Karotis Girişimlerinde Embolik Koruma Cihazları

Hangisi daha yararlıdır?

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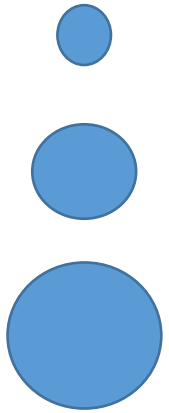
Partikül, mikroemboli, makroemboli,, olay...

- ***Gerek CAS gerekse tüm perkütan girişimlerde mikroemboli vardır.***
- **Nörovasküler sahadaki işlemlerde embolizasyon çok daha barizdir.**

- Jordan ve ark.; TCD çalışması; CEA / CAS karşılaştırılmış
  - Tüm grupta hasta başına emboli sayıları;
    - CEA grubunda; 8.8 emboli
    - CAS grubunda; 74 emboli
    - Olay + olanlarda 85 emboli
    - Olay – olanlarda 59 emboli
- Jeager ve ark; DW-MR çalışması
  - Korumasız CAS yapılan 67 hasta;
  - %29 hastada ipsilateral yeni iskemik odak +
- Gaunt ve ark; TCD ile kognisyon....
  - CEA hastalarının %92' sinde mikroemboli +
  - Hasta başına >10 emboli postoperatif kognitif bozuklukla ilişkilidir.



0-100 mikron Mikroemboli

100-200 mikron Makroemboli

>200 mikron partikül

muhtemel klinik olay

- Gaunt ME , Martin PJ , et al . Clinical relevance of intraoperative embolization detected by transcranial Doppler ultrasonography during carotid endarterectomy: a prospective study of 100 patients . Br J Surg-1994 .
- Jaeger HJ , Mathias KD , et al . Cerebral ischemia detected with diffusion - weighted MR imaging after stent implantation in the carotid artery . Am J Neuroradiol-2002
- Jordan WD , Voellinger DC , et al . Microemboli detected by transcranial Doppler monitoring in patients during carotid angioplasty versus carotid endarterectomy . Cardiovasc Surg-1999

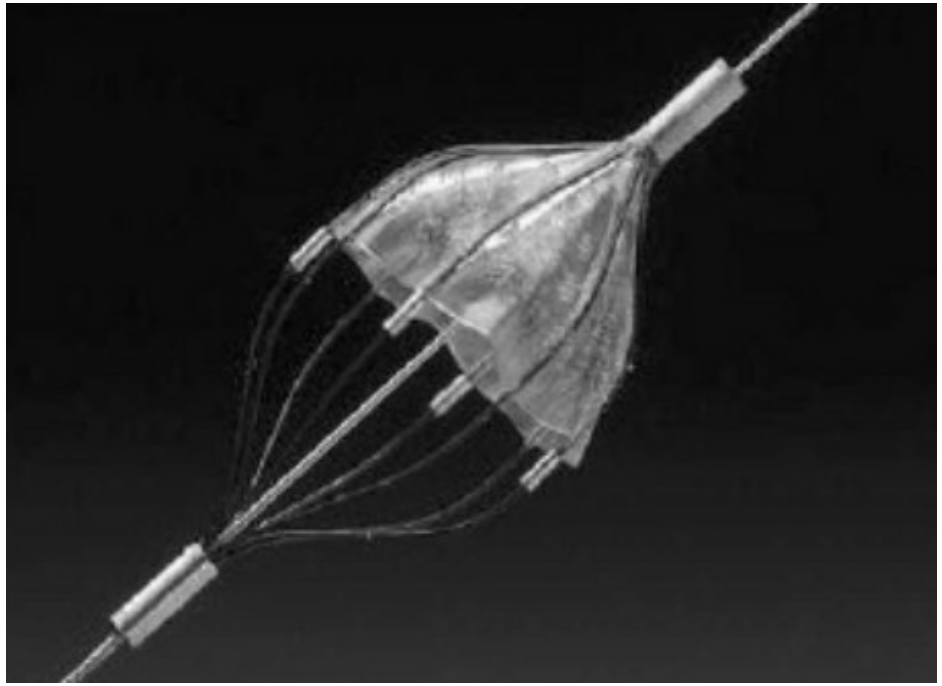
Karotis girişimlerinde hedef;

