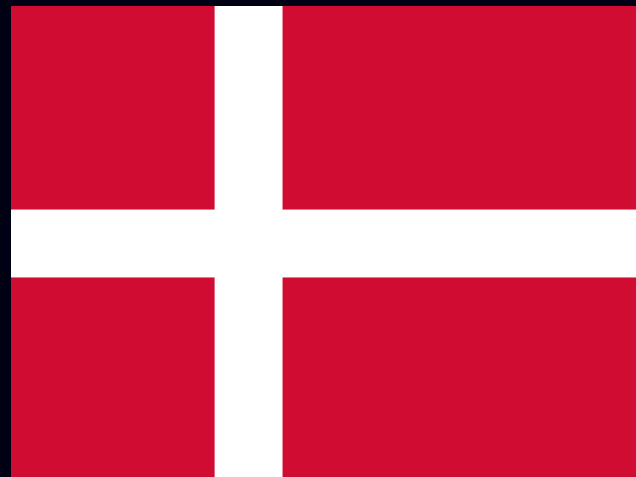
# Hybrid catheter intervention for acute massive pulmonary thromboembolism

Departments of Minimally Invasive Treatment and Radiology, Nippon Medical School Musashikosugi Hospital, Kawasaki
Department of Radiology, Nippon Medical School Hospital, Tokyo*
Vascular Centre, Skane University Hospital, Malmoe**
Iri Clinic, Saitama***

H Tajima, T Kaneshiro, T Ichikawa, S Murata*, K Nakazawa*, T Mine*, T Ueda*, F Sugihara*, R Takagi*, S Onozawa**, N Tajima***

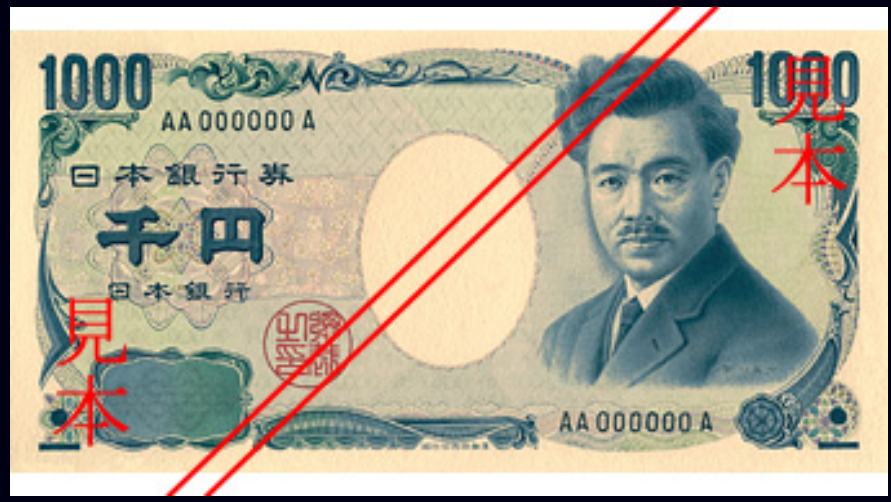
# Short story: Nippon Medical School, Hideyo Noguchi, and Danmark

# Nippon Medical School, Hideyo Noguchi, and Danmark


Nippon Medical School was founded in 1876.

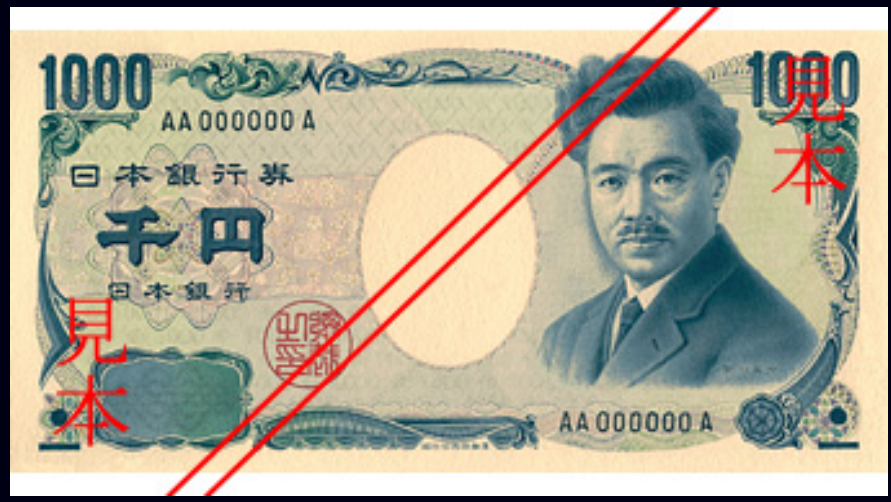
# Banknotes of Japanese １０００ Yen




Hideyo Noguchi MD,P h D (1876-1928)

Japanese famous bacteriologist.

# Banknotes of Japanese １０００ Yen



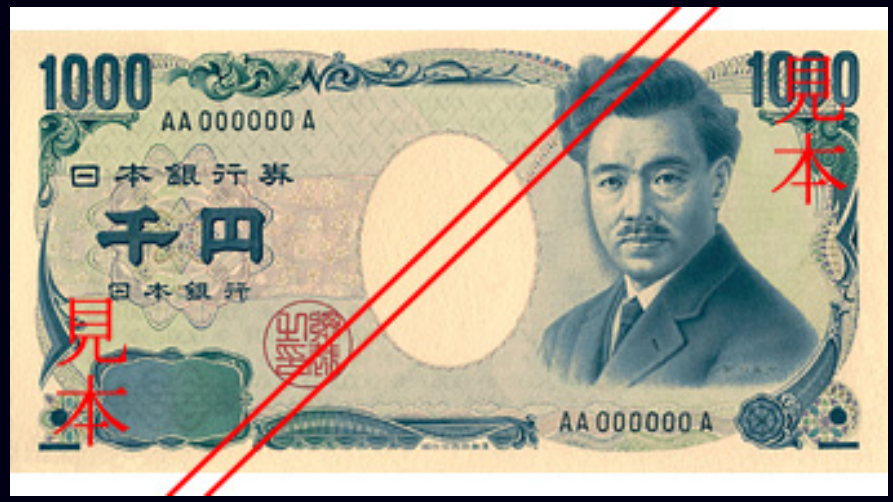

Hideyo Noguchi MD,P h D

Studied medicine at

SAISEIGAKUSYA

( Nippon Medical School) .

# Banknotes of Japanese １０００ Yen



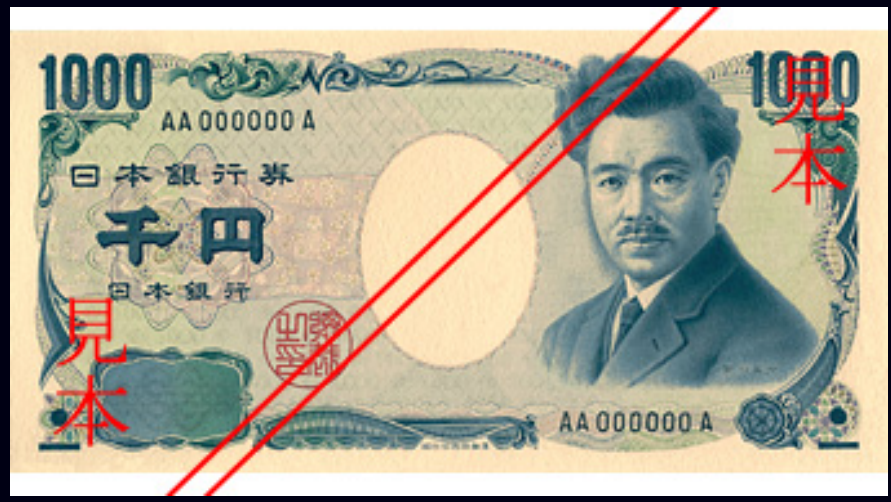


Hideyo Noguchi MD,P h D

Worked as a guest researcher at Statens Serum Institut, Copenhagen,1903.

# T Madsen,Director of Statens Serum Institut and H Noguchi

# Banknotes of Japanese １０００ Yen




Hideyo Noguchi MD,P h D (1876-1928)

Returned to Rockfeller Institute, New York.

Succeeded in pure culture of syphillis spirochaete.

Candidate for Nobel Prize ; 4 times.

Died of yellow fever at Ghana, Africa.

# Hybrid catheter intervention for acute massive pulmonary thromboembolism

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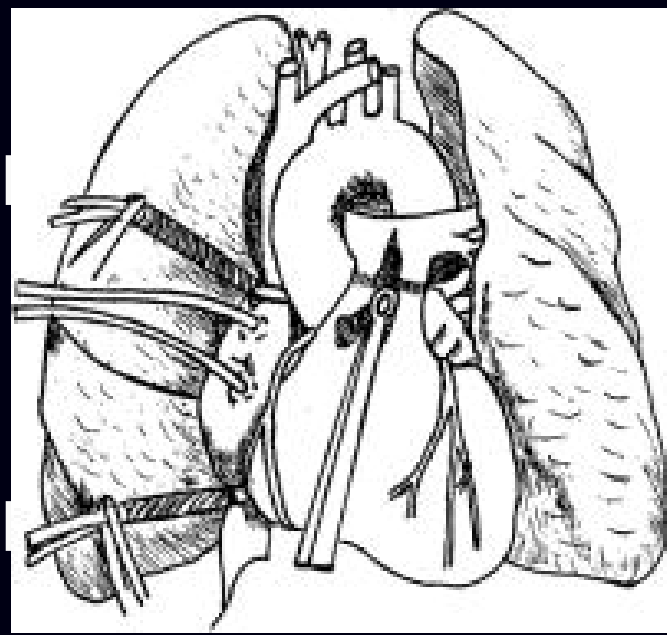
# Background:
# Traditional treatment of acute pulmonary thromboembolism

1 . Anticoagulation
2 . Systemic thrombolysis
→Percutaneous catheter intervention
3 . Surgical thrombectomy
→Percutaneous catheter intervention



(JVIR 2001;12:147)

# Indication:

Acute massive PTE→Severe right heart failure

・ Haemodynamics

1.Mean PAP > 25mmHg （ Pulmonary HT ）

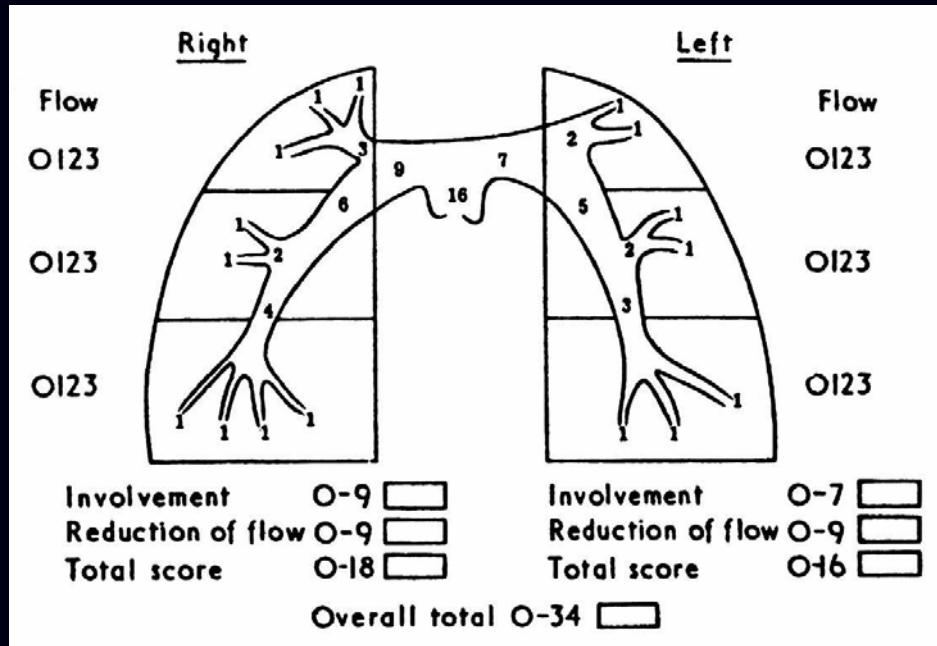
2.Shock index（ HR/SBP ） > 1

・ Angiographic findings

1.Angiography severity index > 9（ max 18 ）

2.Miller score > 20

（ max 34 ）




Brit Med J 1971; 2: 681

**Contents:**

Percutaneous catheter interventions for the treatment of acute massive pulmonary thromboembolism

