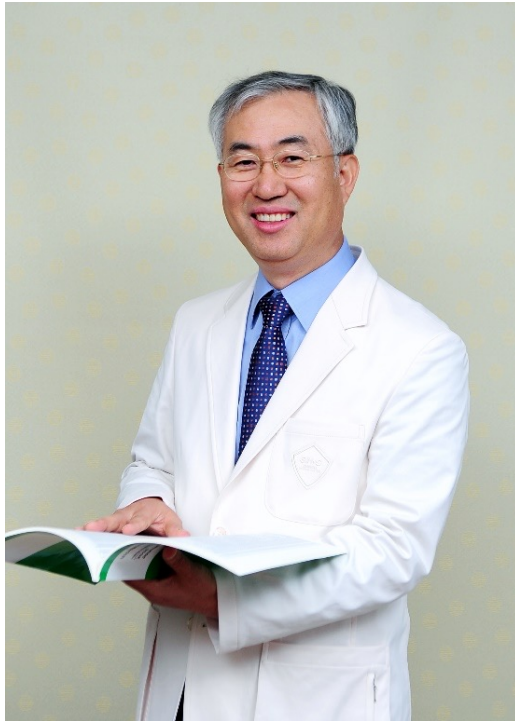


# Primary closure vs. Patch angioplasty in carotid endarterectomy



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- **Congress President, 2015 Seoul UIP.**

