Assessment of Myocardial Ischemia by SPECT in the RESCUE Trial

- Why is this important?
- Where do you find the information?
- Where does it go on the RESCUE CRFs?
Assessment of Myocardial Ischemia by SPECT in the RESCUE Trial

- Why is this important?
- Where do you find the information?
- Where does it go on the RESCUE CRFs?
Flow of Patients in RESCUE

Pt with symptoms of stable angina or angina equivalent CCS Class I-III

CCTA
- < 50% Stenosis
  - No Obstructive CAD
    - Follow for MACE/Revascularization
  - ≥ 50% Stenosis
    - OMT
      - Persistent or worsening symptoms
        - Revascularization (ICA)
          - Follow for MACE
          - Follow for MACE

SPECT MPI
- ≥ 10% reversible defect or TID with ECG changes of ischemia
  - Diagnostic ICA
    - ≥ 50% Stenosis
      - OMT
        - Follow for MACE
        - Follow for MACE
    - < 50% Stenosis
      - No Significant Ischemia
        - Follow for MACE/Revascularization

- < 10% reversible defect
  - No Significant Ischemia
    - Follow for MACE/Revascularization
Stress

Rest

Normal stress and rest perfusion images
Flow of Patients in RESCUE

Pt with symptoms of stable angina or angina equivalent CCS Class I-III

CCTA

- < 50% Stenosis
  - No Obstructive CAD
    - Follow for MACE/Revascularization
  - OMT
    - Persistent or worsening symptoms
      - Revascularization (ICA)
        - Follow for MACE
    - Follow for MACE

- ≥ 50% Stenosis
  - OMT
    - Persistent or worsening symptoms
      - Follow for MACE

SPECT MPI

- LM Dz
  - ≥ 10% reversible defect or TID
    - Diagnostic ICA
      - ≥ 50% Stenosis
        - OMT
          - Follow for MACE
        - < 50% Stenosis
          - Follow for MACE
      - < 10% reversible defect with ECG changes of ischemia
        - No Significant Ischemia
          - Follow for MACE/Revascularization
Anteroseptal, septal, apical, and inferior ischemia

(ischemia = “reversible” defects stress => rest)

% LV ischemia by quantitative software program = 18% => “positive” for RESCUE purpose
Flow of Patients in RESCUE

Pt with symptoms of stable angina or angina equivalent CCS Class I-III

CCTA

< 50% Stenosis

≥ 50% Stenosis

No Obstructive CAD

OMT

Persistent or worsening symptoms

Revascularization (ICA)

Follow for MACE/Revascularization

SPECT MPI

LM Dz

≥ 10% reversible defect or TID with ECG changes of ischemia

< 10% reversible defect

Diagnostic ICA

≥ 50% Stenosis

OMT

Follow for MACE

No Significant Ischemia

Follow for MACE

< 50% Stenosis
Assessment of Myocardial Ischemia by SPECT in the RESCUE Trial

• Why is this important?

• Where do you find the information?

• Where does it go on the RESCUE CRFs?
In order to assess ≥ 10% ischemia objectively, commercial analysis software is needed.

- Quantitative Software Processing and Display Programs:
  - QPS (Cedars-Sinai Med Ctr)
  - ECTb or Emory Cardiac Toolbox (Emory U)
  - Corridor 4DM formerly 4DM SPECT (U of Mich)
  - Wackers-Liu CQ (Yale U)
  - Etc.
Q19 – Is this a “+” scan (for RESCUE cath)?

Multiple possibilities to assess:

1. Yes - if there are EKG changes that meet criteria for ischemia AND if there is Transient Ischemic Dilatation (TID)

2. Yes - if there is a Left Ventricle (LV) reversible defect ≥ 10% by quantitative software

3. Yes - if Summed Difference Score (SDS) in a 17 segment model ≥ 7

4. Yes - if Summed Difference Score (SDS) in a 20 segment model ≥ 8
RESCEUE Trial SPECT Ischemia Assessment

1. Yes - there are ECG changes that meet the criteria for ischemia AND there is Transient Ischemic Dilatation (TID)

- Ischemic ECG response is based on the results of the stress exercise or pharmacologic stress test ECGs
- Evaluation of TID may be done visually or by calculating the ratio between stress and rest images (reported by software)
  - "TID ratio" > 1.2 usually considered abnormal
Question 19 – Is this a “positive” scan (for RESCUE directed cath)?

