

160513 論文紹介

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Leon MB, Smith CR, Mack MJ, et al.

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1年次研修医
So

Abstract

背景

手術高リスク群でのTAVRは、手術と同等の成績

目的

手術中リスク群における、TAVRと手術のRCT

方法

アメリカ・カナダの2032症例を2年間調査
primary end point : 全死亡・disabling stroke

結果

TAVR全体では手術に対して非劣性($p=0.001$)
経大腿アプローチでは有意に減少($p=0.05$)

結果

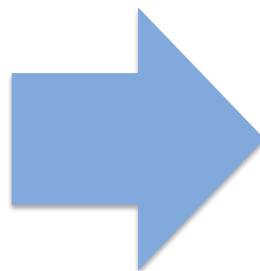
手術中リスク群でもTAVRは手術と同等の成績

背景:TAVRと手術

手術高リスク群



手術低～中リスク群



介入試験

術者の経験
新しいデバイス

患者数が多い
観察研究しかない

方法

TAVR/手術のRCT

対象者 : アメリカ・カナダの2032人
 STS score ≥ 4.0

デバイス : SAPIEN XT

研究デザイン: TAVR vs 手術、ITTで解析

End point : 全死亡・disabling stroke

modified Rankin scale ≥ 2

対象者

Characteristic	TAVR (N=1011)	Surgery (N=1021)
Age — yr	81.5±6.7	81.7±6.7
Male sex — no. (%)	548 (54.2)	560 (54.8)
Body-mass index†	28.6±6.2	28.3±6.2
STS risk score‡	5.8±2.1	5.8±1.9
NYHA class III or IV — no./total no. (%)	782/1011 (77.3)	776/1020 (76.1)
Coronary artery disease — no. (%)	700 (69.2)	679 (66.5)
Previous myocardial infarction — no. (%)	185 (18.3)	179 (17.5)
Previous CABG — no. (%)	239 (23.6)	261 (25.6)
Previous PCI — no. (%)	274 (27.1)	282 (27.6)
Previous balloon aortic valvuloplasty — no. (%)	51 (5.0)	50 (4.9)
Cerebral vascular disease — no. (%)	325 (32.1)	317 (31.0)
Peripheral vascular disease — no. (%)	282 (27.9)	336 (32.9)
Diabetes mellitus — no. (%)	381 (37.7)	349 (34.2)
COPD — no. (%)		
Any	321 (31.8)	306 (30.0)
Oxygen-dependent	34 (3.4)	32 (3.1)
Creatinine >2 mg/dl — no. (%)§	51 (5.0)	53 (5.2)
Atrial fibrillation — no. (%)	313 (31.0)	359 (35.2)
Permanent pacemaker — no. (%)	118 (11.7)	123 (12.0)
Frail condition — no./total no. (%)		
5-Meter walk-test time >7 sec	416/936 (44.4)	418/901 (46.4)
Serum albumin <3.5 g/dl	150/988 (15.2)	140/951 (14.7)
Liver disease — no. (%)	19 (1.9)	26 (2.5)
Aortic-valve area — cm ²	0.7±0.2	0.7±0.2
Mean gradient — mm Hg	44.9±13.4	44.6±12.5
Left ventricular ejection fraction — %	56.2±10.8	55.3±11.9
Left ventricular mass index — g/m ²	119.8±31.5	120.6±32.6
Moderate or severe mitral regurgitation — no./total no. (%)	151/899 (16.8)	171/894 (19.1)