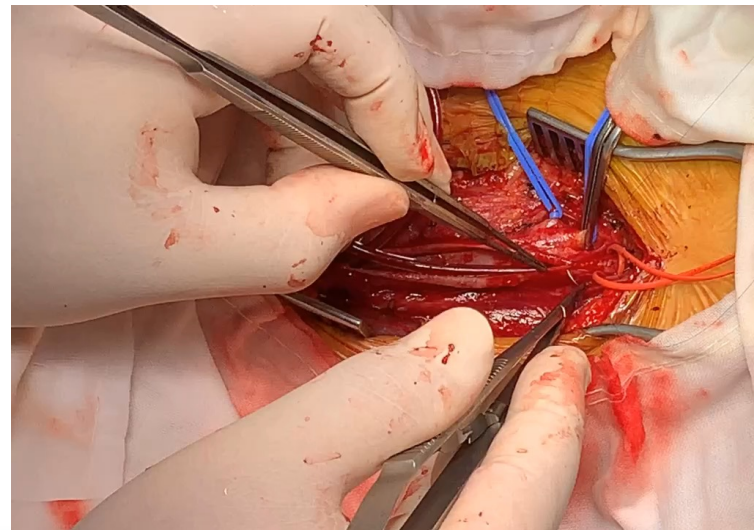
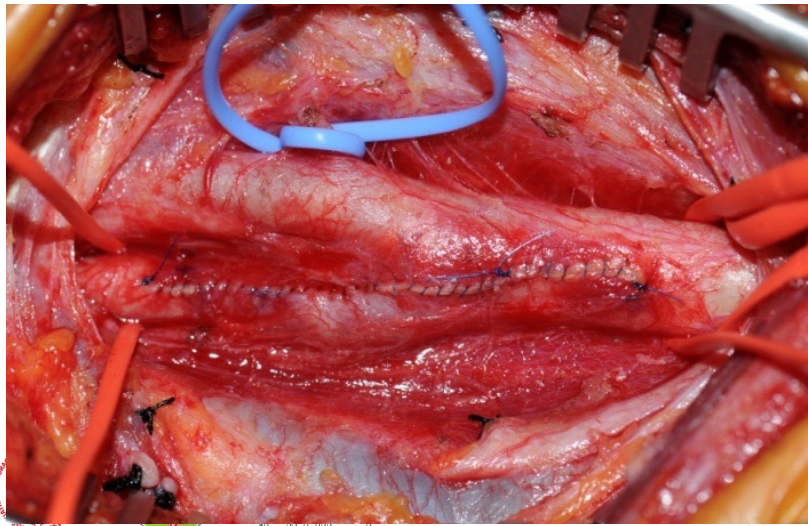
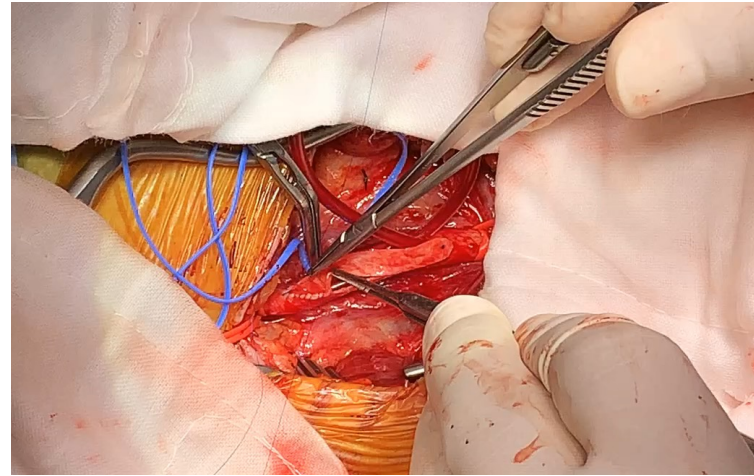
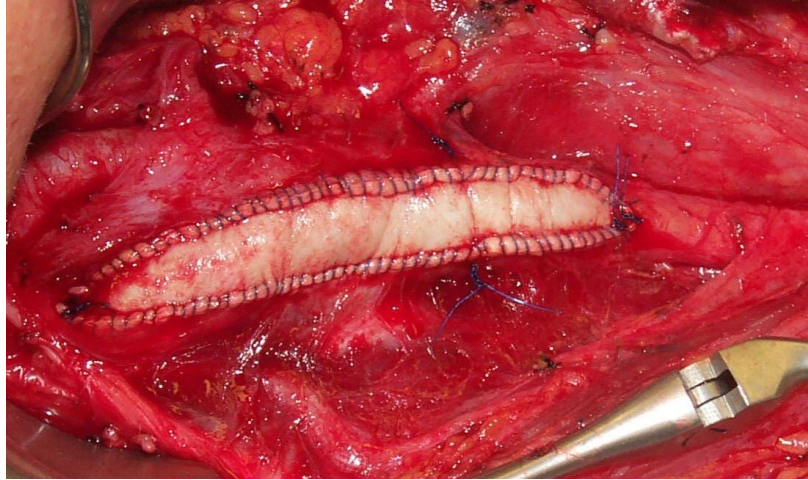