- Asemptomatik hastada
  - Semptomatik hale gelmesini engellemek
- Semptomatik hastada
  - Olay tekrarını engellemek

- Her iki grupta amaç;
  - Periprosedüral olayların (inme , MI, ölüm) daha az yaşanması
  - Takipte klinik olarak anlamlı olayın engellenmesi
  - Restenozun / yeniden girişim ihtiyacının azaltılması

- İlk karotis anjiyoplasti 1980; Kerber ve ark.
- İlk stent işlemi (CAS) 1994; Yadav ve ark. (ABD)
- İlk önemli RCT 2001;
  - CAVATAS Study; cerrrahi için yüksek riskli 500 hasta... CAS / CEA
  - 250 CAS hastasının 55 inde stent +,
  - EPD kullanılmamış
- İlk modern embolik koruma cihazları (EKC); 1996-2000; ABD
  - Roubin ve ark. 1994-2002 arası 1200 hasta; (%33' ünde EKC +)
  - En yüksek inme insidansı 96-97 arasında %9.1 ; (EKC başlamış)
  - En düşük oranlar 2002 de %0.6 (daha sık EKC kullanımı)
- İlk CAS+EKV içeren RCT 2002; Yadav ve ark.

CAS + EKC vs. CEA



- Yadav ve ark.; 334h; RCT, 1 yıl prospektif,
  - 1-30 gün MI, inme, ölüm.
  - 31. gün – 1 yıl; ipsilateral inme, ölüm.
- PEP
  - CAS grubunda 20h. (%12.2)
  - CEA grubunda 32h. (%20.1)
  - P=0.053 (noninferiority +)
  - EKC: Tüm hastalarda;
    - Angioguard, Angioguard XP

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 7, 2004 VOL. 351 NO. 15

Protected Carotid-Artery Stenting versus Endarterectomy in High-Risk Patients

Jay S. Yadav, M.D., Mark H. Wholey, M.D., Richard E. Kuntz, M.D., M.Sc., Pierre Fayad, M.D., Barry T. Katzen, M.D., Gregory J. Mishkel, M.D., Tanvir K. Bajwa, M.D., Patrick Whitlow, M.D., Neil E. Strickman, M.D., Michael R. Jaff, D.O., Jeffrey J. Popma, M.D., David B. Snead, Ph.D., Donald E. Cutlip, M.D., Brian G. Firth, M.D., Ph.D., and Kenneth Ouriel, M.D., for the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy Investigators*

- MEDICARE 2005;
  - CAS işlemlerinin faturlandırılmasında proximal / distal koruma cihazı şartı...
  - Eğer cihaz yerleştirilmez ise prosedür iptal edilmeli / ertelenmeli....

- EVA-3S
  - 527 hasta CAS / CEA ; %9.6 / %3.9, p= 0.001
  - EKC grubunda az sayıda hasta
  - 30 günlük sonuçlar... EPD +/-: %7.9 / %25, p<0.001
- SPACE
  - 1200 hasta, sadece %27 EKC kullanımı var.
  - 30 günlük ipsilateral inme / ölüm
  - CAS / CEA %6.35 / %6.8 (p=0.09)
  - EKC + / -; %6.5 / 8.3

- ICSS
  - Semptomatik 1713 hasta
    - CAS grubunda EKC kullanımı %72
  - 120 gün MACCE CAS ile daha yüksek
    - CAS / CEA %8.5 / %5.2
  - DW-MR ile iskemik odak varlığı:
    - CAS / CEA ; %68 / %35
  - EKC kullanan merkezlerin hastalarında lezyon sıklığı daha fazla***

- CREST (2010)
  2522 h, 117 merkez, 4 yıla kadar takip +
  1144 CAS + EKC (%96)
  PEP; CAS grubunda %7.2 / CEA grubunda %6.8; noninferiority +
  İnme(minör) %4.1/ %2.3
  MI %1.1/ %2.3

- Kılavuzlara kadar yayınlanmış EKC +/- karşılaştıran tek RCT;

A randomized trial of carotid artery stenting with and without cerebral protection

- Barboto ve ark; 2008
- 35 hasta; 36 prosedür...
  - RX ACCULINK Carotid Stent
  - RX ACCUNET EKC
- İnme oranı %11
  - toplam 3 minör, 1majör
  - Tek major inme korumasız grupta...