Table 1

Primary end points

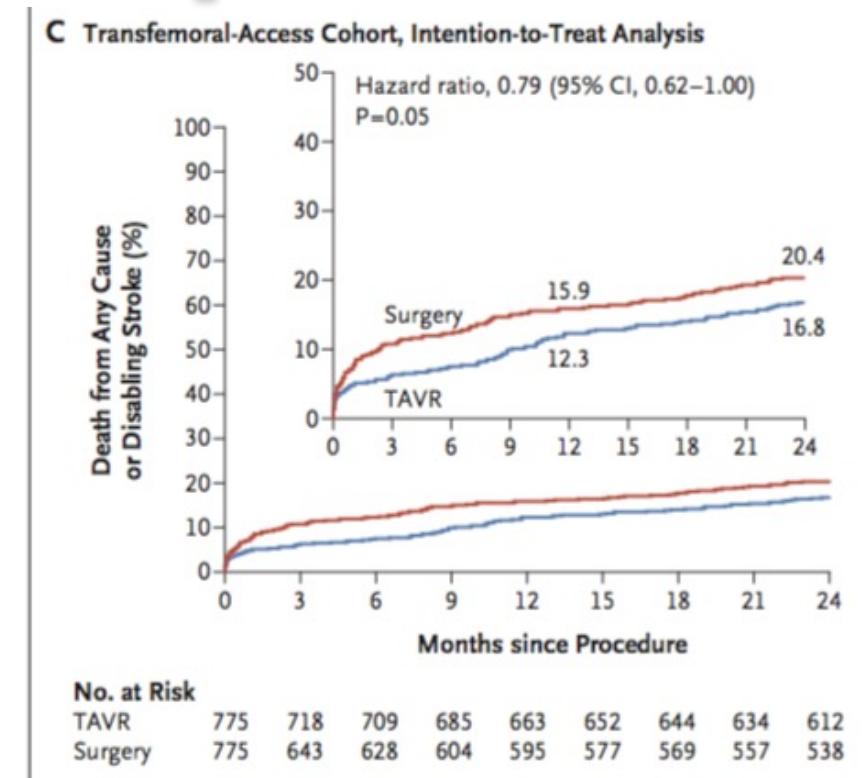
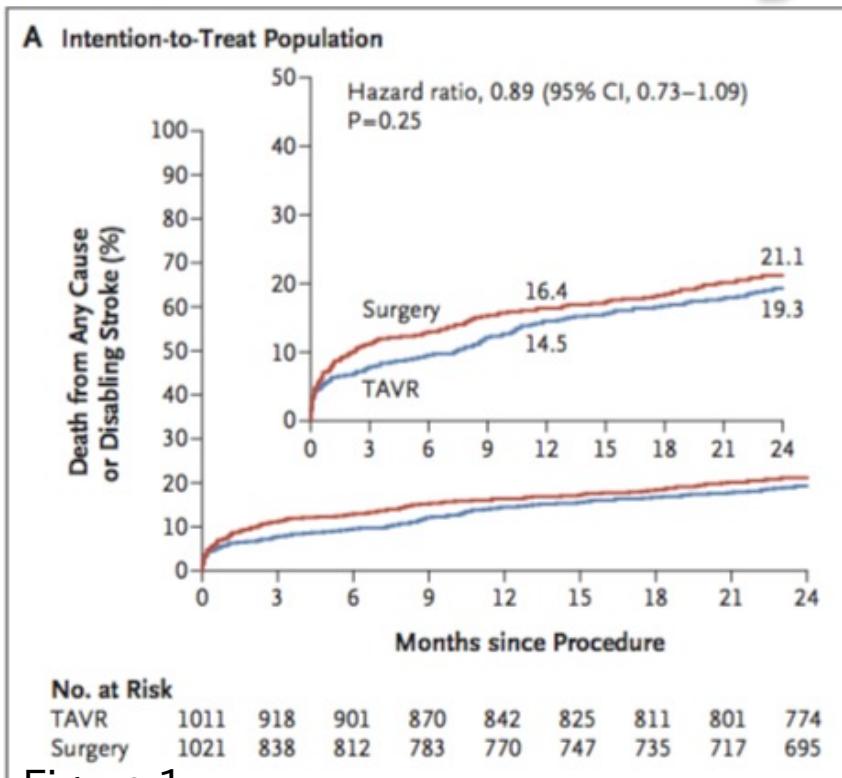


Figure 1

- TAVR全体：有意差なし
- 経大腿アプローチ群：有意差あり
(p=0.05)