## Controversies in carotid endarterectomy

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- Indications for surgery
- Perioperative medication
- General vs. regional anesthesia
- Surgery vs. stent
- Shunt vs no. shunt
- Stent vs no. stent
- **Primary closure vs. patch angioplasty**
- Standard vs. eversion
- Intraoperative neurological monitoring vs. no

# How to close the arteriotomy in CEA





## Review of articles : Patch angioplasty vs. Primary closure

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- **Patch angioplasty** can reduce the risk of perioperative stroke or re-stenosis and subsequent ischemic stroke
- **Primary closure** is not inferior to patch angioplasty

# Patch angioplasty preferred article : CREST study

- Brott et al. (Mayo clinic) Stroke 2015; 46:757
- Patch closure is associated with reduction in restenosis, though it is not associated with improved clinical outcomes.

Two-year restenosis rates after CEA with patch versus no patch

	Patch # events (rate ± SEM)	No Patch # events (rate ± SEM)	Hazard Ratio for Patch vs No Patch (95% CI) *	P-value	Hazard Ratio (95% CI) †	P- value
<b>Restenosis</b>	20 (3.1±0.7)	32 (10.7±1.8)	0.27 (0.15,0.48)	<0.0001	0.35 (0.16,0.74)	0.006

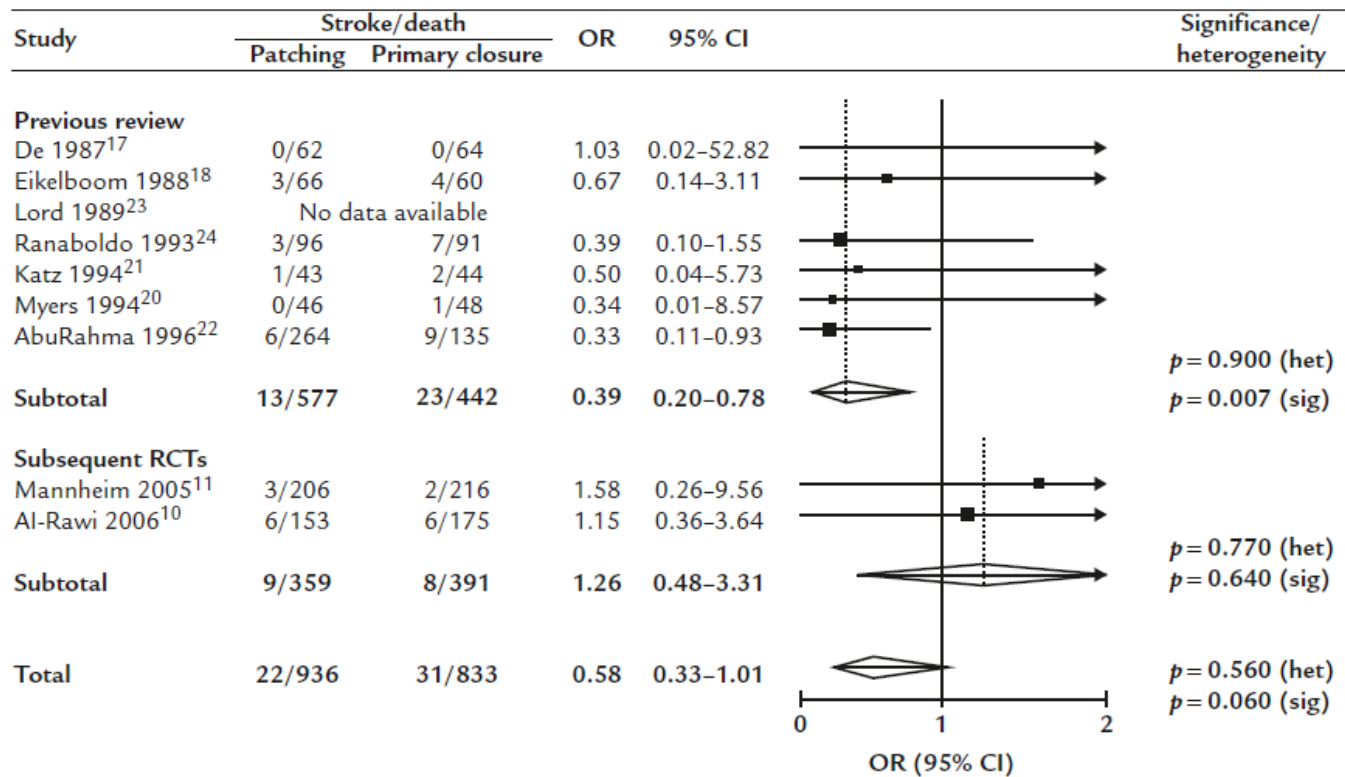
\* adjusted for symptomatic status

† adjusted for symptomatic status and surgeon board specialty

46 patients (13 no patch; 33 patch) are not included in the restenosis endpoint as they did not have ultrasounds read by the u patch) did not have information on board specialty.

# Patch angioplasty preferred article : Cochran Review 2009

- Review of prospective randomized trials (1,967 patients)
- Meta-analysis suggests that **patch angioplasty reduces the combined perioperative and long-term risk of stroke and the risk of restenosis.**



# CEA patch not always needed : J Vasc Surg 2016;64:678

- Avgerinos et al. (Univ. Pittsburgh) J Vasc Surg 2016;64:678 .
- **1,737 CEA patients** (mean FU : 49.8 month)
- Primary closure ( 412 - 23.7%), Patch (873 - 50.3%), Eversion (452 – 26.0%)
- **Baseline risk factors and statin use, but not the type of closure, affect perioperative and long-term outcomes after CEA.**

**Table II.** Perioperative outcomes stratified by carotid endarterectomy (CEA) technique

	PRC	PAC	EVC	P value
Nerve injury	7 (2.0)	20 (2.7)	11 (3.2)	.620
Reintervention for bleeding	6 (1.5)	14 (1.6)	5 (1.2)	.812
MI	2 (0.5)	16 (1.8)	8 (1.8)	.153
Stroke	9 (2.2)	14 (1.6)	9 (2.0)	.742
Death	2 (0.5)	7 (0.8)	4 (0.9)	.767
Combined stroke/death	11 (2.7)	19 (2.2)	13 (2.9)	.709
Combined MI/stroke/death	11 (2.7)	31 (3.6)	19 (4.2)	.471

EVC, Eversion closure; MI, myocardial infarction; PAC, patch closure; PRC, primary closure.  
Data are presented as number (%).