1. Yes - if there are EKG changes that meet criteria for ischemia AND if there is Transient Ischemic Dilatation (TID)

2. Yes - if there is a Left Ventricle (LV) reversible defect \( \geq 10\% \) by quantitative software

3. Yes - if Summed Difference Score (SDS) in a 17 segment model \( \geq 7 \)

4. Yes - if Summed Difference Score (SDS) in a 20 segment model \( \geq 8 \)
RESCUE SPECT Ischemia Assessment

- There are many types of quantitative software programs and numerous versions of each program
- Two possible analysis methods:
  - "Quantitative" – gives you "%LV ischemic" etc
    - Preferred if you have it
  - "Semi-quantitative" – gives you "segmental scores" (SDS etc)
    - Use these if you do not have %LV ischemic as above
SPECT Software Analysis Programs

• The most common are:
  • QPS (Cedars Sinai)
  • Emory Cardiac Toolbox (ECTb)
  • Corridor 4DM (or 4DM SPECT)

• The program AND the version of the program will determine if “% LV ischemia” is reportable on the SP Form or if the “summed segment scores” are reported on the SP Form
Question 19 – Is this a “positive” scan (for RESCUE directed cath)?

1. Yes - if there are EKG changes that meet criteria for ischemia AND if there is Transient Ischemic Dilatation (TID)

2. Yes - if there is a Left Ventricle (LV) reversible defect ≥ 10% by quantitative software

3. Yes - if Summed Difference Score (SDS) in a 17 segment model ≥ 7

4. Yes - if Summed Difference Score (SDS) in a 20 segment model ≥ 8
2. Yes - there is a Left Ventricle (LV) reversible defect $\geq 10$

- Requires both the rest study and stress study
- Requires quantification software that reports the % of the entire LV defect that is fixed (infarct) and reversible (ischemia)
**Step 1**

- Click on the Extent/Mass tab to view the myocardial mass options.

**Step 2**

- The Estimated Myocardial Mass is 141g (GATED data).
- Stress Defect:
  - Estimated Mass: 11g, 19g, 0g, 0g, 0g, 30g
  - % of Myocardium: 8%, 14%, 0%, 0%, 0%, 22%
- Reversibility:
  - Estimated Mass: 11g, 11g, 0g, 0g, 22g
  - % of Defect: 95%, 57%, 0%, 0%, 0%, 71%
  - % of Myocardium: 8%, 8%, 0%, 0%, 0%, 16%
- Stress Total Severity Score = 394
- Rest Total Severity Score = 161
- Reversibility Total Severity Score = 180
- Probability of Survival: 1 yr: 91%, 2 yr: 81%, 3 yr: 69%, 4 yr: 52%
- Reversible defect size = 16%
- Fixed defect size = Entire defect - Reversible defect (22% - 16% = 6%)
- Fixed defect size = 6%
- Positive scan LV reversible defect ≥ 10%
Reversible (ischemic) defect size = 16% (Q16a)

Fixed defect size = Stress – reversible defect = 22% - 16% = 6% (Q16b)
Corridor 4DM or 4DM SPECT

“Images & Quant”

<table>
<thead>
<tr>
<th>Region</th>
<th>Gstress TC [FBP] Extent</th>
<th>sGREST TC [FBP] Extent</th>
<th>Nml</th>
<th>Reversibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAD</td>
<td>57 %</td>
<td>0 %</td>
<td>43 %</td>
<td>1 %</td>
</tr>
<tr>
<td>LCX</td>
<td>10 %</td>
<td>0 %</td>
<td>90 %</td>
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</tr>
<tr>
<td>TOT</td>
<td>39 %</td>
<td>0 %</td>
<td>61 %</td>
<td>0 %</td>
</tr>
</tbody>
</table>

LV fixed defect size = 0 %
LV reversible defect size = 39%

Positive scan LV reversible defect ≥ 10%
LV Reversible defect size = 31%
Positive scan:
LV reversible defect ≥ 10%
Question 19 – Is this a “positive” scan (for RESCUE directed cath)?