- DW-MRI
  - Defekt görülen hasta sayısı EKC ile fazla --- (istatistiksel olarak anamsız)
  - Defekt büyüklük veya sayısal ortalaması arasında fark yok...

	Cerebral protection	
	Yes (n = 18)	*No (n = 18)*
Non-Q-wave MI	1	0
Hypotension	2	3
Orthostatic hypotension	1	0
Minor stroke	2	1
Major stroke	0	1
Gastrointestinal bleeding	0	1
Bradycardia (asymptomatic)	0	1
Hyperperfusion syndrome	0	1
ICA vasospasm	1	0
Femoral bleed	0	1
Retroperitoneal hematoma	0	1

	Cerebral protection		
Defect	*Yes (n = 18)*	*No (n = 18)*	*P*
Any MRI diffusion defect	13 (72%)	8 (44%)	.09
Any ipsilateral diffusion defect	12 (67%)	7 (39%)	.09
Average No. of defects	6.1	6.2	NS
DW MRI defect size, mean mm^3	16.63	15.61	NS

Meta-analiz....

- Gang ve ark.;2009
- Pubmed ve Cochrane taramaları;
- 1995-2007 arası en az 20 prosedür...
- Distal balon /filtre, proximal balon
- 2485 değerlendirme 134 uygun çalışma
  - 54 EKC +, 52 çalışmada EKC –
  - 24 çalışmada EKC +/- gr. mevcut

- İnme riski***
  - EKC kullanılan çalışmalarda %0 - %7.9
  - EKC kullanılmayanlarda %0 - %20
  - RR 0.62 (95% CI 0.54 - 0.72) (p< 0.05).

TABLE 4
Pooled Analysis for Total Stroke Rate Within 30 Days After Protected and Unprotected Carotid Stenting in 134 Studies*

	With Protection (n=82)		Without Protection (n=76)			
	Procedures	Total Strokes	Procedures	Total Strokes	RR	CI
All patients	12,263	324 (2.6%)	11198	474 (4.2%)	0.62†	0.54 to 0.72
Symptomatic	2427	91 (3.8%)	3149	176 (5.6%)	0.67†	0.52 to 0.86
Asymptomatic	2460	41 (1.7%)	2032	56 (2.8%)	0.61†	0.41 to 0.9

RR: relative risk, CI: confidence interval.
* 24 studies included data on both protected and unprotected CAS. Of all studies, only 67 studies reported outcomes on symptomatic patients (34 with protected and 39 with unprotected stenting), while 56 reported outcomes on asymptomatic patients (28 with protected and 30 with unprotected stenting).
† P<0.05.

Kılavuzlar....

ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/ SCAI/SIR/SNIS/SVM/SVS Guideline

2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/ SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease: Executive Summary

A Report of the American College of Cardiology Foundation/American Heart Association Task

Class IIa

1. **Embolic protection device (EPD) deployment during CAS can be beneficial to reduce the risk of stroke when the risk of vascular injury is low.[66,67] *(Level of Evidence: C)***

Kılavuzlar...

AHA/ASA Guideline

Guidelines for the Prevention of Stroke in Patients With Stroke or Transient Ischemic Attack

A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association

The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists.

The American Association of Neurological Surgeons and Congress of Neurological Surgeons have reviewed this document and affirm its educational content.

- EPD' nin önemi ayrıntılandırılmış...
- Özel bir öneri sınıfı, kanıt derecesi belirtilmemiş...

Kılavuzlar...