**Table III.** Long-term stroke (including the postoperative ones) and restenosis rates after carotid endarterectomy (CEA) stratified by CEA technique

	PRC	PAC	EVC	P value
Five-year any stroke	5.3 ± 1.2 (n = 158)	8.8 ± 1.2 (n = 283)	5.7 ± 1.2 (n = 122)	.407
Ten-year any stroke	15.0 ± 4.0 (n = 33)	16.9 ± 2.8 (n = 40)	10.5 ± 2.7 (n = 7)	.407
Five-year ipsilateral stroke	3.4 ± 1.0 (n = 158)	4.5 ± 0.8 (n = 292)	3.4 ± 0.9 (n = 123)	.750
Ten-year ipsilateral stroke	8.0 ± 3.0 (n = 33)	8.5 ± 2.2 (n = 40)	6.8 ± 2.2 (n = 7)	.750
Five-year restenosis 50%	13.4 ± 2.4 (n = 73)	15.4 ± 2.1 (n = 120)	18.5 ± 3.0 <sup>b</sup> (n = 52)	.124
Five-year restenosis 70%	4.8 ± 1.4 (n = 76)	6.3 ± 1.4 (n = 124)	8.4 ± 2.0 (n = 56)	.122
Ten-year restenosis 50%	23.6 ± 5.8 (n = 8)	24.3 ± 5.8 (n = 8)	40.7 ± 8.6 <sup>b</sup> (n = 1)	.124
Ten-year restenosis 70%	6.7 ± 2.3 (n = 8)	11.9 ± 4.2 (n = 8)	11.2 ± 3.4 (n = 2)	.122
Symptomatic restenosis	4/34 (11.8%)	9/63 (14.3%)	7/49 (14.3%)	.932
Follow-up, months, mean ± SD	53.616 ± 41.902	51.215 ± 36.178	43.435 ± 30.137 <sup>a,b</sup>	
Reintervention	9/34 (26.5%)	12/63 (19.0%)	16/49 (32.7%)	.256

EVC, Eversion closure; PAC, patch closure; PRC, primary closure; SD, standard deviation.  
Data are presented as percentage ± standard error (number at risk) unless otherwise indicated.  
<sup>a</sup>Indicates P < .05 compared with the PRC group.  
<sup>b</sup>Indicates P < .05 compared with the PAC group.

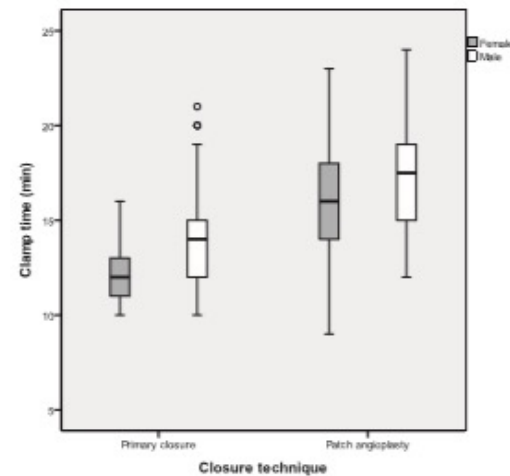


# CEA patch not always needed : Ann Vasc Surg 2016; 30 : 248

- Maertens et al. (Sint-Lucas Hosp. Belgium). Ann Vasc Surg 2016; 30 : 248
- **Primary closure appears to be an equivalent closure technique compared with patch angioplasty when used in selected patients.**

**Table I.** Complication rate comparing primary closure and patch angioplasty closure technique

Complication type	Closure technique		P value
	Primary closure, n (%)	Patch angioplasty, n (%)	
No complications	106	98	
Total complications	4 (3.6)	5 (4.9)	0.68
Bleeding	2 (1.8)	1 (1.0)	0.24
Cerebrovascular event	0	1 (1.0)	1.00
Infection	0	0	—
Acute myocardial infarction	0	0	—
Nerve damage	2 (1.8)	2 (1.9)	1.00
Hyperperfusion and mortality	0	1 (1.0)	1.00



**Fig. 1.** Box plot illustrating a significant difference in clamp time (min) during patch angioplasty and primary closure ( $P < 0.001$ ).



