Interventional Closure of post myocardial infarction VSD: less invasiveness more efficiency?

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No Conflicts of Interest to declare
### Facts

**Ventricular septal rupture incidence and mortality**

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>30-day Mortality</th>
<th>In-Hospital Mortality</th>
<th>1-year Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>MIDAS</td>
<td>148881</td>
<td>0.25-0.31%</td>
<td>41-44%</td>
<td>56-60%</td>
</tr>
<tr>
<td>GUSTO</td>
<td>41021</td>
<td>0.2%</td>
<td>73.8%</td>
<td></td>
</tr>
<tr>
<td>GRACE</td>
<td>60198</td>
<td>0.25%</td>
<td>41%</td>
<td></td>
</tr>
<tr>
<td>APEX-AMI</td>
<td>5745</td>
<td>0.17%</td>
<td>80%</td>
<td></td>
</tr>
</tbody>
</table>

Facts

Medically managed

94-96% mortality

Surgical Repair VSD

STS National Database. VSD repair in 2876 patients 1999-2010

Bimodal peak within 24h & 3-5 days

Chronic VSD >4-6 weeks

2. GUSTO-I trial
3. SHOCK registry
Pathophysiologicllology


- **Type I**
  - Abrupt, slit-like tear
  - Acute Infarcts < 24h

- **Type II**
  - Erosion of the Infarcted Myocardium
  - Subacute VSD

- **Type III**
  - Aneurysm Formation
  - Thinning IVS -> Rupture
  - Older Infarcts

**Simple or Complex**
8.4.2 Ventricular septal rupture

Ventricular septal rupture usually presents as rapid-onset clinical deterioration with acute heart failure or cardiogenic shock, with a loud systolic murmur occurring during the subacute phase. It may occur within 24 h to several days after MI and with equal frequency in anterior and posterior/lateral MI. The diagnosis is confirmed by echocardiography and Doppler, which will differentiate this from acute mitral regurgitation, and define the rupture and its size, and quantify the left to right shunt, which can be more precisely confirmed by a Swan–Ganz catheter. The shunt may result in signs and symptoms of acute, new-onset right heart failure. IABP may stabilize patients in preparation for angiography and surgery. Intravenous diuretics and vasodilators should be used with caution in hypotensive patients. Surgical repair may be required urgently, but there is no consensus on the optimal timing for surgery. Early surgery is associated with a high mortality rate, reported as 20–40%, and a high risk of recurrent ventricular rupture, while delayed surgery allows easier septal repair in scarring tissue but carries the risk of rupture extension and death while waiting for surgery. For this reason, early surgery should be performed in all patients with severe heart failure that does not respond rapidly to aggressive therapy, but delayed elective surgical repair may be considered in patients who respond well to aggressive heart failure therapy. Percutaneous closure of the defect with appropriately designed devices may soon become an alternative to surgery.

Emergency surgery for mechanical complications of acute myocardial infarction is indicated in case of haemodynamic instability.

- IABP insertion should be considered in patients with haemodynamic instability/cardiogenic shock due to mechanical complications.  
  - IIa B

- Patients with mechanical complication after acute myocardial infarction require immediate discussion by the Heart Team.  
  - I A

- Short-term mechanical circulatory support in ACS patients with cardiogenic shock may be considered.  
  - IIa B

- Percutaneous repair of VSD may be considered after discussion by the Heart Team.  
  - IIb B

- Routine use of IABP in patients with cardiogenic shock is not recommended.  
  - III A