1 . Catheter directed thrombolysis ( CDT)

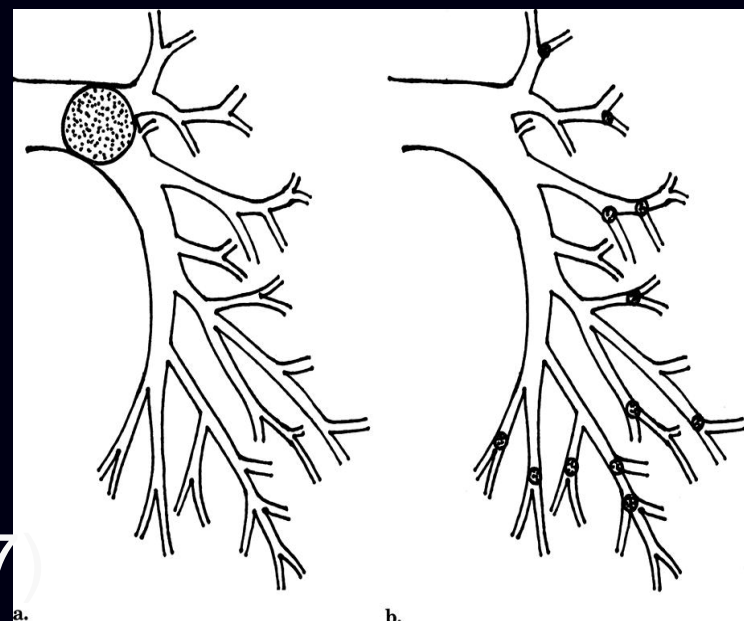
2 . Catheter tip embolectomy

A Aspiration thrombectomy

B Fragmentation

C Rheolytic thrombectomy

(JVIR 2001;12:147)



# Catheter directed thrombolysis ( CDT) ｶﾃｰﾃﾙ血栓溶解療

UK 250,000unit/ h ( + heparin ２０００ IU) x 2 h

+ 100,000unit/ h x 12 - 24 h

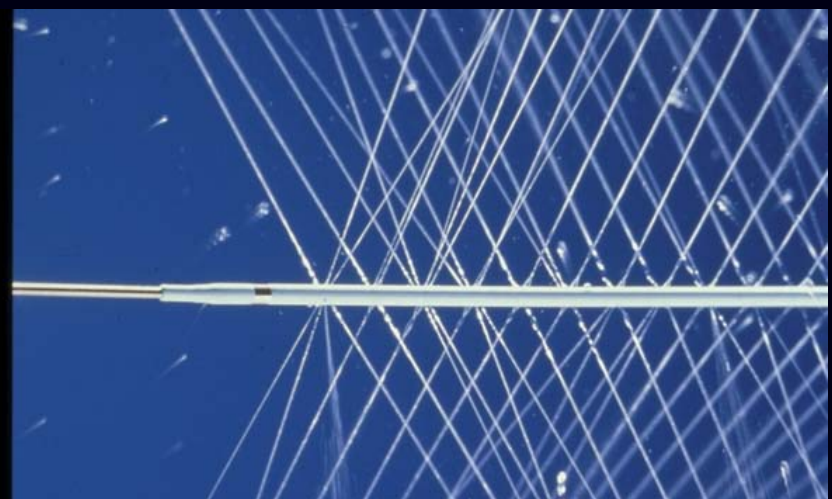
t -PA 10mg Bolus + 20mg/ h x 2 h

or 100mg/7 h

(Uflacker, JVIR 2001;12:14

Super-selective CDT

Pulse-spray thrombol

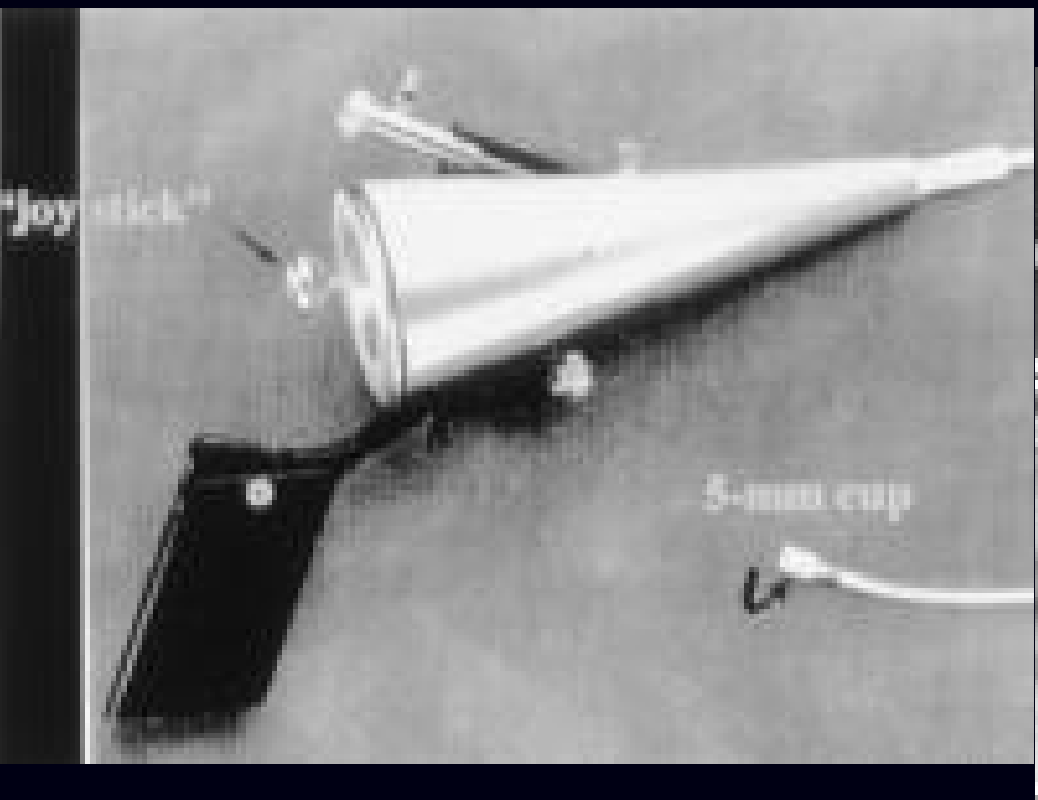


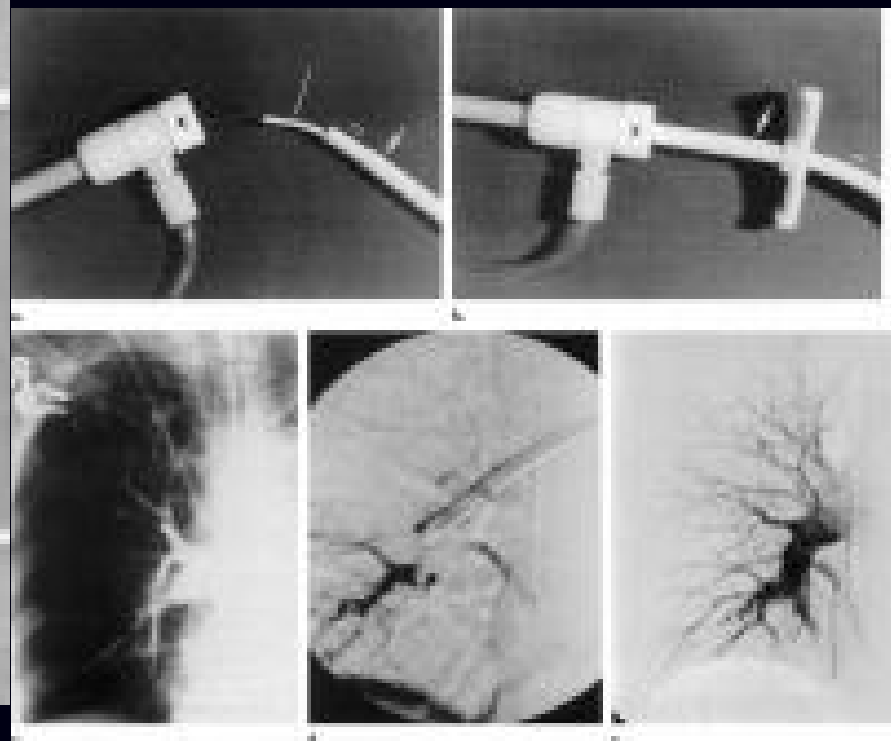
# Aspiration thrombectomy

1 . Catheter directed thrombolysis
2 . Catheter tip embolectomy
A Aspiration thrombectomy
B Fragmentation
C Rheolytic thrombectomy

Greenfield Embolectomy Device
Greenfield LJ et al. J Surg Res 1969;9:347
Timsit J-F et al. Chest 1991;100:655
Greenfield LJ et al. J Vasc Surg 1993;18:450
Lang Percutaneous Thrombectomy Device
Lang EV et al. JVIR1997;8:427.

(Uflacker JVIR 2001;12)



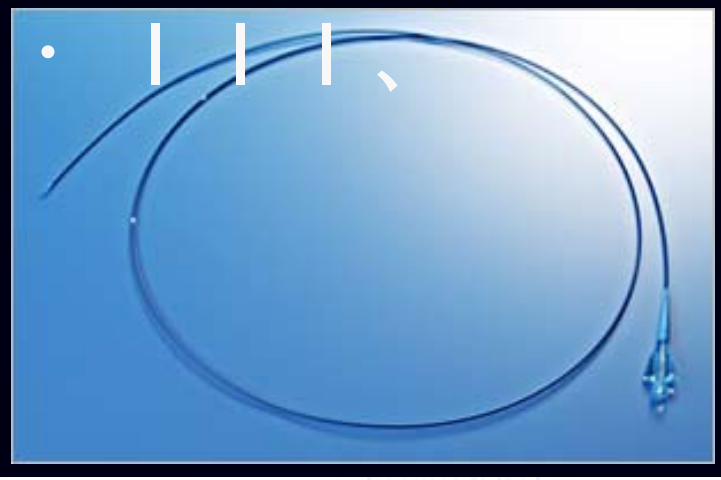


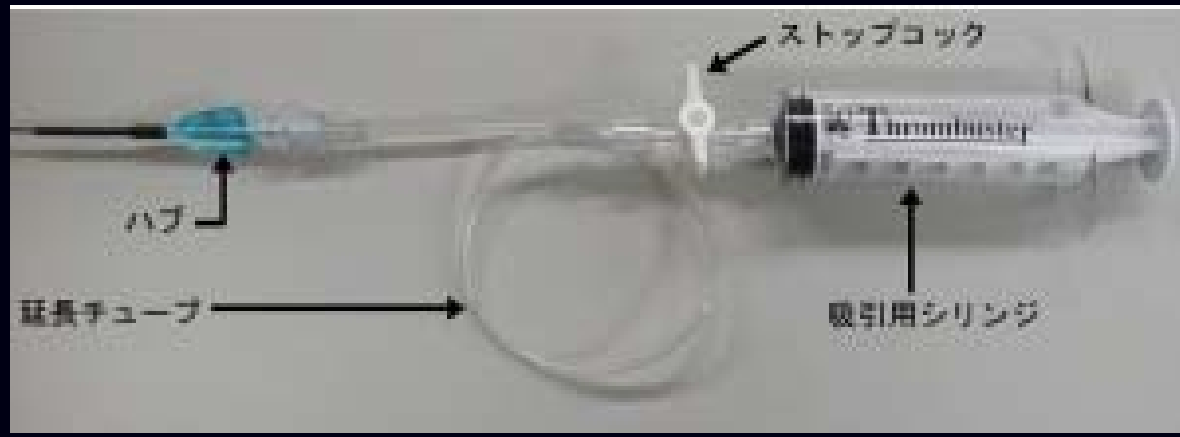
# Aspiration thrombectomy with PTCA guiding catheter (Meyerovitz technique)