# Why ?


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- **Why are there so many differences in their conclusions?**
- **What is the problem of randomized control trials**



# Randomized Control Trial



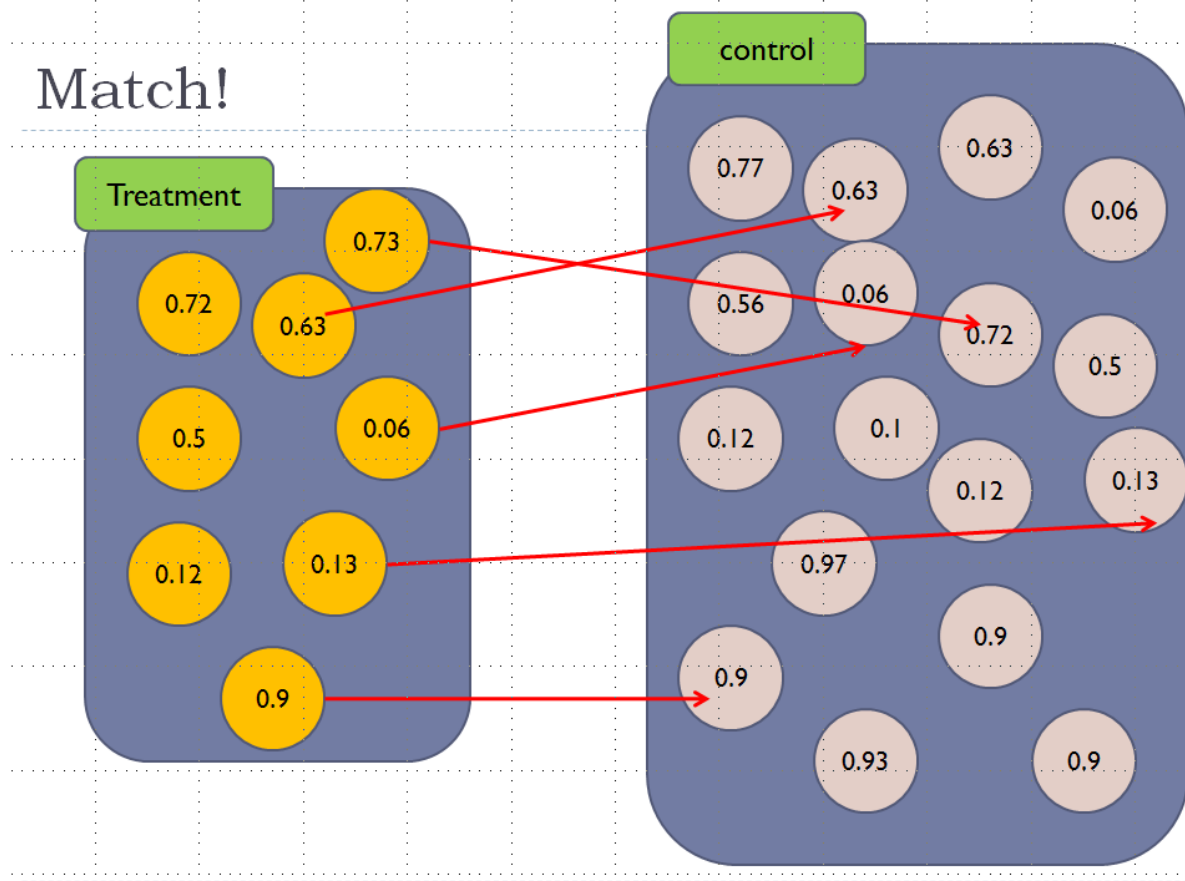
  
**(Group 1)**

  
**(Group 2)**

  
**(Group 3)**

  
**(Group 4)**

# Propensity Matching analysis



# Propensity Score Matching

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- first published by Paul Rosenbaum & Donald Rubin in 1983
- **balance the covariates and mimic randomization**
- **to reduce the bias due to confounding variables** that could be found in an estimate of the treatment effect obtained from simply comparing outcomes among units between control and treated group