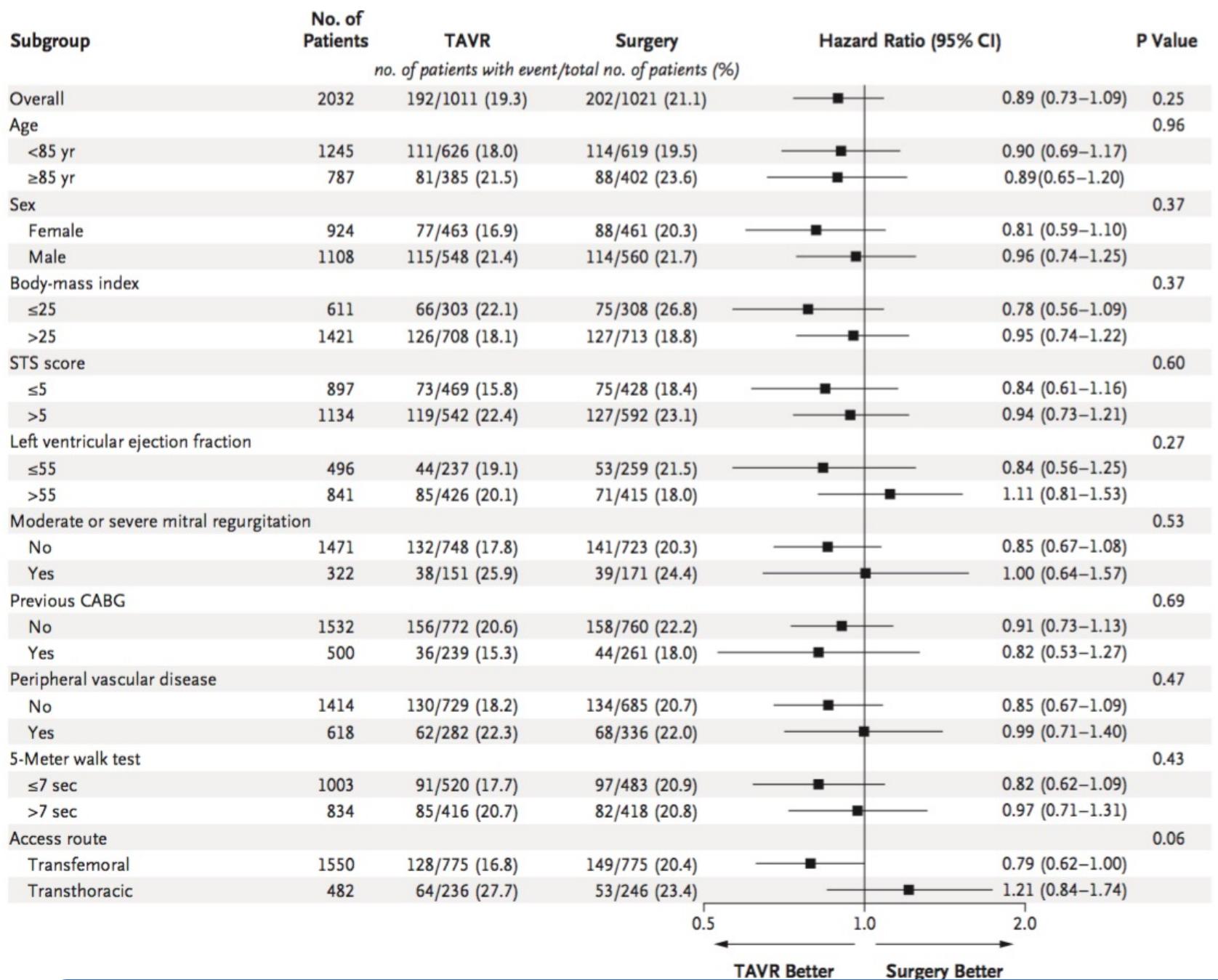


Figure 2

サブ解析：有意差のある項目なし

Table 2. Clinical End Points at 30 Days, 1 Year, and 2 Years.*

End Point	At 30 Days			At 1 Year			At 2 Years		
	TAVR (N=1011)	Surgery (N=1021)	P Value	TAVR (N=1011)	Surgery (N=1021)	P Value	TAVR (N=1011)	Surgery (N=1021)	P Value
	no. of patients (%)			no. of patients (%)			no. of patients (%)		
Death from any cause or disabling stroke	62 (6.1)	80 (8.0)	0.11	145 (14.5)	160 (16.4)	0.24	192 (19.3)	202 (21.1)	0.33
Death									
From any cause	39 (3.9)	41 (4.1)	0.78	123 (12.3)	124 (12.9)	0.69	166 (16.7)	170 (18.0)	0.45
From cardiac causes	33 (3.3)	32 (3.2)	0.92	70 (7.1)	77 (8.1)	0.40	97 (10.1)	104 (11.3)	0.38
Not from cardiac causes	6 (0.6)	9 (0.9)	0.41	53 (5.6)	47 (5.2)	0.71	69 (7.4)	65 (7.4)	0.98
Neurologic event									
Any event	64 (6.4)	65 (6.5)	0.94	99 (10.1)	93 (9.7)	0.76	121 (12.7)	103 (11.0)	0.25
Transient ischemic attack	9 (0.9)	4 (0.4)	0.17	23 (2.4)	16 (1.8)	0.38	34 (3.7)	20 (2.3)	0.09
Any stroke	55 (5.5)	61 (6.1)	0.57	78 (8.0)	79 (8.1)	0.88	91 (9.5)	85 (8.9)	0.67
Disabling stroke	32 (3.2)	43 (4.3)	0.20	49 (5.0)	56 (5.8)	0.46	59 (6.2)	61 (6.4)	0.83
Nondisabling stroke	23 (2.3)	18 (1.8)	0.43	30 (3.0)	24 (2.5)	0.44	33 (3.4)	27 (2.9)	0.51
Rehospitalization	64 (6.5)	62 (6.5)	0.99	142 (14.8)	135 (14.7)	0.92	183 (19.6)	156 (17.3)	0.22