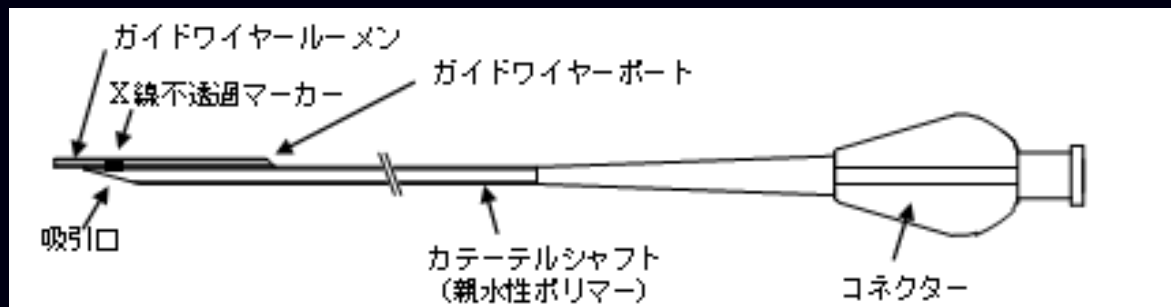
佐藤文則ら　心血管　1989;4:204
中崎育明ら　呼と循 1989;37:1363
井上一郎ら　脈管学 1994;34:875
Bravo SM, Reinhart RD, Meyerovitz MF
Vasc Med　1998;3:66
Hiramatsu S et al　J Cardiol 1999;34:71
Tajima H et al　Rad Med 2004;22:168

# Aspiration thrombectomy devices

Ｔｈｒｏｍｂｕｓｔｅｒ Ⅱ・Ⅲ、
ＴＶＡＣ、
New　Export、
Ｒｅｂｉｒｔｈ、
Eliminate、
etc.





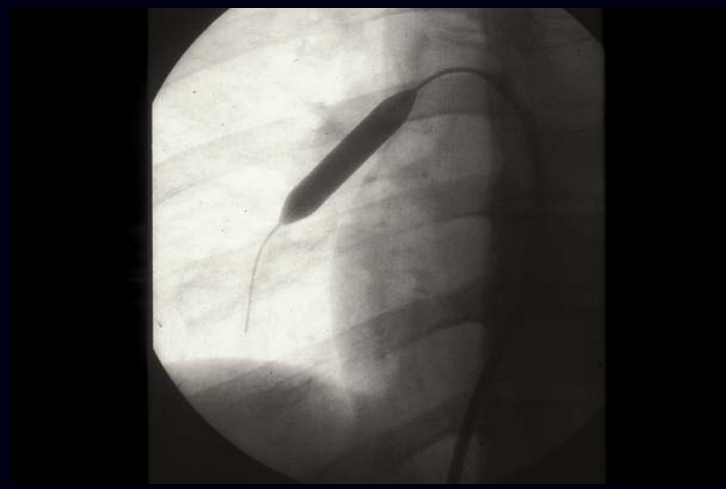
# Fragmentation 1

1．Catheter directed thrombolys
2．Catheter tip embolectomy
A Aspiration thrombectomy
B Fragmentation
C Rheolytic thrombectomy

Guidewire

唐川正洋ら　心血管　１９９３；８：１０５

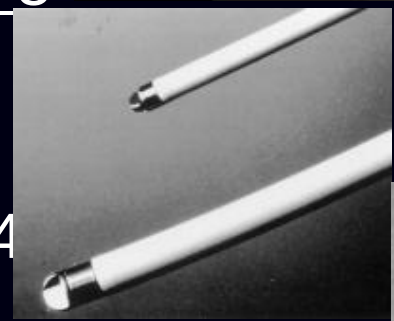
井上一郎ら　心臓　１９９４；２６：１０１０



Balloon Angioplasty

Handa K et al. Angiology　1988;8:775

Fava M et al. JVIR　1997;8:261

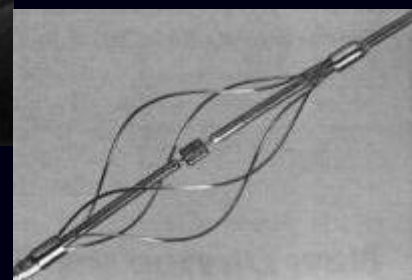


Kensey Dynamic Device

Stein PD et al.　Chest　1990;98:994

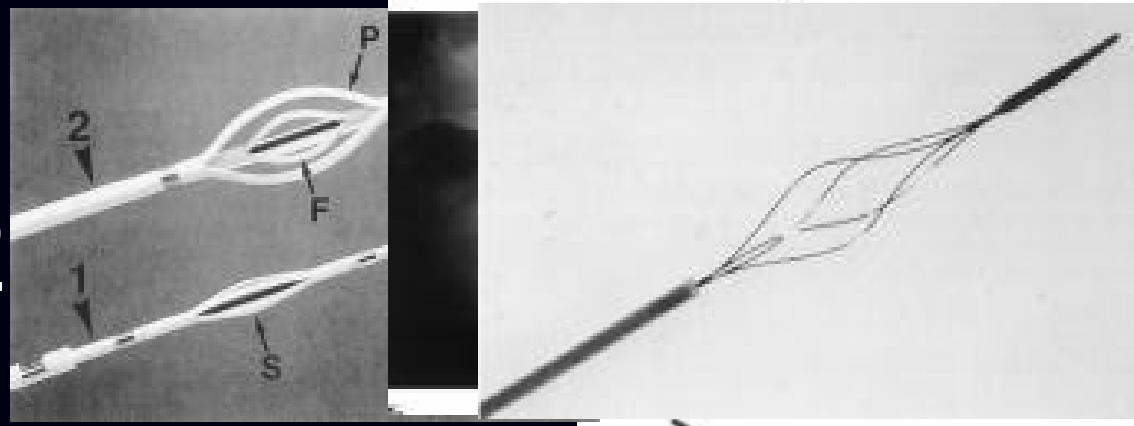
Impeller Basket Device

Schmitz-Rode T et al.　Radiology



(Uflacker JVIR 2001;12)

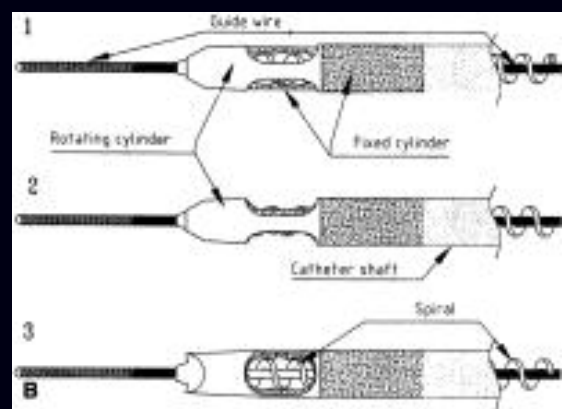
1 . Catheter directed thrombolysis
2 . Catheter tip embolectomy
A Aspiration thrombectomy
B Fragmentation
C Rheolytic thrombectomy




# Fragmentation 2

Thrombolyzer
Schmitz-Rode T et al. CVIR 1996;19:165
Rotatable Pigtail Catheter
Schmitz-Rode T et al. Chest 1998;114:1427
Arrow-Trerotola Device
Brown DB et al. JVIR 1999;10:733
Amplatz Thrombectomy Device
Uflacker R et al. JVIR 1996;7:519
Rotarex Catheter
Schmitt H-E et al. CVIR 1999;22:504

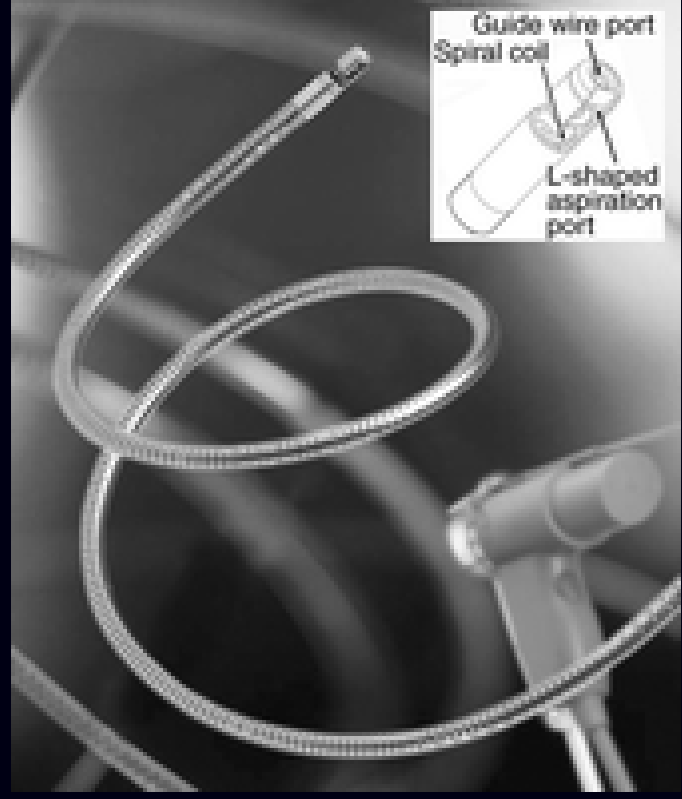

(Uflacker JVIR 2001;12)



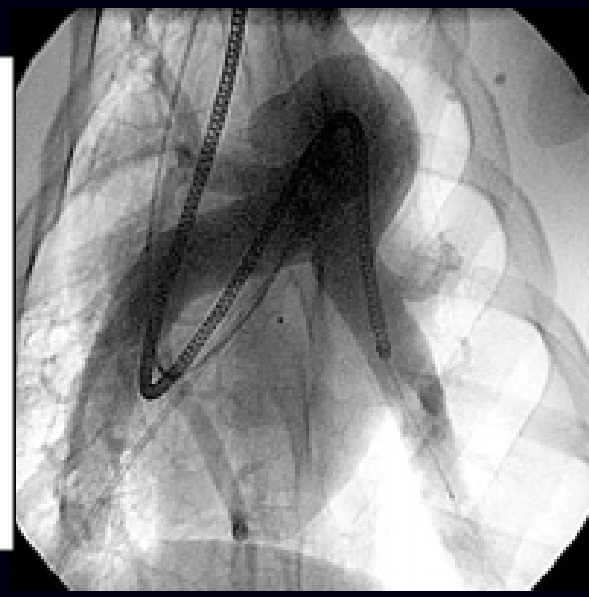
# Fragmentation 3

Aspirex （ Straub Medical)

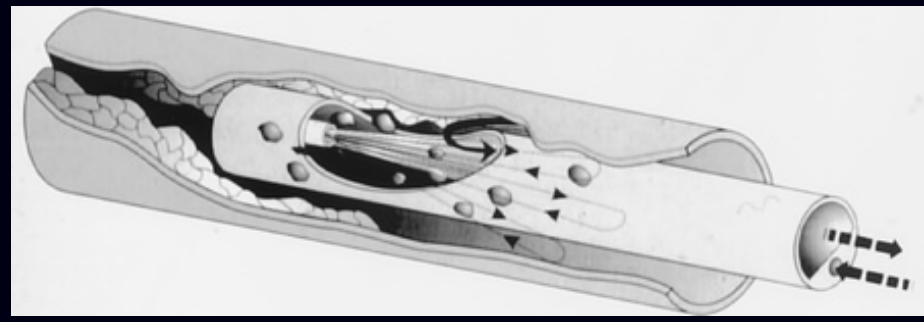
Radiology 2005;236:852




| Parameter | Value |
|---|---|
| Length | 120 cm |
| Maximum external diameter | 11.2 F (3.75 mm) |
| Sheath compatibility | 11 F |
| Guidewire compatibility | 0.035 inch; length, 260 cm |
| Catheter body | Polyurethane, stainless steel, perfluoroethylenepropylene |
| Flexible catheter tip length | 41 cm |
| Motor-catheter connection | Magnetic clutch with torque lock |
| Rotary speed | 32 500 rpm |
| Speed torque | 25 mNm |
| Maximum aspiration pressure* | 11.3 kPA |
| Minimum catheter bend radius | 21 mm |