European Heart Journal (2011) **32**, 2851–2906
doi:10.1093/eurheartj/ehr211

ESC GUIDELINES

ESC Guidelines on the diagnosis and treatment of peripheral artery diseases

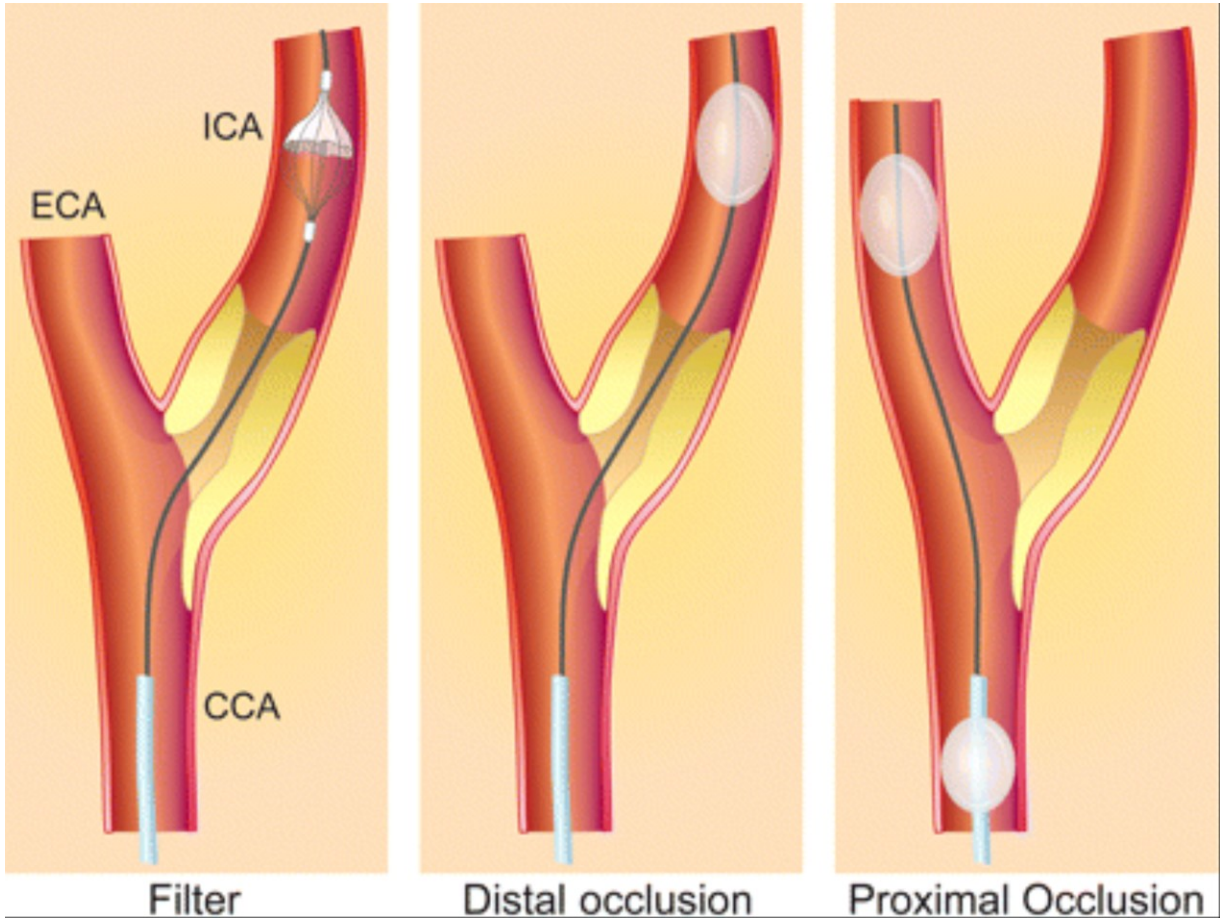
Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries

The Task Force on the Diagnosis and Treatment of Peripher Artery Diseases of the European Society of Cardiology (ESC

Recommendations	Class[a]	Level[b]	Ref[c]
Dual antiplatelet therapy with aspirin and clopidogrel is recommended for patients undergoing CAS.	I	B	67, 68
The use of EPDs may be considered in patients undergoing CAS.	IIb	B	73