Death from any cause or rehospitalization	99 (9.8)	101 (10.2)	0.78	234 (23.4)	225 (23.3)	0.97	303 (30.5)	281 (29.6)	0.67
Death from any cause, any stroke, or rehospitalization	140 (13.9)	153 (15.3)	0.37	274 (27.4)	276 (28.3)	0.64	344 (34.6)	326 (33.9)	0.75
Myocardial infarction	12 (1.2)	19 (1.9)	0.22	24 (2.5)	29 (3.0)	0.47	33 (3.6)	37 (4.1)	0.56
Major vascular complication	80 (7.9)	51 (5.0)	0.008	84 (8.4)	54 (5.3)	0.007	86 (8.6)	55 (5.5)	0.006
Life-threatening or disabling bleeding	105 (10.4)	442 (43.4)	<0.001	151 (15.2)	460 (45.5)	<0.001	169 (17.3)	471 (47.0)	<0.001
Acute kidney injury	13 (1.3)	31 (3.1)	0.006	32 (3.4)	48 (5.0)	0.07	36 (3.8)	57 (6.2)	0.02
New atrial fibrillation	91 (9.1)	265 (26.4)	<0.001	100 (10.1)	272 (27.2)	<0.001	110 (11.3)	273 (27.3)	<0.001
New permanent pacemaker	85 (8.5)	68 (6.9)	0.17	98 (9.9)	85 (8.9)	0.43	114 (11.8)	96 (10.3)	0.29
Endocarditis	0	0	—	7 (0.8)	6 (0.7)	0.84	11 (1.2)	6 (0.7)	0.22
Aortic-valve reintervention	4 (0.4)	0	0.05	11 (1.2)	4 (0.5)	0.10	13 (1.4)	5 (0.6)	0.09
Coronary obstruction	4 (0.4)	6 (0.6)	0.53	4 (0.4)	6 (0.6)	0.53	4 (0.4)	6 (0.6)	0.53

* All percentages are Kaplan-Meier estimates at the specific time point and thus do not equal the number of patients divided by the total number of patients in the treatment group. P values are for point-in-time comparisons.