1. Yes - if there are EKG changes that meet criteria for ischemia AND if there is Transient Ischemic Dilatation (TID)

2. Yes - if there is a Left Ventricle (LV) reversible defect ≥ 10% by quantitative software

3. Yes - if Summed Difference Score (SDS) in a 17 segment model ≥ 7

4. Yes - if Summed Difference Score (SDS) in a 20 segment model ≥ 8
Some software programs do not provide “quantitative analysis” to report “%LV ischemia” (eg Cedars QPS many versions)

Almost all programs provide “segmental scores” (known as “semi-quantitative analysis”)

Software breaks myocardium into “segments” (total either 17 or 20 segments), assigns a score (0 – 4) to each segment, with 0 = normal, 4 = very severe defect
Automated Summed Segment Scores

Scoring Code
0 = Normal
1 = Slightly Reduced / Equivocal
2 = Moderately Reduced / Abnormal
3 = Severely Reduced
4 = Absent
Automated Summed Segment Scores

- Program assigns segmental scores to the rest study and the stress study
- Scores for each study are “summed” (adds up scores of the 17 or 20 segments)
- Generates stress, rest and reversibility (difference) segmental scores:
  - summed stress score (SSS)
  - summed rest score (SRS)
  - summed difference score (SDS = SSS - SRS)
Question 19 – Is this a “positive” scan (for RESCUE directed cath)?

1. Yes - if there are EKG changes that meet criteria for ischemia AND if there is Transient Ischemic Dilatation (TID)

2. Yes - if there is a Left Ventricle (LV) reversible defect ≥ 10% by quantitative software

3. Yes - if Summed Difference Score (SDS) in a 17 segment model ≥ 7

4. Yes - if Summed Difference Score (SDS) in a 20 segment model ≥ 8
Test is “+” since SDS ≥ 8 in a 20 segment model.
Test is “+” since SDS ≥ 7 in a 17 segment model.
SSS = 16
SRS = 0
SDS = 16
Test is positive SDS > 10
Test is “+” since SDS ≥ 7 in a 17 segment model.
Assessment of Myocardial Ischemia by SPECT in the RESCUE Trial

- Why is this important?
- Where do you find the information?
- Where does it go on the RESCUE CRFs?
<table>
<thead>
<tr>
<th>Question Number</th>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 a.</td>
<td>LV reversible defect size (responses ≥ 10% indicates a positive scan and should be noted in Q19):</td>
<td>% [82] Unk / Not performed [83]</td>
</tr>
<tr>
<td>16 b.</td>
<td>LV fixed defect size:</td>
<td>% [84] Unk / Not performed [85]</td>
</tr>
<tr>
<td>17 a.</td>
<td>Resting EF:</td>
<td>% [86] Unknown / Gating Not performed [87]</td>
</tr>
<tr>
<td>17 b.</td>
<td>Post-stress EF:</td>
<td>% [88] Unknown / Gating Not performed [89]</td>
</tr>
<tr>
<td>18 a.</td>
<td>TID ratio (if quantitative)</td>
<td></td>
</tr>
<tr>
<td>18 b.</td>
<td>Was Transient Ischemic dilation (TID) observed?</td>
<td>O No (skip to Q19) O Yes (complete Q18a)</td>
</tr>
<tr>
<td>19 a.</td>
<td>Per 4701 RESCUE protocol, is this a positive scan?</td>
<td>O No O Yes (complete MA form)</td>
</tr>
<tr>
<td>20 a.</td>
<td>Per 4701 RESCUE protocol - which treatment is recommended based on results?</td>
<td>O Diagnostic ICA O None</td>
</tr>
</tbody>
</table>
ACRIN4701
Randomized Evaluation of Patients with Stable Angina Comparing Utilization of Diagnostic Examinations

