Do we have to Abandon Thrombus Aspiration?

가톨릭의대 순환기내과 김동빈



72 yrs. Male, Inferior STEMI



Aspiration or not?



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ST elevation MI

Pathogenesis

- Thrombus formation by plaque rupture

- Treatment
 - Thrombus remove
- Thrombus aspiration

 Prevent distal embolism
 The continuet
 - Theoretically right



Thrombus formation



















TAPAS TASTE TOTAL



TAPAS

2008 Netherland



Thrombus Aspiration During PCI in AMI Study: TAPAS



Thrombus Aspiration (n=535) 1-Year FU Conventional PCI

(n=536)

Thrombus Aspiration (n=530)

Conventional PCI (n=530)

Primary End-Point: Myocardial Blush Grade



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Thrombus Aspiration During PCI in AMI Study: TAPAS

1-Year Mortality





2011 STEMI Update Thrombus Aspiration During PCI for STEMI

NEW Recommendation



Aspiration thrombectomy is reasonable for patients undergoing primary PCI

Kushner et al. Circulation. 2009;120:2271–2306

2012 STEMI ESC Guidelines

Recommendations	Class ^a	Level ^b	Ref ^c
Indications for primary PCI			
Primary PCI is the recommended reperfusion therapy over fibrinolysis if performed by an experienced team within 120 min of FMC.	I	A	69, 99
Primary PCI is indicated for patients with severe acute heart failure or cardiogenic shock, unless the expected PCI related delay is excessive and the patient presents early after symptom onset.	I	В	100
Procedural aspects of primary PCI			
Stenting is recommended (over balloon angioplasty alone) for primary PCI.	1	Α	101, 102
Primary PCI should be limited to the culprit vessel with the exception of cardiogenic shock and persistent ischaemia after PCI of the supposed culprit lesion.	lla	В	75, 103– 105
If performed by an experienced radial operator, radial access should be preferred over femoral access.	lla	В	78, 79
If the patient has no contraindications to prolonged DAPT (indication for oral anticoagulation, or estimated high long- term bleeding risk) and is likely to be compliant, DES should be preferred over BMS.	lla	A	80, 82, 106, 107
Routine thrombus aspiration should be considered.	lla	> B	83-85
Routine use of distal protection devices is not recommended.	Ш	С	86, 108
Routine use of IABP (in patients without shock) is not recommended.	Ш	Α	97, 98

TASTE 2014

SWEDEN



TASTE Trial

• 7244 pts with STEMI

randomly assigned to manual thrombus
 aspiration + PCI or PCI only

- Primary end points
 - 30 day mortality





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Reinfarction, Stent thrombosis