EPD çeşitleri

- Proximal
  - Proximal oklüzyon balonları
  - Akım oklüzyon cihazları
  - Akım çevirici cihazlar
- Distal
  - Filtreler
  - Oklüzyon balonları
- Proximal + Distal
  - İki cihazın birlikte kullanımı



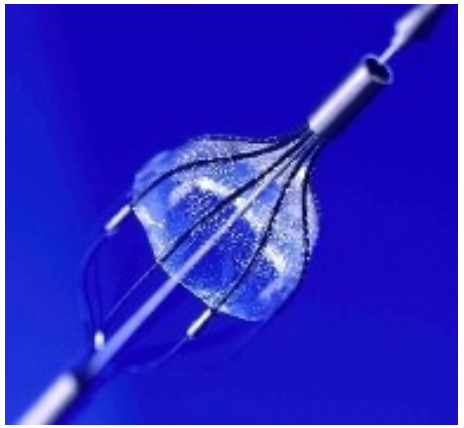
Eur Heart J. 2009;30(22):2693-2704. doi:10.1093/eurheartj/ehp471

Filtreler

- Angioguard
- RX Accunet
- Emboshield
- Emboshield Nav 6
- Spider FX
- FilterWire EZ
- Vb.

Filtreler birbirinden farklı mı?

- Konsantrik / ekzantrik
- Tele sabit / hareketli
- Por genişliği
- Damar çapı uygunluğu
- Elastikiyet
- Profil / geçiş üstünlüğü



Device	Manufacturer	Pore size (µm)	Vessel size (mm)	Fixed wire
Gore Embolic Filter	Gore (Newark, DE, USA)	100	2.5–5.5	Y
Emboshield	Abbott (Chicago, IL, USA)	120	2.5–7	N
Spider	Covidien (Irvine, CA, USA)	50–300	3.0–7.0	N
Accunet	Abbott	125	3.2–5	Y
FilterWire EZ	Boston Scientific (Natick, MA, USA)	110	3.5–5.5	Y
FiberNet	Medtronic (Minneapolis, MN, USA)	>40	3.5–7	Y
Angioguard	Cordis (Bridgewater, NJ, USA)	100	4.5–7.5	Y

Abbreviations: N, no; Y, yes.

Device	Manufacturer	Pore size (µm)	Vessel size (mm)	Fixed wire
Gore Embolic Filter	Gore (Newark, DE, USA)	100	2.5–5.5	Y
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Spider	Covidien (Irvine, CA, USA)	50–300	3.0–7.0	N
Accunet	Abbott	125	3.2–5	Y
FilterWire EZ	Boston Scientific (Natick, MA, USA)	110	3.5–5.5	Y
FiberNet	Medtronic (Minneapolis, MN, USA)	>40	3.5–7	Y
Angioguard	Cordis (Bridgewater, NJ, USA)	100	4.5–7.5	Y

Abbreviations: N, no; Y, yes.

- Konsantrik mi ekzantrik mi?
  - 2 çalışma ; 2 farklı sonuç mevcut.
    - 1 çalışmada ekzantrik cihazlar lehine...
    - Ekzantrik cihazlarla daha stabil bir yerleşim sağlanması mümkün olabilir***
- Por genişliği;
  - En düşük por genişliği FiberNet (Medtronic) ile...
  - En büyük por genişliği Emboshield (Abbott) ve SpiderFx (Covidien) ile
- Yakalanan materyal miktarı önemli mi ?
  - Yakalanan materyal miktarı ile iskemik olaylar / emboli sayısı ilişkili değildir.
  - Yakalanabilen miktar daha önemli