If this is a revised or corrected form, please √ box. □

16. Quantitative perfusion scoring (Percentage required for questions 16 a & b if quantitative analysis available, OR skip to 16c if only automated segment scores are captured)

16a. LV reversible defect size (responses ≥ 10% indicates a positive scan and should be noted in Q19):

□ % [82] □ Unk / Not performed [83]

16b. LV fixed defect size:

□ % [84] □ Unk / Not performed [85]

16c. Automated summed segment scores from program: (SDS response ≥ 7 in a 17 segment model, or ≥ 8 in a 20 segment model, indicates positive scan and should be noted in Q19)

<table>
<thead>
<tr>
<th>SSS</th>
<th>[107] □ Unk / Not performed [108]</th>
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<tr>
<td>SRS</td>
<td>[109] □ Unk / Not performed [110]</td>
</tr>
<tr>
<td>SDS</td>
<td>[111] □ Unk / Not performed [112]</td>
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Segment Model Type (If a response is provided for "SDS" above, indicate segment model type below):[131]

O 17 segment model
O 20 segment model

ACRIN Study 4701
PLACE LABEL HERE

Institution ________________ Institution No. __________
Participant Initials __________ Case No. __________

17. Quantitative function

17a. Resting EF: __________% [86]
□ Unknown / Gating Not performed [87]

17b. Post-stress EF: __________% [88]
□ Unknown / Gating Not performed [89]

18. Was Transient Ischemic dilation (TID) observed? [90]
O No (skip to Q19) O Yes (complete Q18a)

18a. TID ratio (if quantitative) __________ [91]

19. Per 4701 RESCUE protocol, is this a positive scan? [92]
O No O Yes (complete MA form)
Positive scan is defined as:
• ‘Yes’ responses to both questions 9 and 18
• 16a ≥ 10%
• 16c SDS ≥ 7 in 17 segment model
• 16c SDS ≥ 8 in 20 segment model

20. Per 4701 RESCUE protocol - which treatment is recommended based on results? [93]
O Diagnostic ICA
O None
Corridor 4DM or 4DM SPECT

Screen Selector Panel

Positive scan LV reversible defect ≥ 10%

LV fixed defect size = 0 %
LV reversible defect size = 39%

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Reversibility:
- Fixed: 1 %, 0 %, 0 %
- Reversible: 56 %, 10 %, 12 %
ACRIN Study 4701
PLACE LABEL HERE

Institution ____________________ Institution No. ____________
Participant Initials ____________ Case No. ____________

16. Quantitative perfusion scoring (Percentage required for questions 16 a & b if quantitative analysis available, OR skip to 16c if only automated segment scores are captured)

16a. LV reversible defect size (responses ≥ 10% indicates a positive scan and should be noted in Q19):

   □ 39% [82] □ Unk / Not performed [83]

16b. LV fixed defect size:

   □ 0% [84] □ Unk / Not performed [85]

16c. Automated summed segment scores from program:
(SDS response ≥ 7 in a 17 segment model, or ≥ 8 in a 20 segment model, indicates positive scan and should be noted in Q19)

   SSS □ [107] □ Unk / Not performed [108]
   SRS □ [109] □ Unk / Not performed [110]
   SDS □ [111] □ Unk / Not performed [112]

Segment Model Type (If a response is provided for "SDS" above, indicate segment model type below.) [131]

   O 17 segment model
   O 20 segment model

17. Quantitative function

17a. Resting EF: __________ % [86]

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17b. Post-stress EF: __________ % [88]

   □ Unknown / Gating Not performed [89]

18. Was Transient Ischemic dilation (TID) observed? [90]
   O No (skip to Q19) O Yes (complete Q18a)

18a. TID ratio (if quantitative) __________ [91]