Patients Who Did Not Undergo

Patients Who Underwent Randomization				Randomization		
Thrombus Aspiration (N=3621)	PCI Only (N=3623)	Point Estimate (95% CI)	P Value	Thrombus Aspiration (N=1162)	PCI Only (N=3535)	
103/3621 (2.8)	110/3623 (3.0)	Hazard ratio, 0.94 (0.72–1.22)	0.63	124/1138 (10.9)*	362/3442 (10.5)*	
19 (0.5)	31 (0.9)	Hazard ratio, 0.61 (0.34–1.07)	0.09	10 (0.9)	38 (1.1)	
121/3621 (3.3)	140/3623 (3.9)	Hazard ratio, 0.86 (0.67–1.10)	0.23	134/1138 (11.8)*	398/3442 (11.6)*	
9 (0.2)	19 (0.5)	Hazard ratio, 0.47 (0.20–1.02)	0.06	5 (0.4)	18 (0.5)	
63/3498 (1.8)‡	76/3499 (2.2)‡	Hazard ratio, 0.83 (0.59–1.15)	0.27	30/1162 (2.6)	80/3535 (2.3)	
43/3498 (1.2)‡	57/3499 (1.6)‡	Hazard ratio, 0.75 (0.51–1.12)	0.16	25/1162 (2.2)	64/3535 (1.8)	
	Pati Thrombus Aspiration (N = 3621) 103/3621 (2.8) 19 (0.5) 121/3621 (3.3) 9 (0.2) 63/3498 (1.8): (1.8): 43/3498 (1.2):	Patients Who UnderThrombus Aspiration $(N = 3621)$ PCI Only $(N = 3623)$ 103/3621 $103/3621$ (2.8) 110/3623 (3.0) 103/3621 $19 (0.5)$ 110/3623 (3.0) 19 (0.5)31 (0.9)121/3621 (3.3) 140/3623 (3.9) 9 (0.2)19 (0.5)63/3498 (1.8) ;76/3499 (2.2) ;43/3498 (1.2) ;57/3499 (1.6) ;	Patients Who Underwent RandomizationThrombus Aspiration $(N = 3621)$ PCI Only $(N = 3623)$ Point Estimate $(95\% Cl)$ 103/3621110/3623 (3.0) Hazard ratio, 0.94 $(0.72-1.22)$ 103/3621110/3623 (3.0) Hazard ratio, 0.94 $(0.72-1.22)$ 19 (0.5)31 (0.9) (3.9) Hazard ratio, 0.61 $(0.34-1.07)$ 121/3621 (3.3) 140/3623 (3.9) Hazard ratio, 0.86 $(0.67-1.10)$ 9 (0.2)19 (0.5) $(1.8) \ddagger$ Hazard ratio, 0.47 $(0.20-1.02)$ 63/3498 $(1.8) \ddagger$ 76/3499 $(2.2) \ddagger$ Hazard ratio, 0.83 $(0.59-1.15)$ 43/3498 $(1.2) \ddagger$ 57/3499 $(1.6) \ddagger$ Hazard ratio, 0.75 $(0.51-1.12)$	Patients Who Underwent RandomizationThrombus Aspiration $(N = 3621)$ PCI Only $(N = 3623)$ Point Estimate $(95\% CI)$ P Value103/3621 (2.8) 110/3623 (3.0) Hazard ratio, 0.94 $(0.72-1.22)$ 0.63 $(0.72-1.22)$ 19 (0.5)31 (0.9) (3.9) Hazard ratio, 0.61 $(0.34-1.07)$ 0.09 $(0.34-1.07)$ 121/3621 (3.3) 140/3623 (3.9) Hazard ratio, 0.86 $(0.67-1.10)$ 0.23 $(0.67-1.10)$ 9 (0.2)19 (0.5)Hazard ratio, 0.47 $(0.20-1.02)$ 0.06 $(0.59-1.15)$ 63/3498 (1.8) (1.2) (1.6) 57/3499 (1.6) Hazard ratio, 0.75 $(0.51-1.12)$	Patients Who Underwent RandomizationRandomThrombus Aspiration $(N = 3621)$ PCI Only $(N = 3623)$ Point Estimate $(95\% Cl)$ P ValueThrombus Aspiration $(N = 1162)$ 103/3621 (2.8) 110/3623 (3.0) Hazard ratio, 0.94 $(0.72-1.22)$ 0.63 $(0.72-1.22)$ 124/1138 $(10.9)^*$ 19 (0.5)31 (0.9) $(0.34-1.07)$ Hazard ratio, 0.61 $(0.34-1.07)$ 0.09 $(1.8)^*$ 10 (0.9)121/3621 (3.3) 140/3623 (3.9) Hazard ratio, 0.86 $(0.67-1.10)$ 0.23 $(1.8)^*$ 134/1138 $(11.8)^*$ 9 (0.2)19 (0.5) (0.5) Hazard ratio, 0.47 $(0.20-1.02)$ 0.06 (2.6) 5 (0.4) (2.6) 63/3498 $(1.8)^{\ddagger}$ 76/3499 $(2.2)^{\ddagger}$ Hazard ratio, 0.75 $(0.59-1.15)$ 0.16 (2.6) 43/3498 $(1.2)^{\ddagger}$ 57/3499 $(1.6)^{\ddagger}$ Hazard ratio, 0.75 $(0.51-1.12)$ 0.16 (2.2)	