# Rheolytic thrombectomy



(Uflacker JVIR 2001;12)

Hydrolyser

Michalis LK et al. Clin Radiol 1997;52:158

Fava M et al. JVIR 2000;11:1159

畑中義美　ら. IVR学会誌　2002;17:347

Oasis

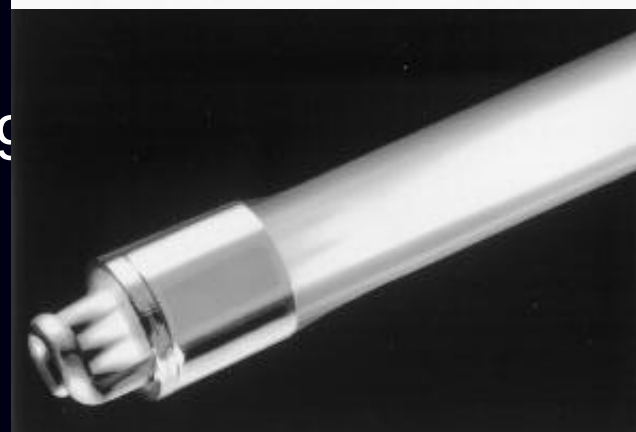
AngioJet

Voigtlaender T et al. Catheter & Cardiovasc Intervent 1999;47:9

Zeni PT et al. JVIR 2003;14:1511

Modified Hydrolyser

Reekers JA et al. CVIR 2003;26:246



1 . Catheter directed thrombolysis(CDT)

2 . Catheter tip embolectomy

A Aspiration thrombectomy

B Fragmentation

C Rheolytic thrombectomy

↓

Hybrid catheter intervention

# Hybrid catheter intervention

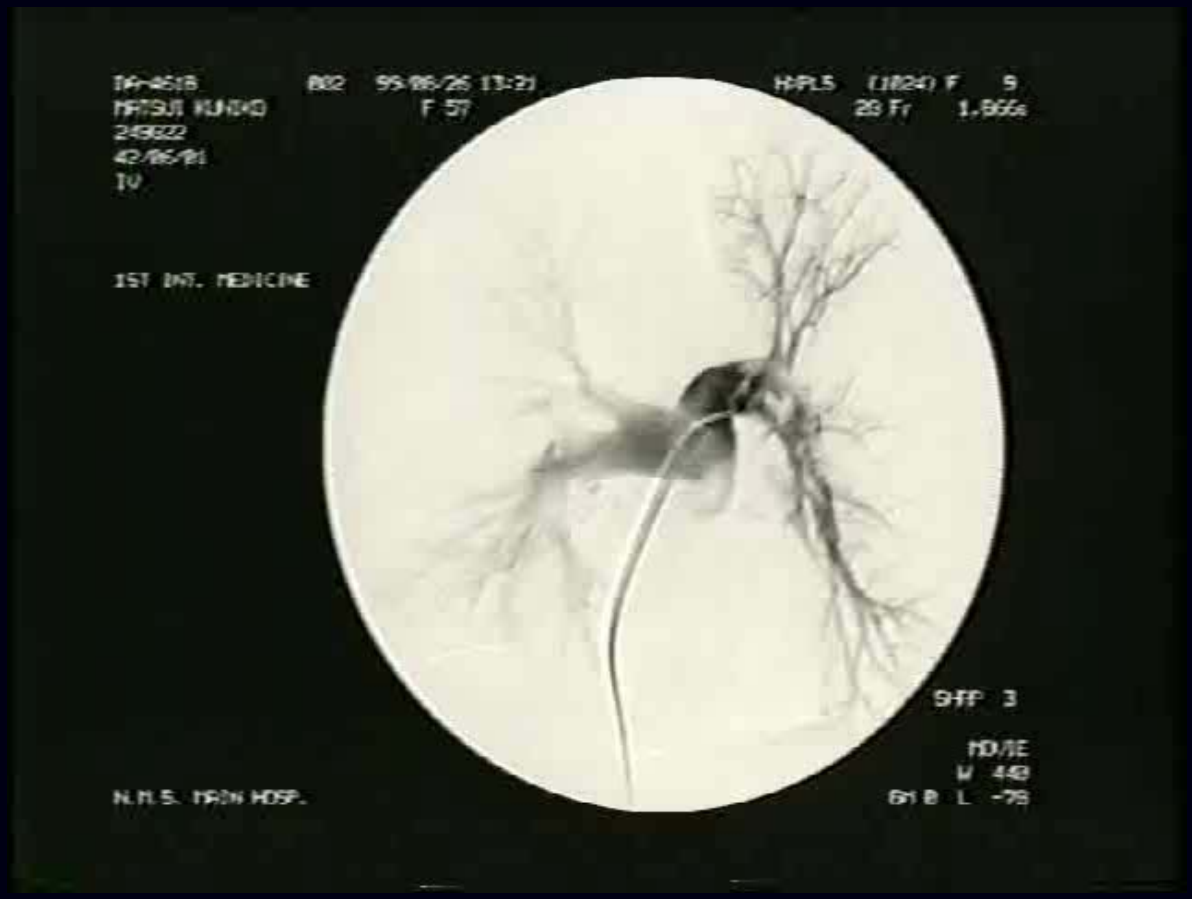
## Procedures:

1.PAP (Pulmonary arterial pressure) measurement, PAG (Pulmonary angiography)
2.Long sheath insertion to PA trunk
3.Local fibrinolytic therapy: r t-P A*
4.Fragmentation using Rotatable Pigtail Catheter
5.Aspiration thrombectomy
6.PAP measurement, PAG
7.Post procedure treatments

*rt-PA:recombinant human-tissue plasminogen activator

(H Tajima et al. AJR 2004;183:589)


IM-4618 884 95/06/26 13:34 H/PLS (1024) F 2
F 57 2 Fr 8.800s
IV
1ST INT. MEDICINE
SHP 5
W 699
N.M.S. MAIN HOSP. L -391


IN-4618 882 95/06/26 13:21
MATSUI KUNIKO F 57
249822
42/06/01
IV
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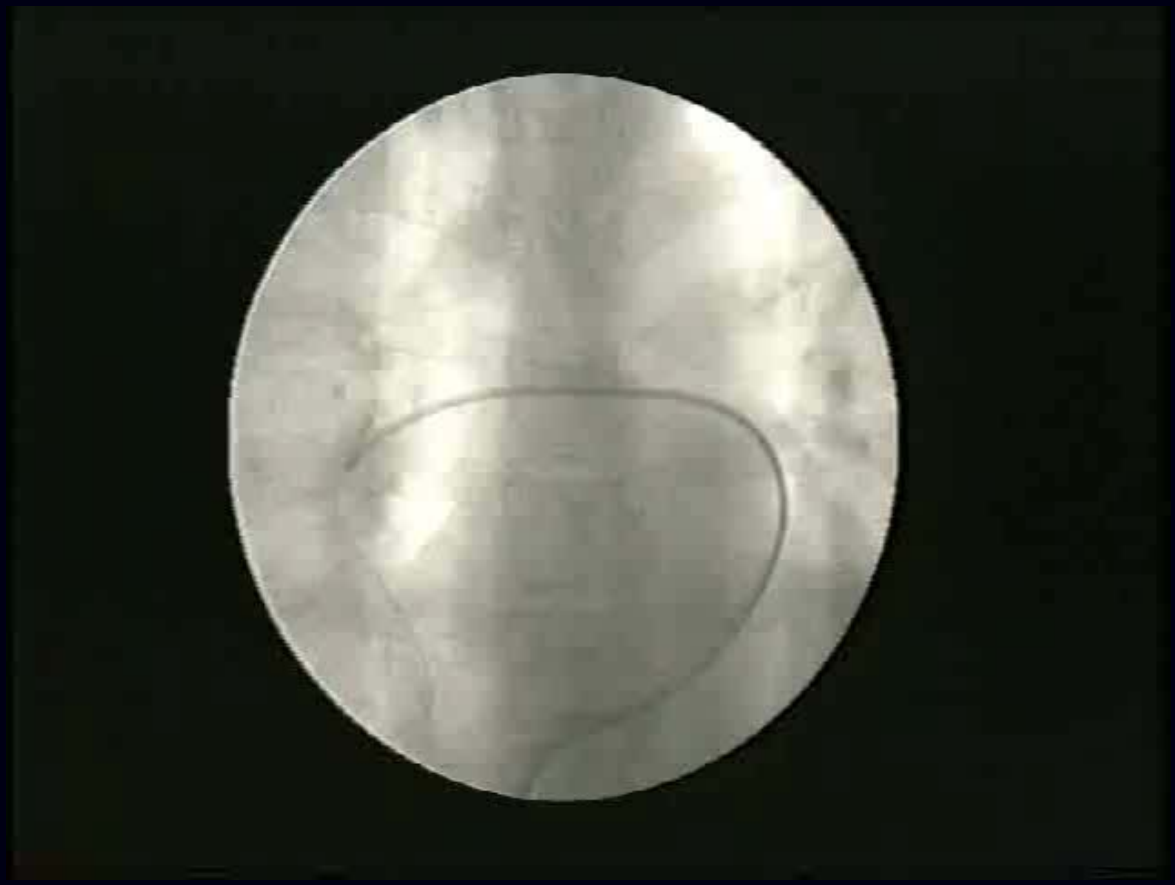