19. Per 4701 RESCUE protocol, is this a positive scan? [92]
   O No □ Yes (complete MA form)

Positive scan is defined as:
   ▪ ‘Yes’ responses to both questions 9 and 18
   ▪ 16a ≥ 10%
   ▪ 16c SDS ≥ 7 in 17 segment model
   ▪ 16c SDS ≥ 8 in 20 segment model

20. Per 4701 RESCUE protocol - which treatment is recommended based on results? [93]
   O Diagnostic ICA □ None
Since you have % LV info for Q16a,b, you do NOT need to fill out Q16c
16. Quantitative perfusion scoring (Percentage required for questions 16a & b if quantitative analysis available, OR skip to 16c if only automated segment scores are captured)

16a. LV reversible defect size (responses ≥ 10% indicates a positive scan and should be noted in Q19):

__________% [82] □ Unk / Not performed [83]

16b. LV fixed defect size:

__________% [84] □ Unk / Not performed [85]

16c. Automated summed segment scores from program:
(SDS response ≥ 7 in a 17 segment model, or ≥ 8 in a 20 segment model, indicates positive scan and should be noted in Q19)

SSS ———— [107] □ Unk / Not performed [108]
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Segment Model Type (If a response is provided for "SDS" above, indicate segment model type below.) [131]

O 17 segment model
O 20 segment model

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17a. Resting EF: __________% [86]
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19. Per 4701 RESCUE protocol, is this a positive scan? [92]
   O No  O Yes (complete MA form)
   Positive scan is defined as:
   • ‘Yes’ responses to both questions 9 and 18
   • 16a ≥ 10%
   • 16c SDS ≥ 7 in 17 segment model
   • 16c SDS ≥ 8 in 20 segment model

20. Per 4701 RESCUE protocol - which treatment is recommended based on results? [93]
   O Diagnostic ICA
   O None
Stress             Rest      Reversibility

SSS = 11          SRS = 0     SDS = 11

Positive scan: SDS ≥ 8 in 20 segment model
16. Quantitative perfusion scoring (Percentage required for questions 16 a & b if quantitative analysis available, OR skip to 16c if only automated segment scores are captured)

16a. LV reversible defect size (responses ≥ 10% indicates a positive scan and should be noted in Q19):

\[ \text{------}% \] [82] \quad \square \text{Unk / Not performed}[83]

16b. LV fixed defect size:

\[ \text{------}% \] [84] \quad \square \text{Unk / Not performed}[85]

16c. Automated summed segment scores from program:
(SDS response ≥ 7 in a 17 segment model, or ≥ 8 in a 20 segment model, indicates positive scan and should be noted in Q19)

\[ \begin{align*}
\text{SSS} & : 11 \quad [107] \quad \square \text{Unk / Not performed} [108] \\
\text{SRS} & : 0 \quad [109] \quad \square \text{Unk / Not performed} [110] \\
\text{SDS} & : 11 \quad [111] \quad \square \text{Unk / Not performed} [112]
\end{align*} \]

Segment Model Type (If a response is provided for "SDS" above, indicate segment model type below.) [131]

\[ \begin{align*}
\square & \text{17 segment model} \\
\times & \text{20 segment model}
\end{align*} \]

17. Quantitative function

17a. Resting EF:

\[ \text{------}% \] [86] \quad \square \text{Unknown / Gating Not performed}[87]

17b. Post-stress EF:

\[ \text{------}% \] [88] \quad \square \text{Unknown / Gating Not performed}[89]

18. Was Transient Ischemic dilation (TID) observed? [90]

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\square & \text{No (skip to Q19)} \\
\times & \text{Yes (complete Q18a)}
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18a. TID ratio (if quantitative) \[ \text{------} \] [91]

19. Per 4701 RESCUE protocol, is this a positive scan? [92]

\[ \begin{align*}
\square & \text{No} \\
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\[ \begin{align*}
\times & \text{Diagnostic ICA} \\
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PLEASE CALL US ANYTIME FOR HELP!