Düz arter modelinde filtre başarıları

Table 34.1 Straight Artery Model

	AngioGuard	FilterWire EZ	AccuNet	Emboshield	SpideRX
250µm					
Injected particle	1.49 ± 0.03	1.51 ± 0.03	1.50 ± 0.03	1.50 ± 0.04	1.49 ± 0.03
Capture weight	1.25 ± 0.05 (83.8%)	1.29 ± 0.06 (85.4%)	1.24 ± 0.07 (82.6%)	0.89 ± 0.09 (59.3%)	1.00 ± 0.08 (66.9%)
Missed particle weight	0.24 ± 0.03 (16.2%)	0.22 ± 0.03 (14.6%)	0.26 ± 0.06 (17.4%)	0.61 ± 0.12 (40.7%)	0.49 ± 0.10 (33.1%)
425µm					
Injected particle	1.50 ± 0.03	1.51 ± 0.04	1.51 ± 0.03	1.51 ± 0.04	1.49 ± 0.02
Capture weight	1.44 ± 0.06 (95.7%)	1.43 ± 0.06 (94.3%)	1.46 ± 0.06 (96.4%)	1.09 ± 0.07 (72.4%)	1.17 ± 0.04 (78.5%)
Missed particle weight	0.06 ± 0.03 (4.3%)	0.08 ± 0.04 (5.7%)	0.05 ± 0.04 (3.6%)	0.42 ± 0.06 (27.6%)	0.32 ± 0.06 (21.5%)

Hafif tortüyoz arter modelinde filtre başarıları

Table 34.2 Slightly Tortuous Artery Model

	AngioGuard	FilterWire EZ	AccuNet	Emboshield	SpideRX
250 µm					
Injected particle	1.50 ± 0.03	1.52 ± 0.02	1.50 ± 0.03	1.50 ± 0.02	1.52 ± 0.02
Capture weight	1.18 ± 0.06 (79.0%)	1.10 ± 0.05 (72.5%)	1.07 ± 0.05 (71.2%)	0.75 ± 0.07 (49.7%)	0.87 ± 0.09 (57.3%)
Missed particle weight	0.32 ± 0.04 (21.0%)	0.42 ± 0.06 (27.5%)	0.43 ± 0.05 (28.8%)	0.75 ± 0.07 (50.3%)	0.65 ± 0.10 (42.7%)
425 µm					
Injected particle	1.50 ± 0.04	1.51 ± 0.03	1.52 ± 0.03	1.53 ± 0.02	1.52 ± 0.03
Capture weight	1.28 ± 0.06 (85.0%)	1.21 ± 0.08 (80.4%)	1.16 ± 0.08 (76.1%)	0.76 ± 0.06 (50.0%)	0.77 ± 0.09 (50.5%)
Missed particle weight	0.22 ± 0.07 (15.0%)	0.30 ± 0.06 (19.6%)	0.36 ± 0.07 (23.9%)	0.77 ± 0.06 (50.0%)	0.75 ± 0.08 (49.5%)