エコー所見

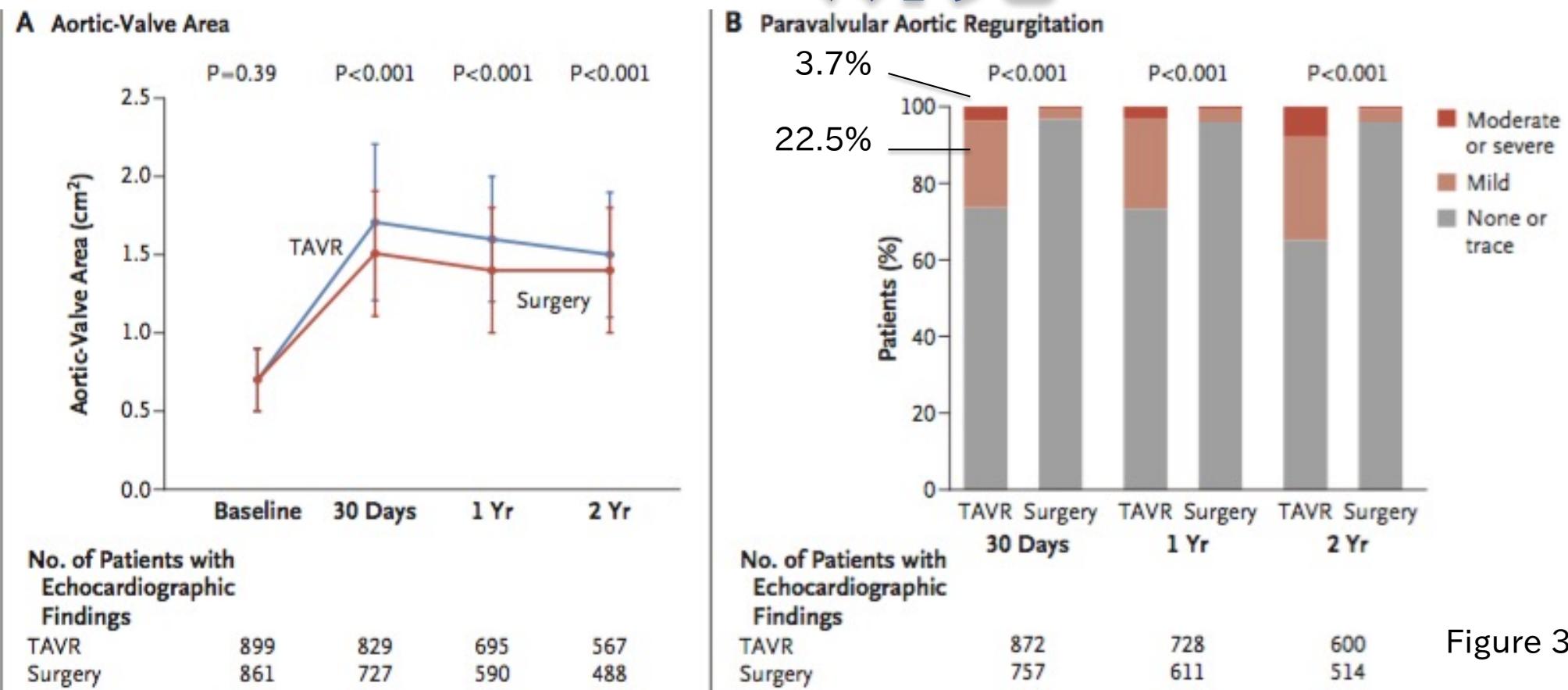


Figure 3

大動脈弁面積・EF・圧格差：有意に改善
弁周囲逆流：有意に増加

C Death from Any Cause, According to Severity of Paravalvular Aortic Regurgitation