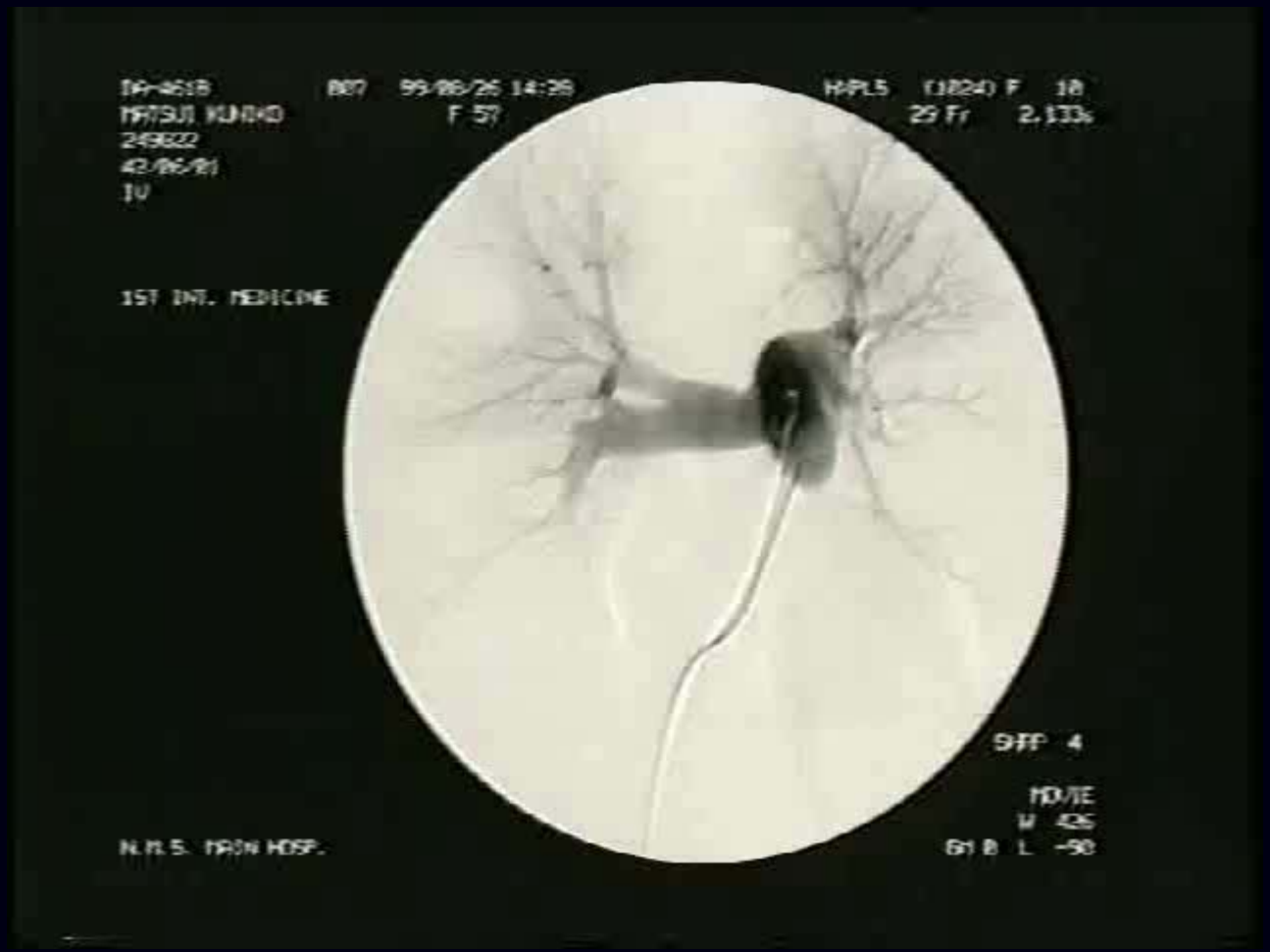
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249822
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IV
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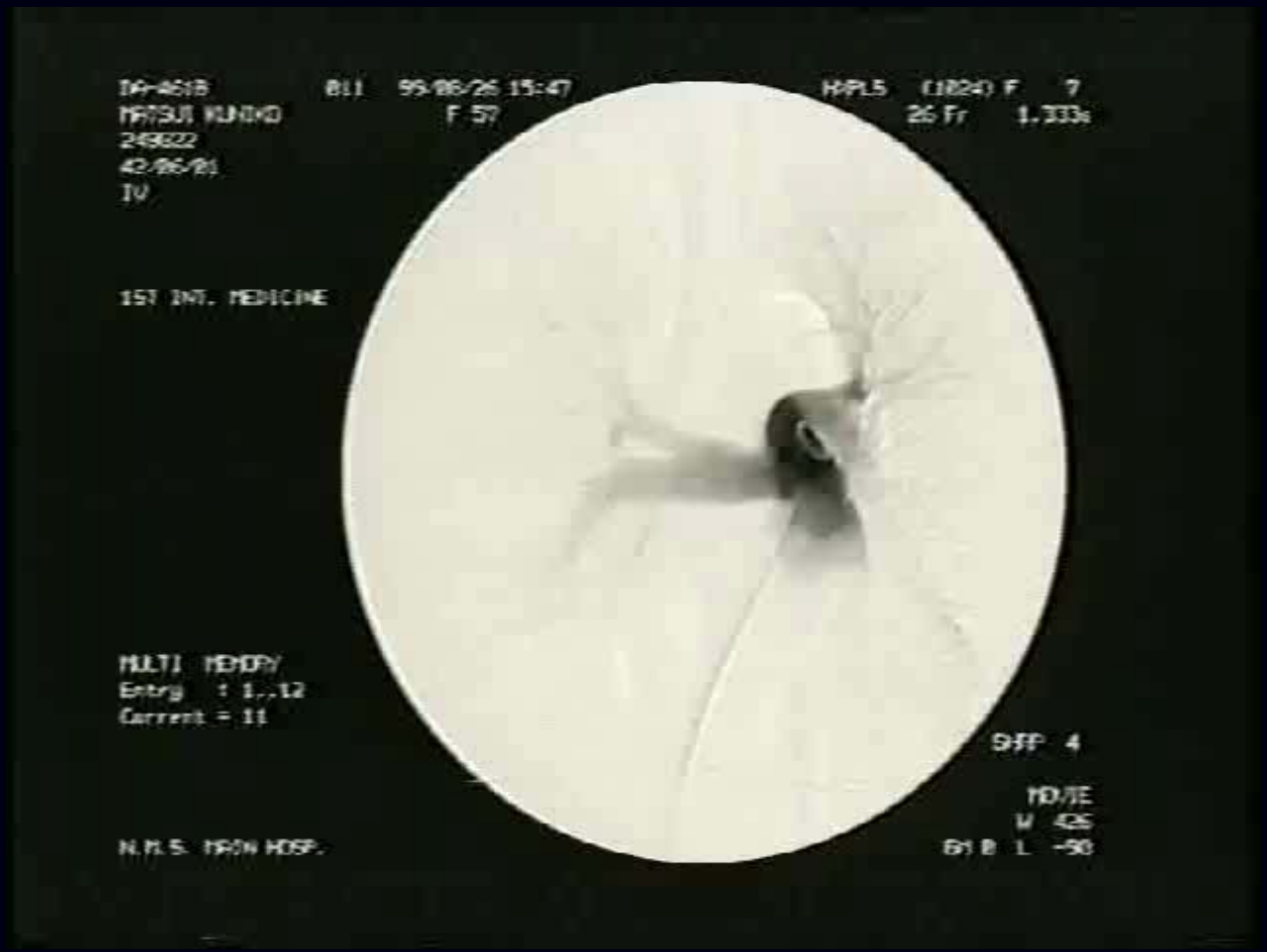
IM-4618 811 95/06/26 15:47 HPLS (1024) F 7
MATSUI KUNIKO F 57 26 Fr 1.333x
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MULTI MEMORY
Entry : 1,,12
Current = 11
SHIP 4
MD/IE
W 426
N.M.S. MAIN HOSP. 611 B L -90

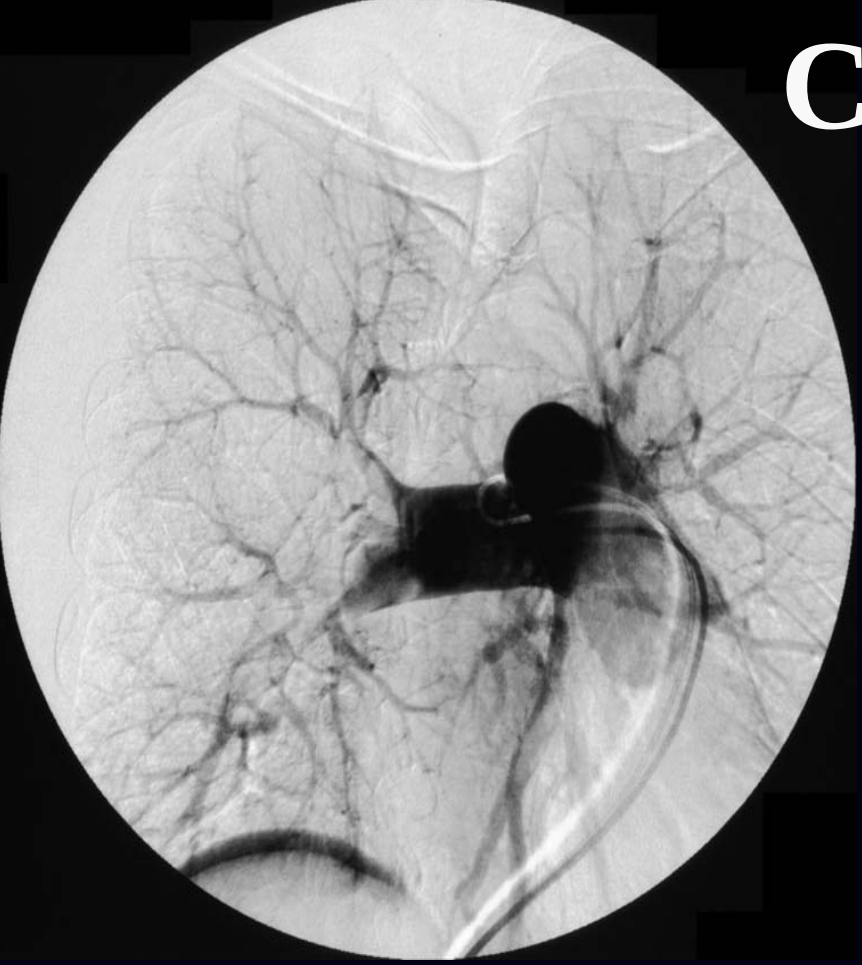
# Hybrid catheter intervention

Post procedure treatments:

1. Temporary IVC filter insertion as protection against recurrent PE
2. Additional systemic urokinase infusion

   The dosing regimen originally was 24-48x$10^4$ IU per day for 3 days
3. Catheter intervention for the residual deep vein thrombosis