İleri derecede tortüyöz arter modelinde filtre başarıları

Table 34.3 Severely Tortuous Vessel Anatomy

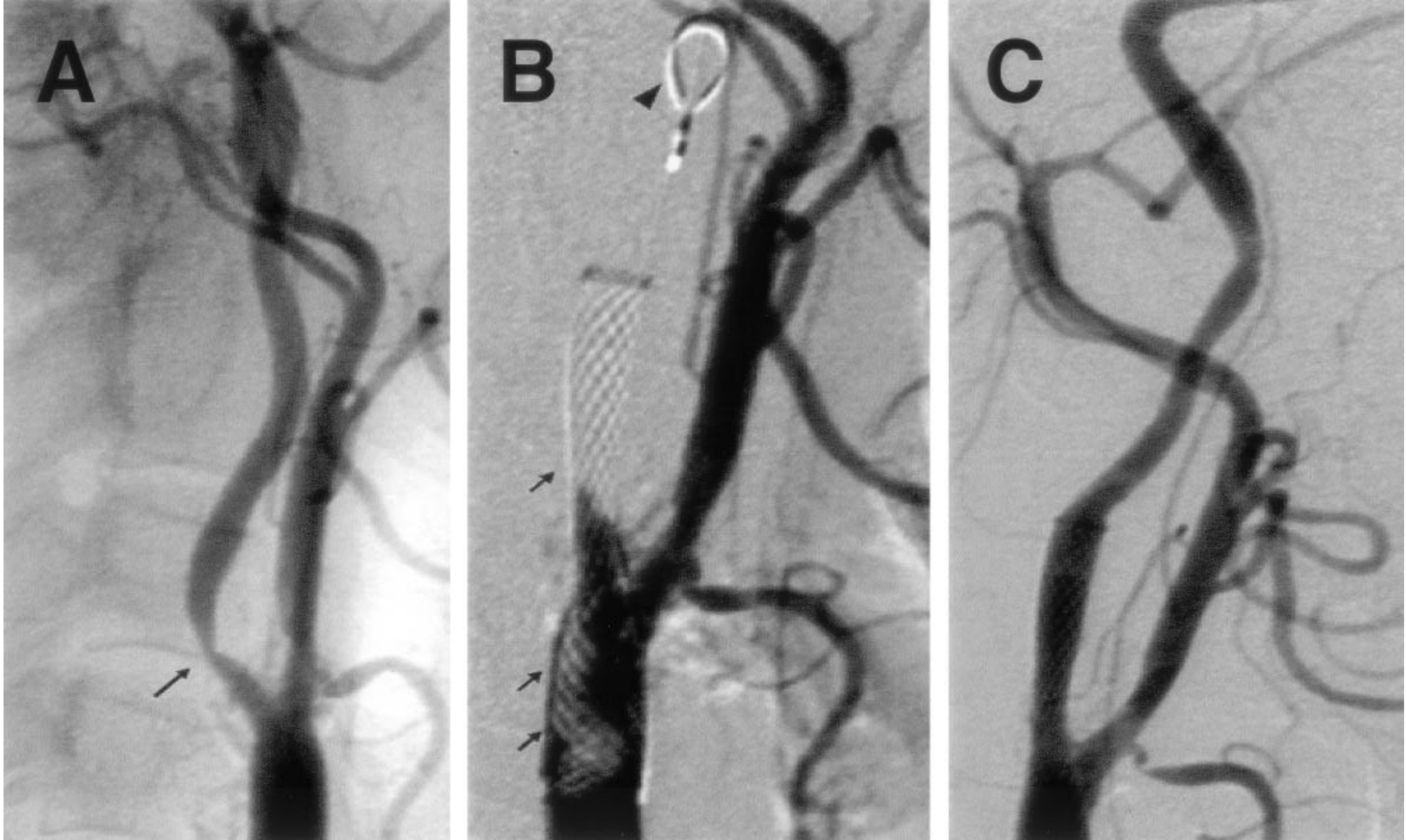
	AngioGuard	FilterWire EZ	AccuNet	Emboshield	SpideRX
250µm					
Injected particle	1.49 ± 0.03	1.50 ± 0.04	1.52 ± 0.03	1.51 ± 0.03	1.52 ± 0.03
Capture weight	1.14 ± 0.05 (76.3%)	1.03 ± 0.08 (68.2%)	0.91 ± 0.09 (60.1%)	0.52 ± 0.06 (34.8%)	0.79 ± 0.10 (52.1%)
Missed particle weight	0.35 ± 0.03 (23.7%)	0.47 ± 0.04 (31.8%)	0.61 ± 0.08 (39.9%)	0.99 ± 0.08 (65.2%)	0.73 ± 0.16 (47.9%)
425µm					
Injected particle	1.50 ± 0.03	1.50 ± 0.03	1.50 ± 0.04	1.51 ± 0.04	1.51 ± 0.04
Capture weight	1.21 ± 0.04 (80.6%)	1.11 ± 0.06 (74.0%)	1.04 ± 0.06 (69.4%)	0.62 ± 0.06 (41.3%)	0.59 ± 0.08 (38.8%)
Missed particle weight	0.29 ± 0.05 (19.4%)	0.39 ± 0.05 (26.0%)	0.46 ± 0.07 (31.6%)	0.89 ± 0.05 (58.7%)	0.92 ± 0.10 (61.2%)

Avantajları ve Dezavantajları

- Avantajları
  - Deneyim daha fazla
  - Daha uygun fiyat
  - Kısa işlem süresi
  - Akımın devamı
  - Kontrast geçişi