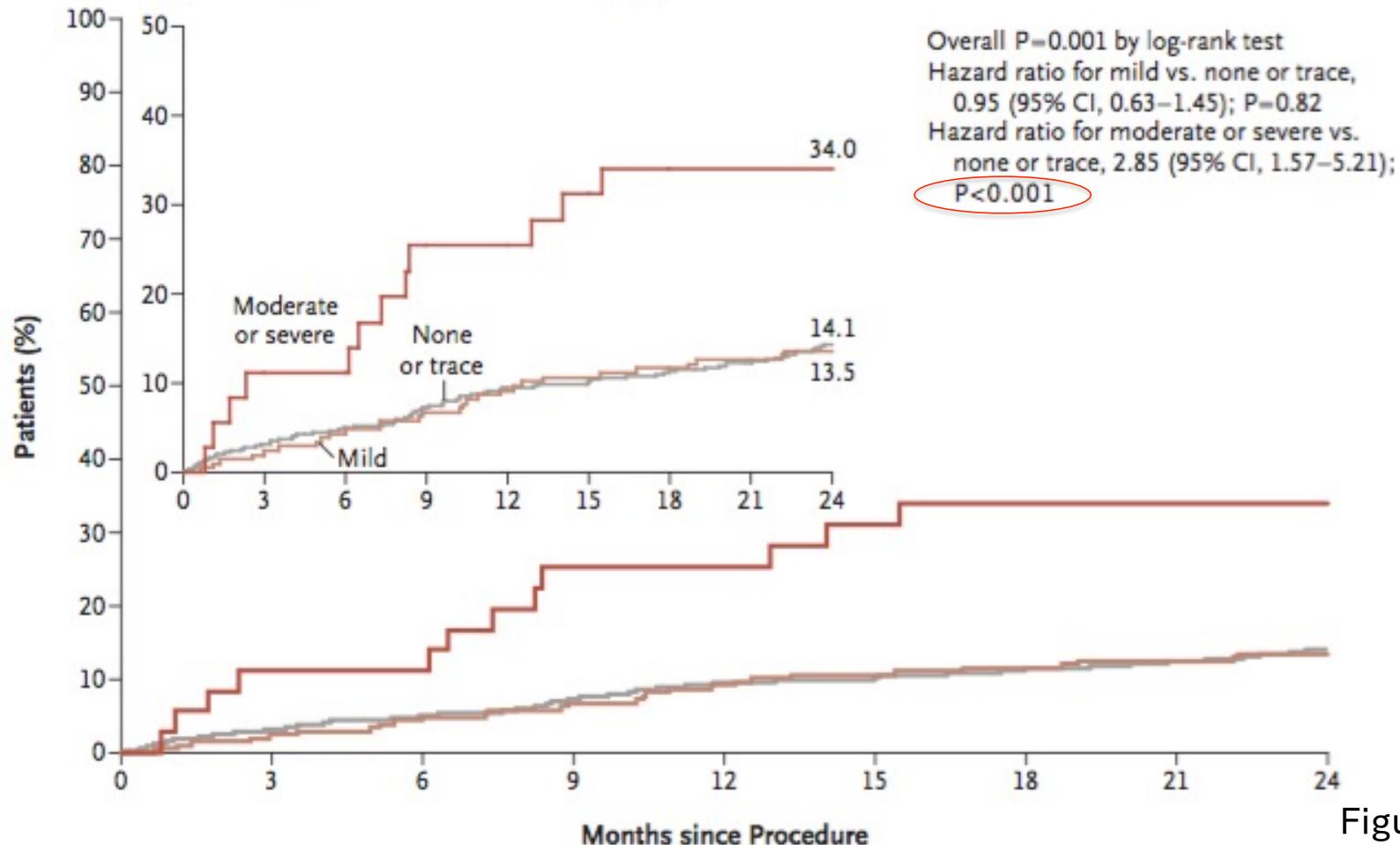


Figure 3

No. at Risk

	0	3	6	9	12	15	18	21	24
None or trace	701	678	664	647	628	621	612	605	585
Mild	210	204	199	194	188	184	182	180	175
Moderate or severe	36	32	32	26	26	24	22	22	21