# Case presentation



Pre intervention

101 min after intervention

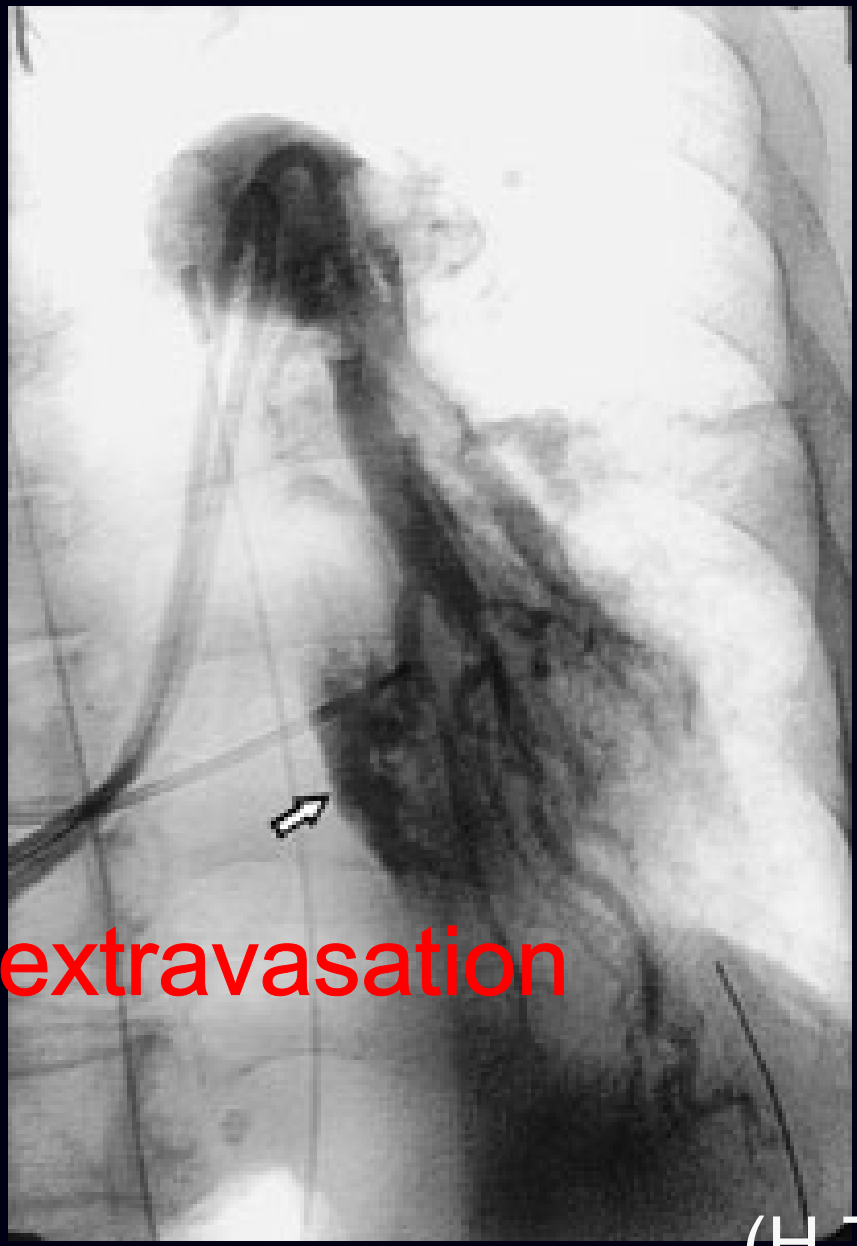
# Hybrid catheter intervention

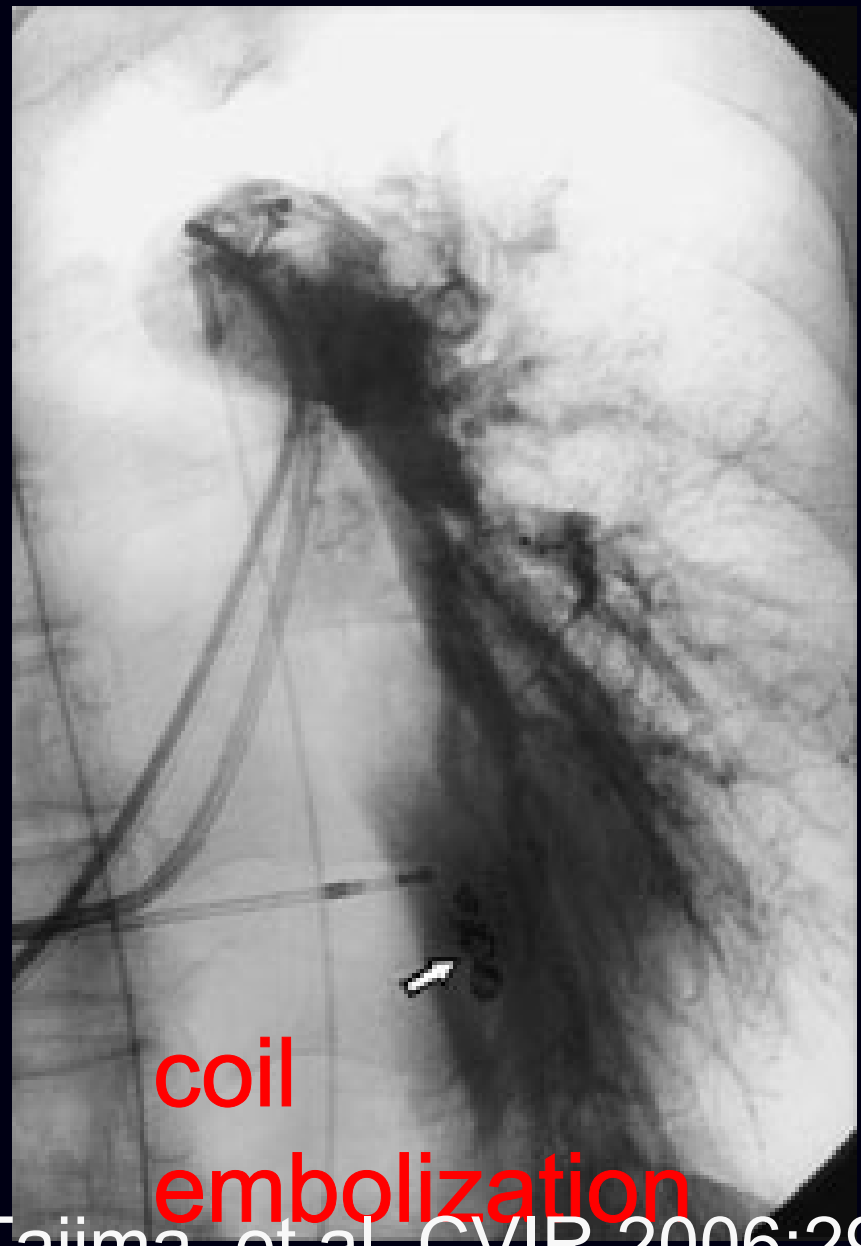
Complications:

(Major) One case of cardiac arrest during pigtail catheter rotation, but recovered. One case of pulmonary artery perforation during aspiration, but rescued by micro-coil embolization.

(Minor) One case of catheter shaft fragmentation during catheter rotation, easily pulled out.

# Coil embolization for vascular injury




(H Tajima, et al. CVIR 2006;29:15

# Hybrid catheter intervention

## Discussion-1-:

The goal of the intervention?

→The angiographic result of the catheter intervention is less important. The procedure should be terminated once hemodynamic improvement is achieved, regardless of the extent of residual emboli in the pulmonary angiogram. (Chest 2008;134:2)

# Hybrid catheter intervention

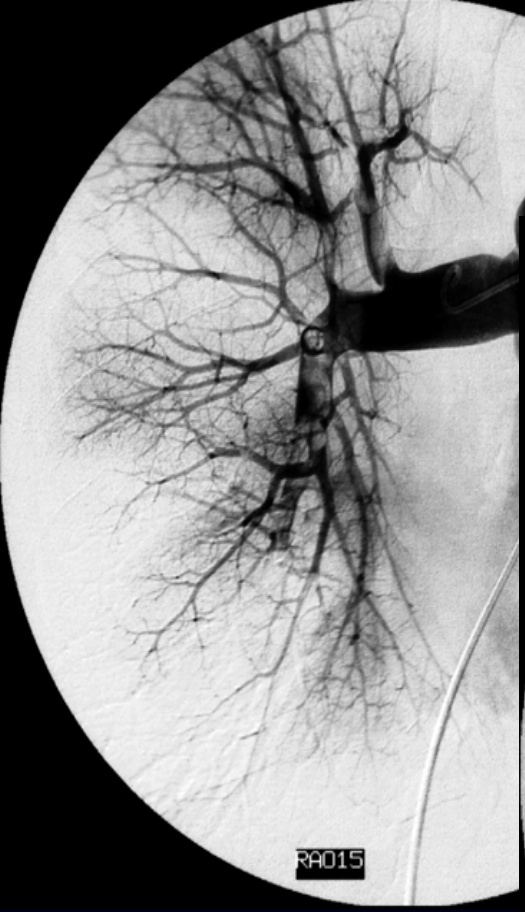
## Discussion-2-:

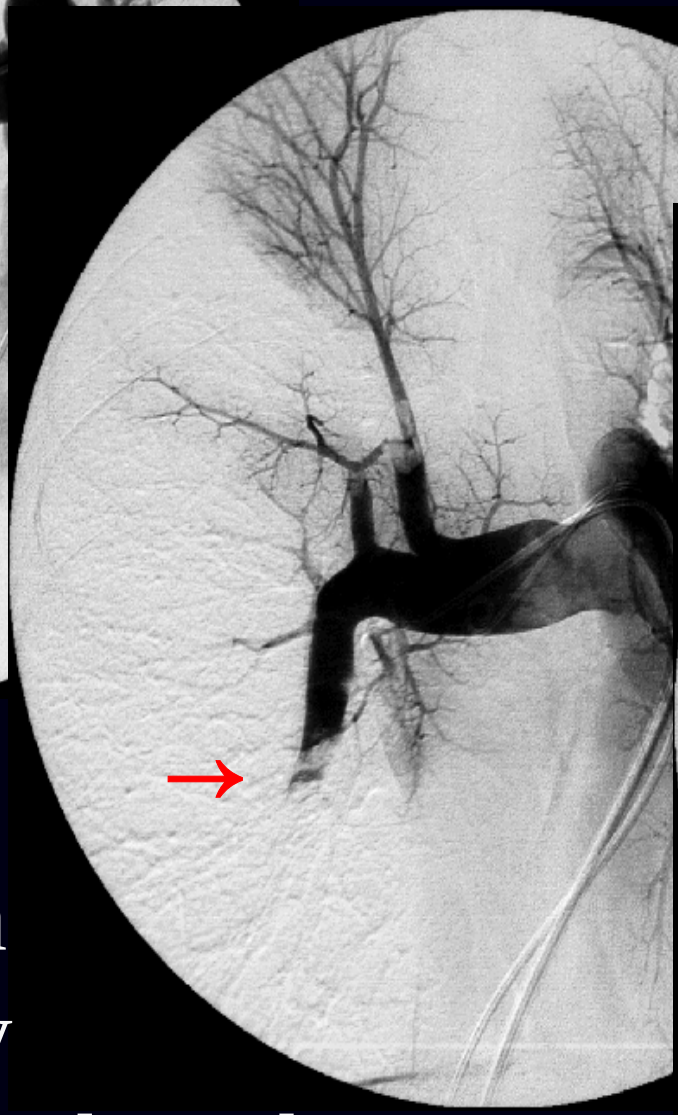
How to prevent distal embolization after the fragmentation of massive thrombi ?

→Aspiration thrombectomy should be added.

（Brit J Radiol 2008；81：848）

# Distal embolization



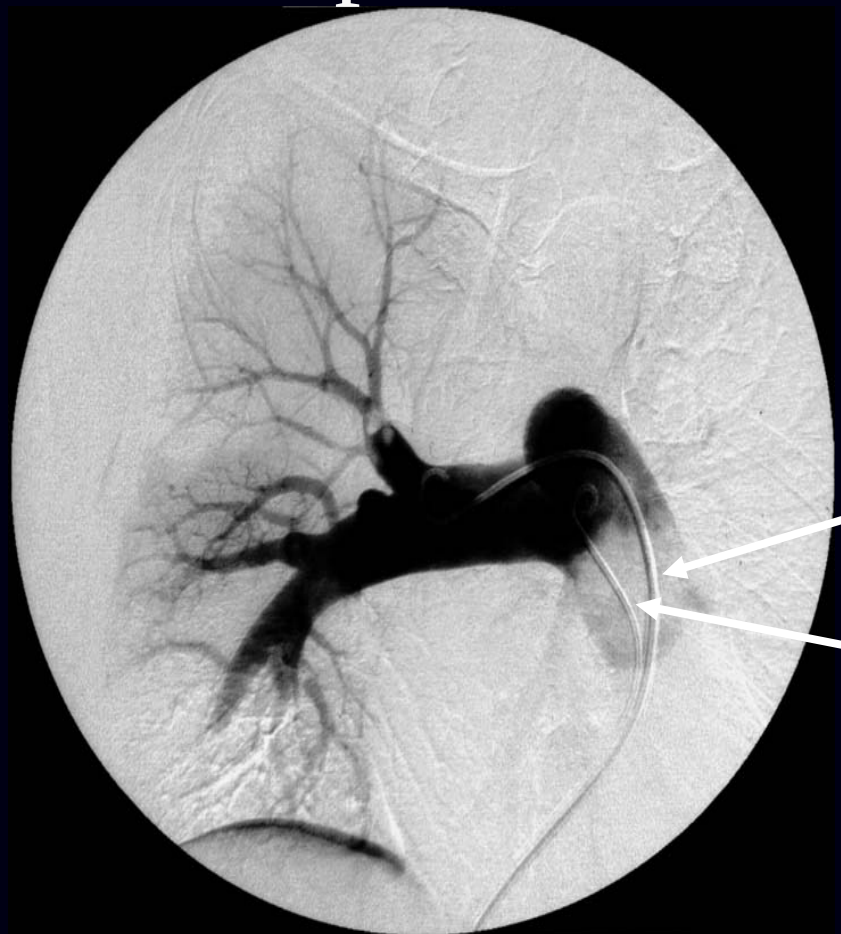



Distal embolization is resqued by the aspiration thrombectomy.

