw *Draw back 3mL of waste in syringe, then 6.5mL in second syringe for analysis*

32. PCWP blood draw time (hh:mm, use 24-hour clock) : ____

Pulmonary Artery (PA) Pressure Measurements:

Breathing Condition	Spontaneous Breathing	End-Expiratory Hold
33. Pulmonary Artery (PA) Systolic Pressure (mmHg)	____	____
34. PA Diastolic Pressure (mmHg)	____	____
35. PA Mean Pressure measured from Mean PA line by machine	____.	____.
36. PA Mean Pressure (calculated) <i>(calculated by PVDOMICS database; record on this form)</i>	____.	____.
37. PA Oxygen Saturation (PA sat) <i>Draw back 3mL of waste in syringe, then 1mL in second syringe for analysis</i>	____ %	

PA OMICS Blood Draw *Draw back 3mL of waste in syringe, then 6.5mL in second syringe for analysis*

38. PA blood draw time (hh:mm, use 24-hour clock) : ____

Resting Right Heart Catheterization, continued

Thermodilution Cardiac Output: Measure thermodilution cardiac output (TDCO) in triplicate. If there is > 10% variability between measurements, additional measurements must be taken until three measurements are in agreement with less than 10% variability. Record the three measurements that agree below.

39. Were Resting RHC Thermodilution CO measurements done? (0=No, 1=Yes).....
- a. TDCO (L/min) – measurement 1
 - b. TDCO (L/min) – measurement 2
 - c. TDCO (L/min) – measurement 3
 - d. Number of measurements taken to get three measures with < 10% variability.....

Direct Fick Cardiac Output:

40. Were Direct Fick Cardiac Output Measurements done? (0=No, 1=Yes)
- a. Resting VO₂ (measured) (ml/kg/min)..... .
 - b. Direct Fick Cardiac Output (L/min)
 - c. Direct Fick Cardiac Index (L/min/m²)..... .

Oxygen Challenge measurements on next page.

Oxygen Challenge

41. Was Oxygen Challenge done? (1=Yes, 2=No, contraindicated per protocol, 3=No, logistical issues) _____
- a. Fraction of Inspired Oxygen (FiO₂ sat) (%) _____
 - b. Pulse Oximetry Oxygen Saturation (O₂ sat) (%) _____
 - c. Arterial Oxygen Saturation (Art O₂ sat) (%) **if available, if not leave blank* _____
 - d. Systolic Blood Pressure (SBP) (mmHg) _____
 - e. Diastolic Blood Pressure (DBP) (mmHg) _____
 - f. How was Blood Pressure measured? (1=Noninvasive Cuff, 2=Arterial Line) _____
 - g. Heart Rate (bpm) _____
 - h. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other) _____

All pressure measurements during the challenge will be taken during spontaneous breathing

Right Atrium Measurements:

42. Right Atrium (RA) Mean Pressure _____
43. RA Peak “a wave” Pressure _____
44. RA Peak “v wave” Pressure _____

Pulmonary Capillary Wedge Pressure (PCWP) Measurements:

45. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave) _____
46. PCW Peak “a wave” Pressure _____
47. PCW Peak “v wave” Pressure _____

PA Measurements:

48. Pulmonary Artery (PA) Systolic Pressure (mmHg) _____
49. PA Diastolic Pressure (mmHg) _____
50. PA Mean Pressure measured from Mean PA line by machine _____
51. *PA Mean Pressure (calculated by PVDOMICS database; record on this form)* _____

Oxygen Challenge, continued

Thermodilution Cardiac Output: Measure thermodilution cardiac output (TDCO) in triplicate. If there is > 10% variability between measurements, additional measurements must be taken until three measurements are in agreement with less than 10% variability. Record the three measurements that agree below.

52. Were Oxygen Challenge Thermodilution CO measurements done? (0=No, 1=Yes).....

- a. TDCO (L/min) – measurement 1
- b. TDCO (L/min) – measurement 2
- c. TDCO (L/min) – measurement 3
- d. Number of measurements taken to get three measures with < 10% variability.....

Direct Fick Cardiac Output:

53. Were Direct Fick Cardiac Output Measurements done? (0=No, 1=Yes)

- a. Resting VO₂ (measured) (ml/kg/min)
- b. Direct Fick Cardiac Output (L/min)
- c. Direct Fick Cardiac Index (L/min/m²)..... .

Vasodilatory Challenge measurements on next page.

Vasodilatory Challenge

54. Was Vasodilatory Challenge done? (1=Yes, 2=No, contraindicated per protocol, 3=No, logistical issues)....._____
- a. Fraction of Inspired Oxygen (FiO₂) (%)....._____
 - b. Pulse Oximetry Oxygen Saturation (O₂ sat) (%) _____
 - c. Arterial Oxygen Saturation (Art O₂) (%) *if available, if not leave blank*....._____
 - d. Systolic Blood Pressure (SBP) (mmHg) _____
 - e. Diastolic Blood Pressure (DBP) (mmHg)....._____
 - f. How was Blood Pressure measured? (1=Non-invasive Cuff, 2=Arterial Line) _____
 - g. Heart Rate (bpm) _____
 - h. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other)....._____

All pressure measurements during the challenge will be taken during spontaneous breathing

Right Atrium Measurements:

55. Right Atrium (RA) Mean Pressure _____
56. RA Peak “a wave” Pressure....._____
57. RA Peak “v wave” Pressure....._____

Pulmonary Capillary Wedge Pressure (PCWP) Measurements:

58. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave)....._____
59. PCW Peak “a wave” Pressure....._____
60. PCW Peak “v wave” Pressure....._____

PA Measurements:

61. Pulmonary Artery (PA) Systolic Pressure (mmHg)....._____
62. PA Diastolic Pressure(mmHg) _____
63. PA Mean Pressure measured from Mean PA line by machine....._____
64. PA Mean Pressure (*calculated by PVDOMICS database; record on this form*)....._____

Vasodilatory Challenge, continued

Thermodilution Cardiac Output: Measure thermodilution cardiac output (TDCO) in triplicate. If there is > 10% variability between measurements, additional measurements must be taken until three measurements are in agreement with less than 10% variability. Record the three measurements that agree below.