## Methods

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- **Retrospective review**
- **Inclusion : 1,383 CEAs**
  - Primary closure (PC): n=608(44%)**
  - Patch angioplasty (PA): n=775(56%)**
- **Exclusion : 200 patients**
  - 1) Concomitant CEA and CABG**
  - 2) Iatrogenic ICA injury**
  - 3) Previous stent insertion**



# Endpoints



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- **Restenosis rate**
- **Perioperative complication**
- **Stenosis free survival**
- **Stroke free survival**
- **Overall survival**



## Details of CEA Procedure

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- **Patient selection** of PC and PA depended on the surgeon's preference
- All CEAs were performed under the **general anesthesia** and **routine carotid shunt** (Pruit-Inahara<sup>®</sup> carotid shunt, LeMaitre Vascular, Inc.)
- **Bovine pericardial patch** for patch angioplasty
- **Postoperative medication** : anti-platelet agent (aspirin, clopidogrel, pletal) or anticoagulation agent (warfarin) was routinely prescribed.





## Methods : FU

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- **Duplex ultrasonography** : to determine restenosis or occlusion (1, 6, 12, 24 month FU)
- **Restenosis** was defined as stenosis  $> 50\%$  or PSV  $> 300\text{cm/sec}$  on DUS
- When significant restenosis was detected, its severity was reconfirmed with CT angiography(CTA).

# Baseline characteristics : pre-matching

Variable	Total (n=1383)	PC (n=608, 44%)	PA(patch) (n=775, 56%)	P
Age ≤60	208 (15)	98 (16.1)	110 (14.2)	0.272
60 < Age ≤70	581 (42)	263 (43.3)	318 (41)	
70 < Age	594 (43)	247 (40.6)	347 (44.8)	
Gender (Male)	1191 (86.1)	532 (87.5)	659 (85)	0.188
Hypertension	1079 (78)	479 (78.8)	600 (77.4)	0.543
Diabetes	570 (41.2)	250 (41.1)	320 (41.3)	0.949
<b>Dyslipidemia</b>	1049 (75.8)	445 (73.2)	604 (77.9)	<b>0.041</b>
Atrial_fibrillation	77 (5.6)	28 (4.6)	49 (6.3)	0.167
<b>Previous PCI or CABG</b>	369 (26.7)	134 (22)	235 (30.3)	<b>0.001</b>
Smoking	664 (48.7)	297 (48.8)	367 (47.4)	0.581
Contralateral ICA occlusion	80 (5.8)	32 (5.3)	48 (6.2)	0.462
<b>Stenosis degree (≥70%)</b>	1186 (85.8)	502 (82.6)	684 (88.3)	<b>0.003</b>
<b>Symptomatic status</b>	470 (34)	184 (30.3)	286 (36.9)	<b>0.010</b>
TIA	184 (39.1)	82 (44.6)	102 (35.7)	
Amaurosis fugax	42 (8.9)	10 (5.4)	32 (11.2)	
Stroke	244 (51.9)	92 (50)	152 (53.1)	

## Baseline characteristics : post matching

Variable	Total (n=1144)	PC (n=572, 50%)	PA(patch) (n=572, 50%)	P
Age ≤60	180 (15.7)	91 (15.9)	89 (15.6)	0.834
60 < Age ≤70	486 (42.5)	247 (43.2)	239 (41.8)	
70 < Age	478 (41.8)	234 (40.9)	244 (42.7)	
Gender (Male)	992 (86.7)	503 (87.9)	489 (85.5)	0.223
Hypertension	894 (78.1)	454 (79.4)	440 (76.9)	0.317
Diabetes	449 (39.2)	235 (41.1)	214 (37.4)	0.204
<b>Dyslipidemia</b>	862 (75.3)	431 (75.3)	431 (75.3)	<b>1.000</b>
Atrial_fibrillation	59 (5.2)	28 (4.9)	31 (5.4)	0.688
<b>Previous PCI or CABG</b>	247 (21.6)	134 (23.4)	113 (19.8)	<b>0.131</b>
Smoking	560 (49)	280 (49)	280 (49)	1.000
Contralateral ICA occlusion	60 (5.2)	29 (5.1)	31 (5.4)	0.791
<b>Stenosis degree (≥70%)</b>	1003 (87.7)	491 (85.8)	512 (89.5)	<b>0.059</b>
<b>Symptomatic status</b>	368 (32.2)	184 (32.2)	184 (32.2)	<b>1.000</b>
TIA	143 (38.9)	82 (44.6)	61 (33.1)	
Amaurosis fugax	32 (8.7)	10 (5.4)	22 (12)	
Stroke	193 (52.4)	92 (50)	101 (54.9)	