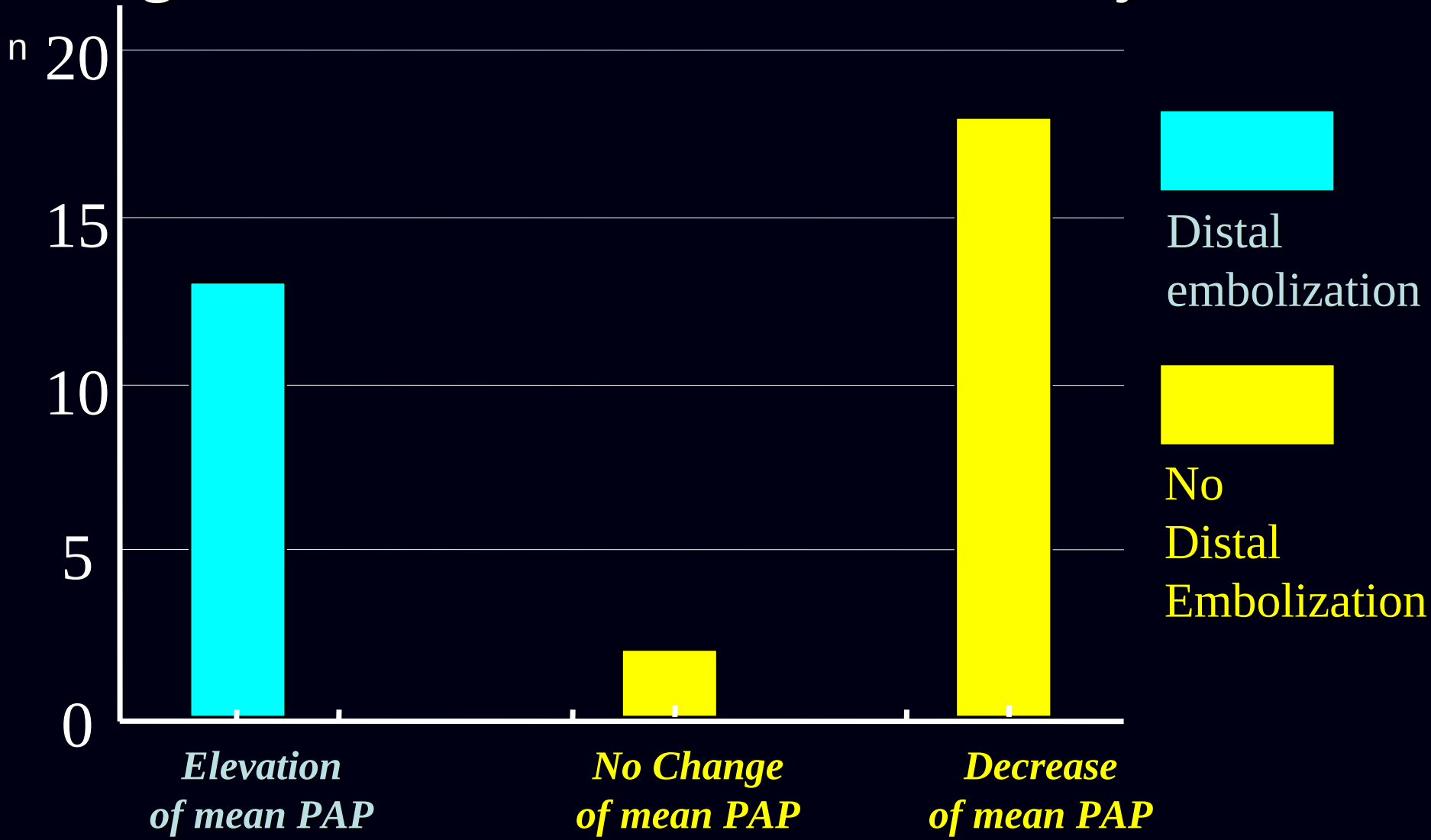
**Discussion -3-:**

For the safety of the procedure：

Continuous monitoring of the pulmonary arterial pressure during the procedures



# Mean pulmonary arterial pressure (PAP) change due to mechanical thrombectomy




( K Nakazawa, H Tajima, et al. Brit J Radiol 2008 ; 81 : 84

# Discussion- 4 -: New references for catheter intervention

E-L Guering, et al; Combined clot fragmentation and aspiration in patients with acute pulmonary embolism. Chest 2008; 134: 54-60

Instituto Nacional de Cardiologia, Mexico City

Severe PTE 18 case

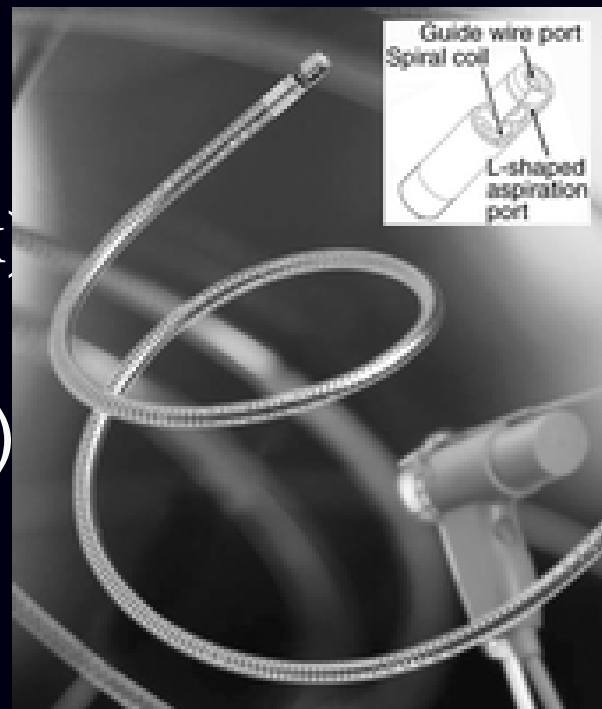
Fragmentation with 6Fr pigtail catheter

+ Aspiration thrombectomy(8Fr Aspirex)

Major side effects11%

( Shock→death:1, Cerebral hemorrhage:1 )

No cardiovascular death and recurrence after 12 months follow up.

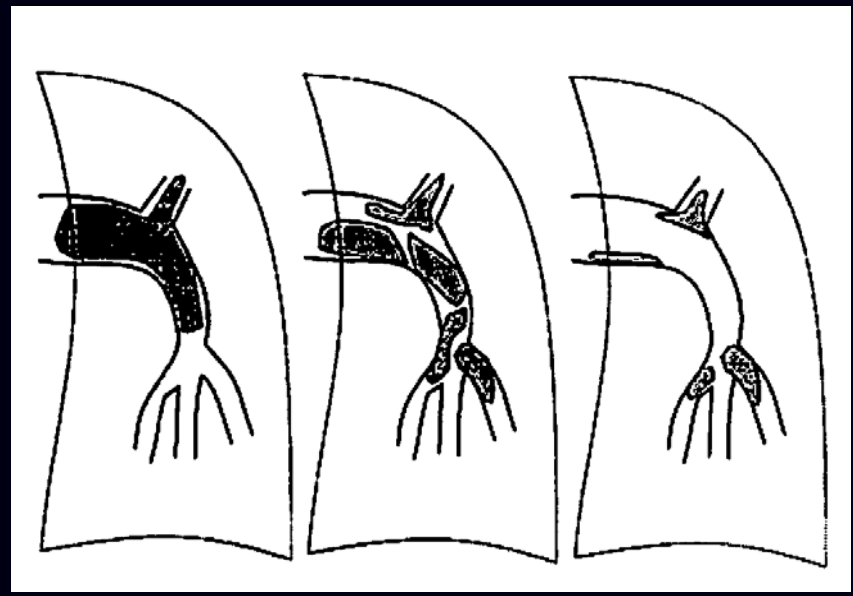


# Discussion-5-: New references for catheter intervention.

Kucher N and Goldhaber SZ: Mechanical catheter intervention in massive pulmonary embolism: Proof of concept. Chest 2008;134:2-4

Fig1. Combination of thrombus fragmentation with aspiration thrombectomy.

They evaluated the futute of combination of thrombus fragmation with aspiration thrombectomy, and stressed that “experienced team” is needed for excellent results.



**Discusssion-5-:**

* To keep respiratory and hemodynamic status →Intubation, PCPS(**Percutaneous Cardio Pulmonary Support**), etc
* Prevention of 2nd attack of PE
  → I V C filter, etc
* Thrombi of the right atrium
  →Contra-indication of catheter intervention

# Recommendation class and evidence level of catheter intervention for acute PTE

- European society of cardiology 2008

# 欧州心臓病学会ガイドライン：急性肺血栓塞栓症の診断と治療

Guidelines on the diagnosis and management of acute massive pulmonary embolism. The task force for the diagnosis and management of acute pulmonary thromboembolism of the European Society of Cardiology. European Heart Journal(2008)29;2276-2315

- Classes of recommendation:

I Evivence and/or general agreement that a given treatment or procedure is beneficial, useful, and effective.

II Conflicting evidence and/or a divergence of option about the usefulness/efficacy of the given treatment or procedure

III Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful

**欧州心臓病学会ガイドライン：急性肺血栓塞栓症の診断と治療**

Guidelines on the diagnosis and management of acute massive pulmonary embolism. The task force for the diagnosis and management of acute pulmonary thromboembolism of the European Society of Cardiology. European Heart Journal(2008)29;2276-2315

- Levels of evidence:

A Data derived from multiple randomized clinical trials or meta-analyses

B Data derived from a single randomized clinical trial or large non-randomized studies

C Consensus of opinion of the experts and/or small studies, retrospective studies, registries

# 欧州心臓病学会ガイドライン：急性肺血栓塞栓症の診断と治療

Guidelines on the diagnosis and management of acute massive pulmonary embolism. The task force for the diagnosis and management of acute pulmonary thromboembolism of the European Society of Cardiology. European Heart Journal(2008)29;2276-2315

Recommendation acute treatment of high risk patients:

Catheter embolectomy or fragmentation of proximal pulmonary arterial clots may be considered as an alternative to surgical treatment in high-risk patients when thrombolysis is absolutely contraindicated or has failed.

- Class of recommendation: II b
- Level of evidence: C

# 欧州心臓病学会ガイドライン：急性肺血栓塞栓症の診断と治療

Guidelines on the diagnosis and management of acute massive pulmonary embolism. The task force for the diagnosis and management of acute pulmonary thromboembolism of the European Society of Cardiology. European Heart Journal(2008)29;2276-2315

Recommendation acute treatment of high risk patients:

Surgical pulmonary embolectomy is a recommended therapeutic alternative in patients with high-risk PE in whom thrombolysis is absolutely contraindicated or has failed.

- Class of recommendation: I
- Level of evidence: C

法

Antithrombotic therapy for venous thromboembolic disease.

American college of chest physicians evidence based clinical practice guidelines (8 t h edition). Chest 2008;133:454S-545S

4.4 Catheter extraction or fragmentation for the initial treatment of PE

For most patients with PE, we recommended against use of interventional catheterization techniques (Grade 1C). In selected highly compromised patients who are unable to receive thrombolytic therapy because of bleeding risk, or whose critical status does not allow sufficient time for systemic thrombolytic therapy to be effective, we suggest use of interventional catheterization techniques if appropriate expertise is available (Grade 2C)

法

Antithrombotic therapy for venous thromboembolic disease.

American college of chest physicians evidence based clinical practice guidelines (8 t h edition). Chest 2008;133;454S-545S

4.5 Pulmonary embolectomy for the initial treatment of PE

In selected highly compromised patients who are unable to receive thrombolytic therapy because of bleeding risk, or whose critical status does not allow sufficient time for systemic thrombolytic therapy to be effective, we suggest that pulmonary embolectomy may be used if appropriate expertise is available (Grade 2C).