65. Were Vasodilatory Challenge Thermodilution CO measurements done? (0=No, 1=Yes).....

a. TDCO (L/min) – measurement 1

b. TDCO (L/min) – measurement 2

c. TDCO (L/min) – measurement 3

d. Number of measurements taken to get three measures with < 10% variability.....

Direct Fick Cardiac Output:

66. Were Direct Fick Cardiac Output Measurements done? (0=No, 1=Yes)

a. Resting VO₂ (measured) (ml/kg/min)

b. Direct Fick Cardiac Output (L/min)

c. Direct Fick Cardiac Index (L/min/m²)

Fluid Challenge measurements on next page.

Fluid Challenge

67. Was Fluid Challenge done? (1=Yes, 2=No, doing iCPET instead*, 3=No, logistical issues, 4=No, contraindicated per protocol)
- a. Fraction of Inspired Oxygen (FiO₂) (%).....
- b. Pulse Oximetry Oxygen Saturation (O₂ sat) (%).....
- c. Arterial Oxygen Saturation (Art O₂) (%) *if available, if not leave blank*
- d. Systolic Blood Pressure (SBP) (mmHg).....
- e. Diastolic Blood Pressure (DBP) (mmHg).....
- f. How was Blood Pressure measured? (1=Noninvasive Cuff, 2=Arterial Line)
- g. Heart Rate (bpm)
- h. Heart Rhythm (1=Sinus, 2=Atrial fibrillation, 3=Paced, 4=Other).....

****Complete Form 291 for invasive CPET.***

All Pressure Measurements during the challenge will be taken during spontaneous breathing

Right Atrium Measurements:

68. Right Atrium (RA) Mean Pressure
69. RA Peak “a wave” Pressure.....
70. RA Peak “v wave” Pressure.....

Pulmonary Capillary Wedge Pressure (PCWP) Measurements:

71. Pulmonary Capillary Wedge (PCW) Mean Pressure (a wave).....
72. PCW Peak “a wave” Pressure.....
73. PCW Peak “v wave” Pressure.....

Pulmonary Artery Measurements:

74. Pulmonary Artery (PA) Systolic Pressure (mmHg).....
75. PA Diastolic Pressure (mmHg).....
76. PA Mean Pressure measured from Mean PA line by machine

77. PA Mean Pressure (calculated by PVDOMICS database; record on this form).....

Fluid Challenge, continued

Thermodilution Cardiac Output: Measure thermodilution cardiac output (TDCO) in triplicate. If there is > 10% variability between measurements, additional measurements must be taken until three measurements are in agreement with less than 10% variability. Record the three measurements that agree below.

78. Were Fluid Challenge Thermodilution CO Measurements done? (0=No, 1=Yes) _____

a. TDCO (L/min) – measurement 1 _____

b. TDCO (L/min) – measurement 2 _____

c. TDCO (L/min) – measurement 3 _____

d. Number of measurements taken to get three measures with < 10% variability _____

Direct Fick Cardiac Output:

79. Were Direct Fick Cardiac Output Measurements done? (0=No, 1=Yes) _____

a. Resting VO₂ (measured) (ml/kg/min) _____

b. Direct Fick Cardiac Output (L/min) _____

c. Direct Fick Cardiac Index (L/min/m²) _____

80. Are any RHC test data missing? _____
(0=No, all necessary data obtained per study protocol, 1=Yes, specify in comments on last page)

81. Were there any adverse events or unexpected problems in completing the RHC? (0=No, 1=Yes) _____

Please report adverse events and unexpected problems to your local IRB per local guidelines for reporting. MedDRA will be used to identify signs and symptoms.

Sign/Symptom (MedDRA) (You will be able to enter as many as needed)	MedDRD (auto populated by database)

82. Are any comments documented? (0=No comments, 1=Yes, specify below) _____

Comments for Core (entered into database):

100. a. Username of physician* overseeing RHC _____

(Username is the first 6 letters of physician's last name and first initial.)

*This should be the center PI or other study physician trained on the PVDOMICS RHC protocol.

b. Username of physician who either completed this form **OR** reviewed and verified accuracy of the data reported on this form _____

(Username of physician is the first 6 letters of last name and first initial.)

101. Date file transferred to CPC Core (mm/dd/yyyy)..... ____/____/____

102. Username of study staff* transmitting RHC data to CPC Core..... ____

(Note: staff member information must be entered on Form 10 in the database before username can be selected from database list of values menu)

For DCC Use Only:

198. RHC insufficient data/unreadable per CPC?.....____

199. Date notified..... ____/____/____

200. Date this form was completed (mm/dd/yyyy) ____/____/____

201. Username of person completing/reviewing completeness of this form.....____

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) ____/____/____

Username of person entering this form _____