9.4.3. Ventricular Septal Rupture

Ventricular septal rupture usually is heralded by a loud systolic murmur and HF or shock, depending on the size of the defect and the degree of RV and LV dysfunction. Data from the GUSTO-1 (The Global Use of Strategies to Open Occluded Coronary Arteries) trial and the SHOCK registry indicate that ventricular septal rupture occurs most often within the first 24 hours in patients with STEMI treated with fibrinolytic therapy (477, 478). Emergency surgical repair is necessary, even in hemodynamically stable patients (479–481), because the rupture site can expand abruptly, resulting in sudden hemodynamic collapse in previously stable patients (481). Temporizing medical treatment consists of inotropic and vasodilator agents, with IABP when needed. The surgical mortality rate remains high, especially among patients with shock, ranging from 20% to 87% in reported series (395, 477–480, 482, 483). Mortality risk is higher for patients with inferior-basal defects than for those with anterior-apical defects. Percutaneous closure is a less invasive option that might allow for initial hemodynamic stabilization, but experience with this approach is limited, and residual shunts are common. Further technical developments and prospective trials are required to identify patients best suited for transcatheter closure.
The Procedure

VSD crossing with a catheter

VSD crossing with a soft guidewire and advancement into the SVC or pulmonary artery

After establishment of arterial-venous circuit, advancement of the sheath from the RIJV through the VSD and guidewire removal

Release of the closure device in the VSD

Inferior/Poster VSDs more challenging
Serpigenous defects difficult to cross
Freshly infarcted myocardium favors leakage and device embolization
Defect Size and available Devices
TTE & TOE & 3D TOE
Invasive Hemodynamic Measurements
LV Angiogram & Fluoroscopic Guidance
Use of multiple devices
Balloon Sizing
Cardiac CT

Devices

- **AMPLATZER PI MUSCULAR VSD OCCLUDER**
  - Diameter up to 24mm

- **AMPLATZER MUSCULAR VSD OCCLUDER**
  - Diameter up to 18mm

- **AMPLATZER SEPTAL OCCLUDER**
  - Diameter up to 38mm

- **Legacy & OTHER**

- **Sizing Balloon**
Evidence & Studies

- Assenza et al, n=30, USA
- Holzer et al, n=18, USA
- Martinez et al, n=5, USA
- Calvert et al, n=53, UK
- Marinakis et al, n=8, Belgium
- Trivedi et al, n=6, France
- Thiele et al, n=29, Germany
- Bialkowski et al, n=19, Poland
- Demkow et al, n=11, Poland
- Xu et al, n=42, China
- Zhu et al, n=35, China
- Nie et al, n=10, Taiwan
- Premchand et al, n=7, India
- Ahmed et al, n=5, New Zealand

Total: 290 patients
Statistics & Characteristics

- ~70 Years Old
- ~70% Male
- ~50% Cardiogenic Shock
- ~60% IABP
- ~55% Anterior/Apical MI

- No randomized trials
- 12 retrospective & 3 prospective studies
- Patient selection on an individual basis
- Primary VSD Closure & VSD Closure after Surgery
- Procedures in the acute, subacute and chronic phases
## Results