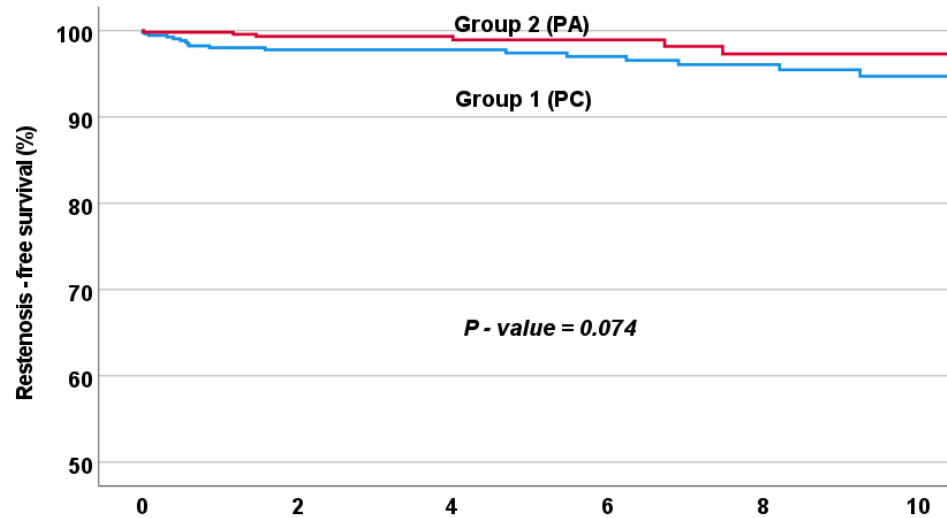
## Early Postoperative Outcomes (< 30 days)

Variable	Total (n=1144)	PC (n=572, 50%)	PA (patch) (n=572, 50%)	P-value
Ipsilateral stroke	11 (1.0)	3 (0.5)	8 (1.4)	0.130
Any stroke	12 (1.0)	4 (0.7)	8 (1.4)	0.246
CN palsy*	44 (3.8)	23 (4.0)	21 (3.7)	0.758
Bleeding requiring re-operation	8 (0.7)	1 (0.2)	7 (1.2)	0.069

\* Hypoglossal nerve, gloss pharyngeal nerve, CN 5,7, vocal cord palsy

\* Permanent CN palsy : n=6

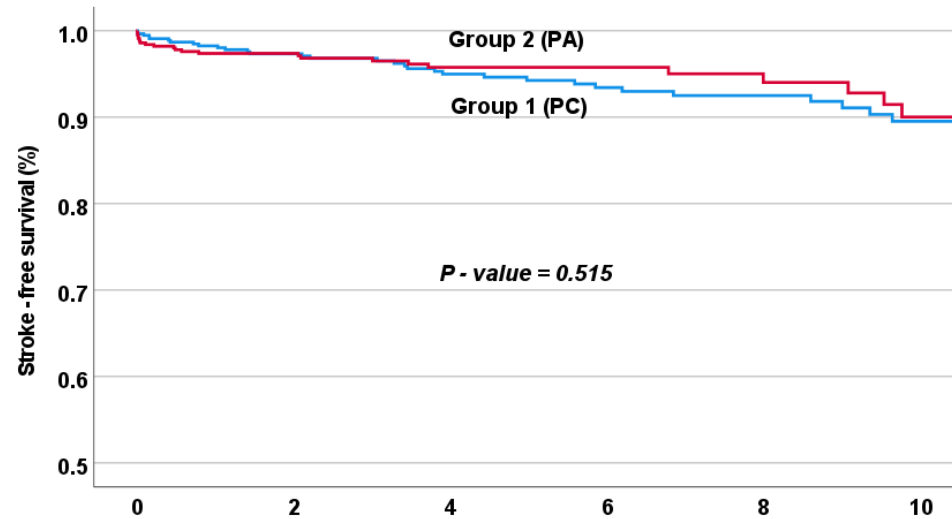
# Restenosis free survival



No.at risk	0	2	4	6	8	10	
	6mo	1yr	2yr	4yr	6yr	8yr	10yr
PC	429	372	301	207	155	107	71
PA	391	343	263	147	93	54	35