Index hernitalization



Sub-group	TA+PCI no. of deaths/total r	PCI only no. of patients		Hazard Ratio (95 % CI)		
All patients	103/3621 1	110/3623			0.94 (0.72-1.22)	
Female Male	37/900 4 66/2721 6	45/920 65/2703	⊢– ∣	◆ •	0.84 (0.54-1.29) 1.01 (0.72-1.42)	0.51
Age > 65 yr Age ≤ 65 yr	95/1955 9 8/1666 1	92/1875 18/1748	├ ── ♦ ──		0.99 (0.74-1.32) 0.47 (0.20-1.07)	0.09
Diabetes No Diabetes	23/448 2 78/3155 8	21/453 36/3155	F F		1.11 (0.61 - 2.00) 0.91 (0.67 - 1.23)	0.55
Smoker Not smoker	14/1083 2 70/2336 7	23/1173 76/2211	⊢−♠	→	0.66 (0.34-1.28) 0.87 (0.63-1.20)	0.46
Previous MI No previous MI	13/402 1 85/3172 9	14/439 92/3138	├		1.01 (0.48-2.15) 0.91 (0.68-1.23)	0.81
Previous PCI No previous PCI	6/337 9 97/3284 1	9/362 101/3261	⊢•		0.71 (0.25 - 2.00) 0.95 (0.72-1.26)	0.60
Symptom to PCI time > 2h Symptom to PCI time \leq 2h	73/2308 13/800	77/2308 14/805	⊢ +		0.95 (0.69-1.30) 0.94 (0.44-1.99)	0.98
ECG to PCI time > median ECG to PCI time ≤ median	61/1765 6 42/1816 4	61/1732 49/1843	 		0.98 (0.69-1.40) 0.87 (0.58-1.31)	0.66
LAD LCX RCA	60/1467 5 10/494 1 24/1436 2	58/1449 13/471 28/1443			1.02 (0.71-1.16) 0.73 (0.32-1.67) 0.86 <mark>(</mark> 0.50-1.49)	0.73
Proximal Lesion No proximal lesion	94/2903 9/718	96/2935 14/688	⊢◆		0.99 (0.74-1.32) 0.62 (0.27-1.42)	0.29
Thrombus grade G4-G5 Thrombus grade G0-G3	41/1138 4 61/2451 6	41/1078 64/2499	F		0.95 (0.61-1.46) 0.97 (0.68-1.38)	0.93
TIMI 0-1 grade before PCI TIMI 2-3 grade before PCI	91/2821 9 12/792	92/2811 18/809	⊢●		0.98 (0.74-1.32) 0.68 (0.33-1.41)	0.36
Bivalirudin* No Bivalirudin*	86/2874 9 17/746 1	92/2835 18/782	<u>ا</u> ــــــــــــــــــــــــــــــــــــ		0.92 (0.69-1.24) 0.99 (0.51-1.92)	0.85
GP IIb/IIIa blocker* No GP IIb/IIIa blocker*	10/558 1 93/3063 9	17/630 93/2993	◆	┝╋┤	0.66 (0.30-1.44) 0.98 (0.73-1.30)	0.36
			0.3 0.5	1 2.0	4.0	
		ТА	A+PCI better	PCI only	better	

TA+PCI better

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TASTE vs. TAPAS



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Conclusions

- large, prospective, registry-based randomized clinical trial
 - no reduction of mortality at 30 days
 - no significant reduction of hospitalization for MI or of stent thrombosis at 30 days
 - no reduction of other important clinical endpoints during hospitalization

 little role for manual thrombus aspiration as a routine adjunct to PCI in STEMI



TOTAL 2015

North America



The TOTAL Trial Study Design



Bailout Thrombectomy allowed if PCI alone strategy fails:

- Persistent TIMI 0 or 1 flow with large thrombus after balloon pre-dilatation
- Persistent large thrombus after stent deployment at target lesion



TOTAL Recruitment



10,732 patients randomized between August 2010 and July 2014







PCI Procedural Details

	Thrombectomy	PCI alone
	N=5033	N=5030
Pre PCI TIMI 0 flow	66.3%	67.8%
TIMI thrombus grade ≥3	90.8%	89.1%
Unfractionated Heparin	80.8%	81.6%
Bivalirudin	18.7%	17.3%
Upfront Glycoprotein IIb/IIIa**	22.7%	25.4%
Drug Eluting Stents	44.7%	45.0%
Radial Access	68.3%	68.2%

**P=0.0002



PCI Variables and Surrogate Outcomes

	Thrombecto my N=5033	PCI alone N=5030	Ρ
PCI Procedure time (median)	39 min	35 min	<0.001
Direct Stenting	38.3%	21.3%	<0.001
Final TIMI 3 flow*	93.1%	93.1%	0.12
Distal Embolization*	1.6%	3.0%	<0.001
ST segment Resolution <70%*	27.0%	30.2%	<0.001

* Investigator Reported Outcomes. Core laboratory analysis is ongoing.