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Acute</th>
<th>Primary</th>
<th>Device</th>
<th>Success %</th>
<th>30-day Mortality %</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assenza et al</td>
<td>30</td>
<td>-</td>
<td>12</td>
<td>Clamshell, CardioSEAL, STARFlex</td>
<td>-</td>
<td>23</td>
<td>1 year</td>
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<tr>
<td>Ahmed et al</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>AMPLATZER PIMVSD</td>
<td>80</td>
<td>40</td>
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<tr>
<td>Bialkowski et al</td>
<td>19</td>
<td>1</td>
<td>14</td>
<td>AMPLATZER SEPTAL, MUSCULAR, PIMVSD</td>
<td>90</td>
<td>26</td>
<td></td>
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<tr>
<td>Calvert et al</td>
<td>53</td>
<td>29</td>
<td>43</td>
<td>AMPLATZER MUSCULAR, PIMVSD, OTHER</td>
<td>89</td>
<td>34</td>
<td>395 days</td>
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<tr>
<td>Demkow et al</td>
<td>11</td>
<td>1</td>
<td>10</td>
<td>AMPLATZER SEPTAL</td>
<td>91</td>
<td>18</td>
<td>25.5 months</td>
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<tr>
<td>Holzer et al</td>
<td>18</td>
<td>5</td>
<td>8</td>
<td>AMPLATZER PIMVSD</td>
<td>89</td>
<td>28</td>
<td>332 days</td>
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<tr>
<td>Maltais et al</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>AMPLATZER PIMVSD</td>
<td>-</td>
<td>42</td>
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<td>Marinakis et al</td>
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<td>6</td>
<td>7</td>
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<td>-</td>
<td>75</td>
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<tr>
<td>Martinez et al</td>
<td>5</td>
<td>3</td>
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<td>AMPLATZER SEPTAL, MUSCULAR, PIMVSD</td>
<td>80</td>
<td>20</td>
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<tr>
<td>Nie et al</td>
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<td>6</td>
<td>10</td>
<td>AMPLATZER SEPTAL, MUSCULAR, PIMVSD</td>
<td>100</td>
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<td>Premchand et al</td>
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<td>AMPLATZER, LIFETECH</td>
<td>71</td>
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<td>Thiele et al</td>
<td>29</td>
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<td>25</td>
<td>AMPLATZER SEPTAL, MUSCULAR</td>
<td>86</td>
<td>66</td>
<td>730 days</td>
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<td>Trivedi et al</td>
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<td>-</td>
<td>5</td>
<td>AMPLATZER SEPTAL, MUSCULAR, PIMVSD</td>
<td>100</td>
<td>50</td>
<td>25 months</td>
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<tr>
<td>Xu et al</td>
<td>42</td>
<td>9</td>
<td>39</td>
<td>AMPLATZER PIMVSD MODIFIED DOUBLE DISC</td>
<td>-</td>
<td>19</td>
<td>53 months</td>
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<tr>
<td>Zhu et al</td>
<td>35</td>
<td>13</td>
<td>32</td>
<td>AMPLATZER PIMVSD MODIFIED DOUBLE DISC</td>
<td>91</td>
<td>14</td>
<td></td>
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<tr>
<td><strong>TOTAL</strong></td>
<td>290</td>
<td>123/254</td>
<td>231</td>
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<td><strong>71-100%</strong></td>
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</table>

Modified from Thiele H. acc.org 2015
Predictors of adverse outcomes & Complications

Closure in the acute phase
Cardiogenic Shock
Increased Qp/Qs
Residual VSD
Age
Female Sex
Use of Inotropes
Defect Size
Creatinine
Revascularisation
AV Block
VT/VF
Device Embolisations
LV Rupture
Blood loss & Hematoma
Hemolysis
Discussion

Is it feasible?
- **YES**
  - Primary percutaneous closure
  - Secondary closure after surgical residual shunt

Does feasibility mean survival?
- **NO**
  - 71-100% success rates but only 25-86% survival rates
  - Presence of Cardiogenic Shock & multiorgan failure

Should we rush to the cath lab after diagnosis?
- **NO/YES**
  - Severely ill patients with hemodynamic instability -> Rush!
  - IABP, LVAD, ECMO, Impella as bridge to definitive treatment
  - Time from MI to closure: Better later if patient stable

The Million $ Question

Is it better than surgery?

- No randomized trials - ethical issues - infrequency of PI VSDs
- Selection bias in all series, surgical and interventional
- More complex VSDs are referred to surgery
- Surges often wait to operate, percutaneous closure may be carried earlier
- Severely compromised patients die before any procedure
- Device selection and performance - Operator & centre experience
So, what should we do?

Take home message

1. Interventional VSD Closure is a viable alternative to surgery

2. The procedure is feasible with high rates of success

3. Technical success is only half the battle. Mortality still remains high

4. The clinical decision (vs surgery) needs to be taken by the Heart Team and take into account the patient, the defect, available devices and local expertise

5. Patients who survive to discharge have excellent outcomes on follow up

“Το ιδανικόν μου δεν είναι να πλουτίσω, ούτε να ζήσω ευτυχής αλλά να εργασθώ, να δράσω, να δημιουργήσω, να κάμω κάτι τι αντάξιον ενός ανθρώπου ηθικού και δυνατού.”

Γεώργιος Παπανικολάου

“My aspiration is not to get rich, nor to live happily, but to work, to act, to create, to do something worthy of a moral and strong man.”

George Papanikolaou