Moderate or severe ARで
有意に死亡率が高い

まとめ

- 手術中リスク群の2年成績は同等
- 弁面積・圧格差で勝るが、逆流が多い
- 出血・AKI・新規Afの出現は少ない
- 経大腿アプローチが持つ可能性

Limitations

- withdrawalsが多かった
- デバイスが最新ではない
- 大動脈弁輪の評価にCTを用いていない
- 長期成績が不明

結論

全死亡と disabling stroke
は手術とTAVRで同等

2年間の成績 手術リスクが中程度のAS

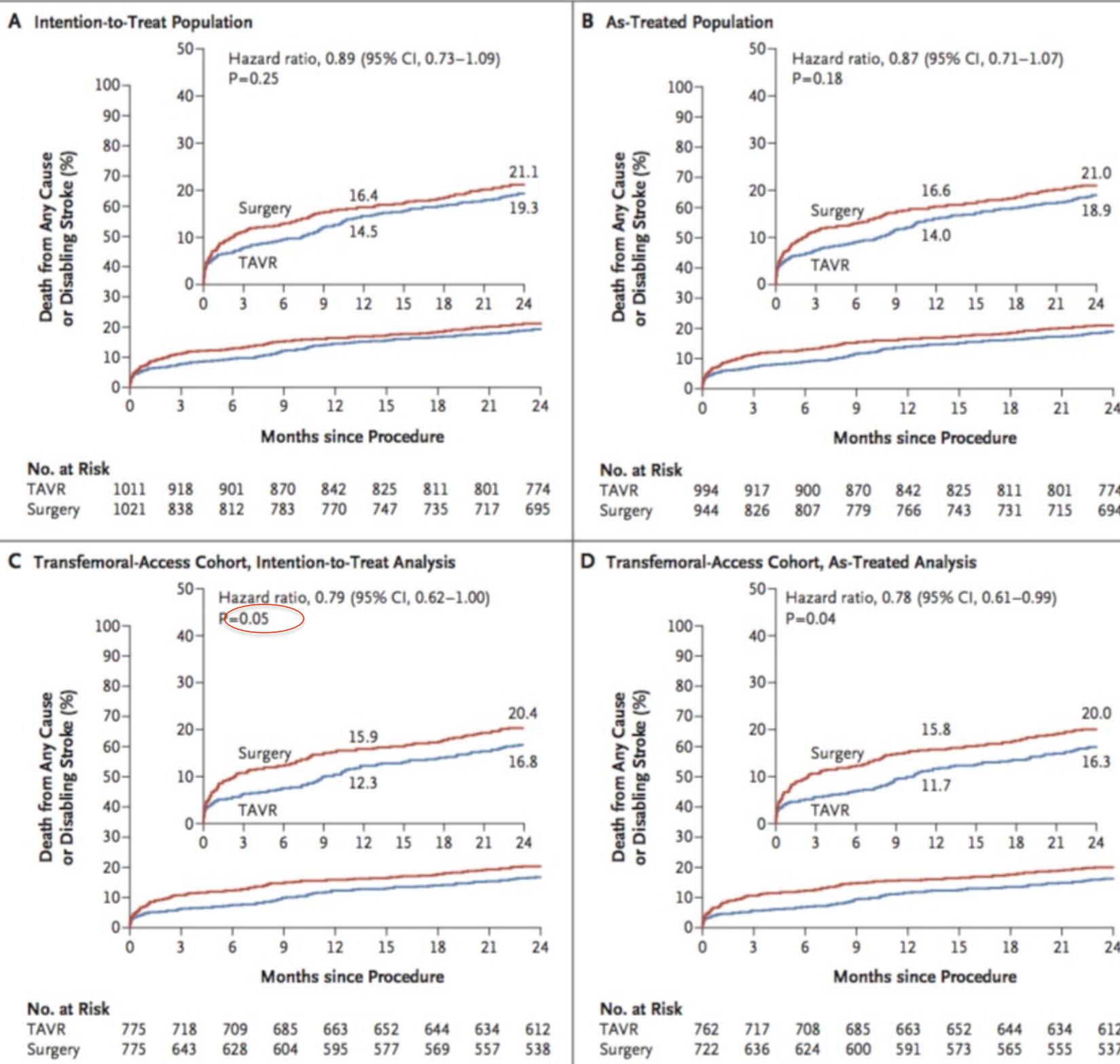


Figure 1

補足

P : 手術中程度リスクのAS

I : SAPIEN3によるTAVR

C : 外科的手術

O : 1年の観察期間において

全死亡・stroke発生・re-intervention・

AR

Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis

Thourani VH¹, Kodali S², Makkar RR³, et al.

Lancet. 2016 Apr 1. pii: S0140-6736(16)30073-3