# Levels of evidence

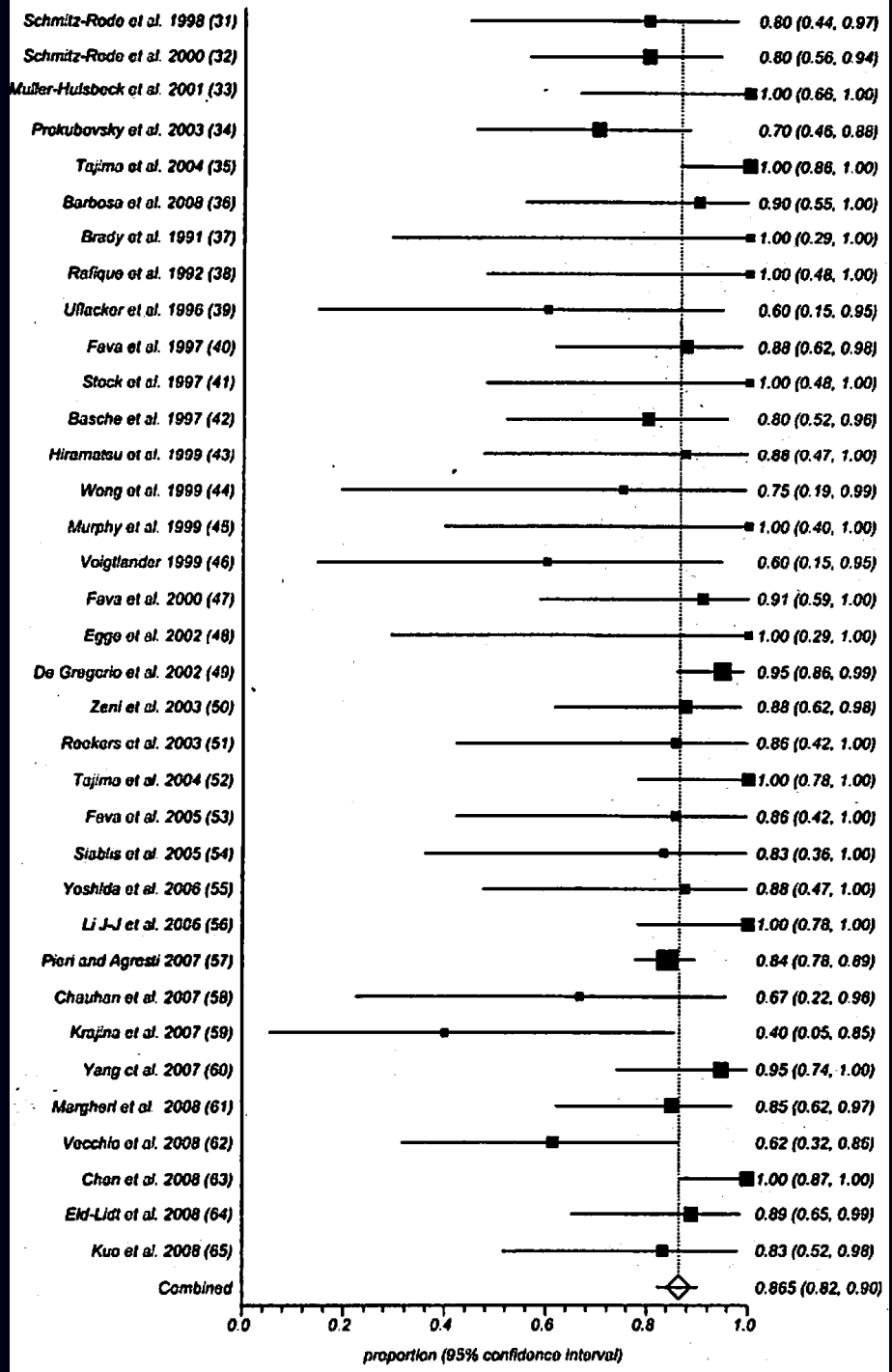
A Data derived from multiple randomized clinical trials or meta-analyses

B Data derived from a single randomized clinical trial or large non-randomized studies

C Consensus of opinion of the experts and/or small studies, retrospective studies, registries

Catheter-directed therapy for the treatment of massive pulmonary embolism: Systemic review and meta-analysis of modern techniques. Kuo WT, et al. JVIR2009;20:1431-1440

- Jan 1990-Sept 2008
- 594 patients
- 35 studies (6 prospective, 29 retrospective)
- Meta-analysis
- Clinical success: stabilization of hemodynamics resolution of hypoxia, and survival to hospital discharge


Schmitz-Rode et al. 1998 (31) 0.80 (0.44, 0.97)
Schmitz-Rode et al. 2000 (32) 0.80 (0.56, 0.94)
Muller-Hulsbeck et al. 2001 (33) 1.00 (0.66, 1.00)
Prokubovsky et al. 2003 (34) 0.70 (0.46, 0.88)
Tajima et al. 2004 (35) 1.00 (0.86, 1.00)
Barbosa et al. 2008 (36) 0.90 (0.55, 1.00)
Brady et al. 1991 (37) 1.00 (0.29, 1.00)
Rafique et al. 1992 (38) 1.00 (0.48, 1.00)
Ullackor et al. 1996 (39) 0.60 (0.15, 0.95)
Fava et al. 1997 (40) 0.88 (0.62, 0.98)
Stock et al. 1997 (41) 1.00 (0.48, 1.00)
Basche et al. 1997 (42) 0.80 (0.52, 0.96)
Hiramatsu et al. 1999 (43) 0.88 (0.47, 1.00)
Wong et al. 1999 (44) 0.75 (0.19, 0.99)
Murphy et al. 1999 (45) 1.00 (0.40, 1.00)
Voigtlander 1999 (46) 0.60 (0.15, 0.95)
Fava et al. 2000 (47) 0.91 (0.59, 1.00)
Egge et al. 2002 (48) 1.00 (0.29, 1.00)
De Gregorio et al. 2002 (49) 0.95 (0.86, 0.99)
Zeni et al. 2003 (50) 0.88 (0.62, 0.98)
Rookers et al. 2003 (51) 0.86 (0.42, 1.00)
Tajima et al. 2004 (52) 1.00 (0.78, 1.00)
Fava et al. 2005 (53) 0.86 (0.42, 1.00)
Siablis et al. 2005 (54) 0.83 (0.36, 1.00)
Yoshida et al. 2006 (55) 0.88 (0.47, 1.00)
Li J-J et al. 2006 (56) 1.00 (0.78, 1.00)
Pieri and Agresti 2007 (57) 0.84 (0.78, 0.89)
Chauhan et al. 2007 (58) 0.67 (0.22, 0.96)
Krajina et al. 2007 (59) 0.40 (0.05, 0.85)
Yang et al. 2007 (60) 0.95 (0.74, 1.00)
Merghori et al. 2008 (61) 0.85 (0.62, 0.97)
Vecchio et al. 2008 (62) 0.62 (0.32, 0.86)
Chen et al. 2008 (63) 1.00 (0.87, 1.00)
Eid-Lidt et al. 2008 (64) 0.89 (0.65, 0.99)
Kuo et al. 2008 (65) 0.83 (0.52, 0.98)
Combined 0.865 (0.82, 0.90)
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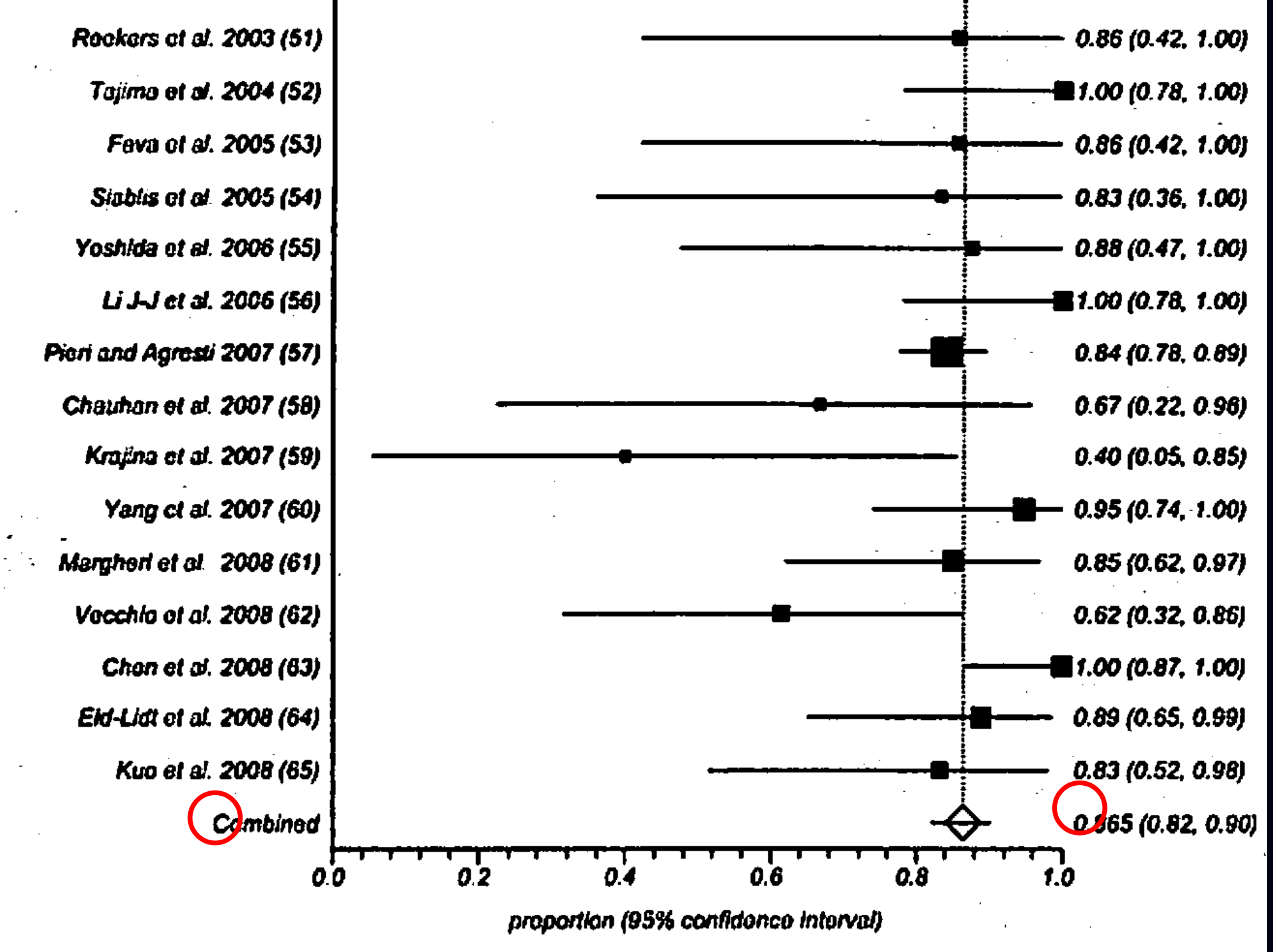
0.4
0.6
0.8
1.0
proportion (95% confidence interval)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proportion (95% confidence interval)

Catheter-directed therapy for the treatment of massive pulmonary embolism: Systemic review and meta-analysis of modern techniques. Kuo WT, et al. JVIR2009;20:1431-1440

Pooled clinical success rate 86.5% (95% Confidence Interval:82.1%,90.2%)

Pooled risks of minor procedural complications 7.9% (95%CI:5.0%,11.3%)

Pooled risks of major procedural complications 2.4% (95%CI:1.9%,4.3%)

Conclusions: Modern CDT is a relatively safe and effective treatment for acute massive PE. At experienced centers, CDT should be considered as a first-line treatment for patients with massive

# Sumary（１）
# Catheter interventions for acute massive PTE

・ No controlled clinical trials have been performed　that have compared surgical embolectomy with catheter interventions.（Chest 2007;132:657)

比較的新しい治療法であり、ほかの内科的治療法や外科的治療法との多施設前向きランダム試験は現時点まで実施されていない。

・ The results of small cohort studies have suggested that the clinical outcome after percutaneous catheter intervention is comparable to that after surgical embolectomy.　（Am J Cardiol 2007;99:415）小規模のコホート研究ではあるが、本法の臨床成果は外科的血栓摘除術に匹敵することが示唆されている。

# Summary（２）　meta-analysis

Modern CDT is a relatively safe and effective treatment for acute massive PE. At experienced centers, CDT should be considered as a first-line treatment for patients with massive PE.
（JVIR2009;20:1431）

急性塊状肺血栓塞栓症に対するIVR治療は、比較的安全で効果的な治療法である。経験の十分なセンターにおいては、まず試みられるべき治療法である。

# Banknotes of 500 DDK

Niels Bohr (1885-1962)

# Niels Bohr ,1937 KAMAKURA

# Niels Bohr ,1937 KAMAKURA

# SJRS 2008 KAMAKURA