Primary Outcome

Day 180	Thrombectomy (N=5033) (%)	PCI alone (N=5030) (%)	HR	95% CI	р
CV death, MI, shock or class IV heart failure	347 (6.9%)	351 (7.0%)	0.99	0.85-1.15	0.86
CV death	157 (3.1%)	174 (3.5%)	0.90	0.73-1.12	0.34
Recurrent MI	99 (2.0%)	92 (1.8%)	1.07	0.81-1.43	0.62
Cardiogenic Shock	92 (1.8%)	100 (2.0%)	0.92	0.69-1.22	0.56
Class IV heart failure	98 (1.9%)	90 (1.8%)	1.09	0.82-1.45	0.57



Safety Outcomes

	Thrombectomy (N=5033) (%)	PCI alone (N=5030) (%)	HR	95% CI	р
Stroke within 30 days	33 (0.7%)	16 (0.3%)	2.06	1.13-3.75	0.015
Stroke or TIA within 30 days	42 (0.8%)	19 (0.4%)	2.21	1.29-3.80	0.003
Stroke within 180 days	52 (1.0%)	25 (0.5%)	2.08	1.29-3.35	0.002



Outcomes at 30 days

	Thrombectomy (N=5033) (%)	PCI alone (N=5030) (%)	HR	95% CI	р
CV Death, MI, shock or class IV heart failure	281 (5.6%)	287 (5.7%)	0.98	0.83-1.15	0.79
Stent Thrombosis	59 (1.2%)	69 (1.4%)	0.85	0.60-1.21	0.37
Target Vessel Revascularization	126 (2.5%)	132 (2.6%)	0.95	0.75-1.22	0.69



Subgroup Analysis Primary Outcome

	TI	hrombectom	y PCI Alone	1
		(%)	(%)	
OVERALL	10063	6.9	7.0	P (INTERACTION)
TIMI Thrombus Gra	de:			
≥3	9052	7.0	7.3	
<3	998	5.2	3.9	0.264
TIMI Thrombus Gra	de:			<u> </u>
≥4	7943	7.3	7.5	
<4	2107	5.3	4.8	0.516
Symptom Onset:				
<6 hrs	8375	6.6	6.6	
6-12 hrs	1665	8.1	8.8	0.660
Initial TIMI Flow:				<u> </u>
0-1	7443	7.4	7.8	
2-3	2519	5.6	4.7	0.219
Site Primary PCI Vo	lume:			
Tertile 1	2450	7.3	7.9	-
Tertile 2	2139	7.2	6.5	
Tertile 3	5474	6.6	6.7	0.659
MI Type:				
Anterior	4016	9.0	9.2	÷.
Non-Anterior	6037	5.6	5.5	0.774
Age:				
ັ≤65 yrs	6662	4.7	4.3	
>65 yrs	3401	11.4	12.1	
				0.5 1.0 2.0

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Primary Outcome at 1 year





CATHOLIC MEDICAL CENTER

Primary Outcome at 1 year

1 year	Thrombectomy (N=5033) (%)	PCI alone (N=5030) (%)	HR	95% CI	р
CV death, MI, shock or class IV heart failure	395 (7.8)	394 (7.8)	1.00	(0.87 – 1.15)	0.99
CV death	179 (3.6)	192 (3.8)	0.93	(0.76 – 1.14)	0.48
Recurrent MI	125 (2.5)	118 (2.3)	1.05	(0.82 -1.36)	0.68
Cardiogenic Shock	95 (1.9)	105 (2.1)	0.90	(0.68 - 1.19)	0.47
Class IV heart failure	106 (2.1)	96 (1.9)	1.01	(0.83 – 1.45)	0.50



Conclusions

- Routine thrombectomy compared to PCI alone with only bailout thrombectomy did not reduce CV death, MI, shock or heart failure within 180 days
- Routine thrombectomy was associated with increased risk of stroke within 30 days
- TOTAL and TASTE emphasize the need to conduct large randomized trials of common interventions even when small trials appear positive



Discussion



Thrombus aspiration

- Theoretically right
- Routine aspiration in RCT 18,000 Pts.
 - Not reduced Infarct size, MI, stent thrombus, heart failure, mortality
 - Not beneficial in subgroup
 - Associated with higher rate of stroke

2014 ESC guideline

Stenting is recommended (over balloon angioplasty) for primary PCI.	I	A	241,242
New-generation DES are recommended over BMS in primary PCI.	I	A	128,247,248, 268,269
Radial access should be preferred over femoral access if performed by an experienced radial operator.	lla	A	237,238,270
Thrombus aspiration may be considered in selected patients.	ПР	A	250–256,259



Role of thrombus aspiration?





I HAVE TO ABANDON THROMBUS ASPIRATION

with present device and technique



Future of thrombus aspiration

We need development of New device and new technique



Thank you