- *Median follow up :*
  - PC group, 4.3 years (range, 0 - 26.9 years)
  - PA group, 3.4 years (range, 0 - 22.6 years)

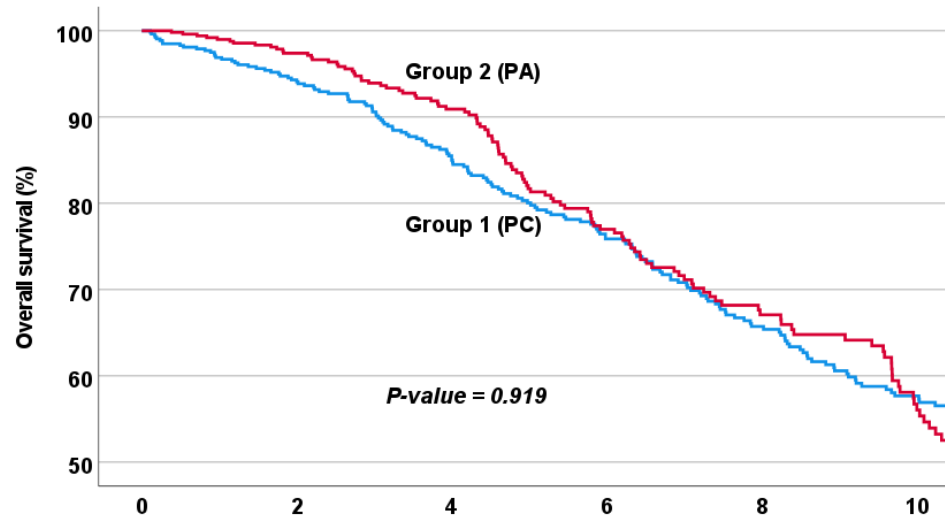
# Stroke free survival



No.at risk	0	2	4	6	8	10	
	6mo	1yr	2yr	4yr	6yr	8yr	10yr
PC	488	450	383	289	220	160	108
PA	479	440	363	235	154	94	59

- Median follow up :
  - PC group, 4.3 years (range, 0 - 26.9 years)
  - PA group, 3.4 years (range, 0 - 22.6 years)

# Overall survival



No.at risk	0	2	4	6	8	10
PC	508	477	424	337	267	154
PA	508	477	403	281	186	82

- *Median follow up :*
  - *PC group, 4.3 years (range, 0 - 26.9 years)*
  - *PA group, 3.4 years (range, 0 - 22.6 years)*



# Articles (Dr. DI KIM)



Eur J Vasc Endovasc Surg (2017) 54, 573–578

## Editor's Choice — Comparison of Early Outcomes and Restenosis Rate Between Carotid Endarterectomy and Carotid Artery Stenting Using Propensity Score Matching Analysis

J Korean Surg Soc 2010;78:314-319

DOI: 10.4174/jkss.2010.78.5.314

## Comparison of Outcomes between Primary Closure vs. Patch Angioplasty in Carotid Endarterectomy

Surg Today (2007) 37:187–191

DOI 10.1007/s00595-006-3385-4

## Primary Closure After a Carotid Endarterectomy

DONG-IK KIM<sup>1</sup>, JI-YOUNG MOON<sup>1</sup>, CHUL-HYUNG LEE<sup>1</sup>, DO-YOOL KIM<sup>1</sup>, YOUNG-SAM JANG<sup>1</sup>, GYEONG-MOON KIM<sup>2</sup>, CHIN-SANG CHUNG<sup>2</sup>, KWANG-HO LEE, and SEON-WOO KIM<sup>3</sup>







## Conclusions

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- **There was no significant differences in postoperative clinical outcomes between primary closure and patch angioplasty.**
- **Our clinical data suggested that primary closure deserves more recommendable for experienced vascular surgeon rather than patch angioplasty .**

**Thank you for your attention**