- Dezavantajları
  - Lezyondan ilk geçiş riski
  - Stiff / Bulky cihaz ~ 3 fr.
  - Travma / diseksiyon riski
  - Fokal vazospazm
  - Toplanmadaki güçlük
  - Akut stent oklüzyonu
    - Yaklaşık %10
    - 30 günlük inme / mortalite > %9

Casserly IP, Abou-Chebl A, Fathi RB, et al. Slow-flow phenomenon during carotid artery intervention with embolic protectiondevices:predictors and clinical outcome. J Am Coll Cardiol. 2005;46(8).

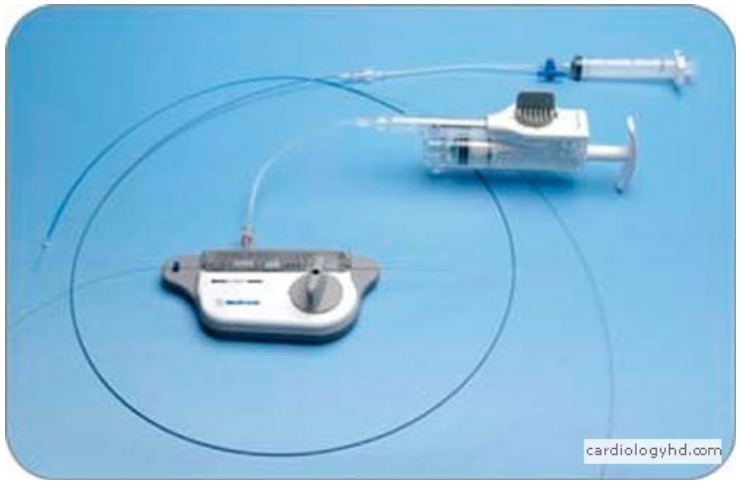

A
B
C

Distal oklüzyon balonları

- İlk uygulanan yöntem sadece lezyon distalinin oklüzyonu (1986)...

  Théron J, Cosgrove R, Melanson D, Ethier R. Embolization with tem- porary balloon occlusion of the internal carotid or vertebral arteries. *Neuroradiology*. 1986;28(3):246–253.

- Daha sofistike yöntemler debrisin aspirasyonuna izin verenler...
  - The GuardWire Protection system (PercuSurge, Sunnyvale, CA, USA),
  - Export (Medtronic) aspirasyon kateteri.
- Avantajı;
  - Vazospazm daha az
  - Geçiş üstünlüğü var
    - Korumasız predilatasyon ihtiyacı daha az
- Dezavantajı
  - Distal embolizasyon riski daha fazla??
  - Nörolojik tolerans daha az...



Powell RJ, Alessi C, Nolan B, et al. Comparison of embolization protection device-specific technical difficulties during carotid artery stenting. *J Vasc Surg*. 2006;44(1):56–61.

Distal balon mu filtre mi ?

- Powell ve ark. 2006
  - 99 balon dilatasyon hastası;
    - GuardWire embolic protection device.
  - 42 filtre hastası ;
    - Guidant Accunet
    - Cordis Angio guard
    - Boston FilterWire
  - Lezyon ve hasta karakteristikleri benzer

Table III. Thirty-day perioperative outcome

	Filter (*n* = 42) (%)	*Balloon* (*n* = 99) (%)	P
Major stroke	2.3	1.0	.51
Minor stroke	2.3	2.0	.82
TIA	0	1.0	.73
MI	0	2.0	.56
Reperfusion	0	2.0	.56
BP control	9.5	5	.63
Seizure	2.3	2.0	.82

TIA, Transient ischemic attack; *MI*, myocardial infarction; *BP*, blood pressure control requiring pressors.

Table IV. Technical complications

	Filter (*n* = 42) (%)	*Balloon* (*n* = 99) (%)	P
Neurologic comp	0	10	.002
Unable to cross lesion	12	0	.001
Filter clogged	5	0	.07
ICA spasm	12	2	.002
Malpositioned stent	0	2	.56
Other*	7	1	.16

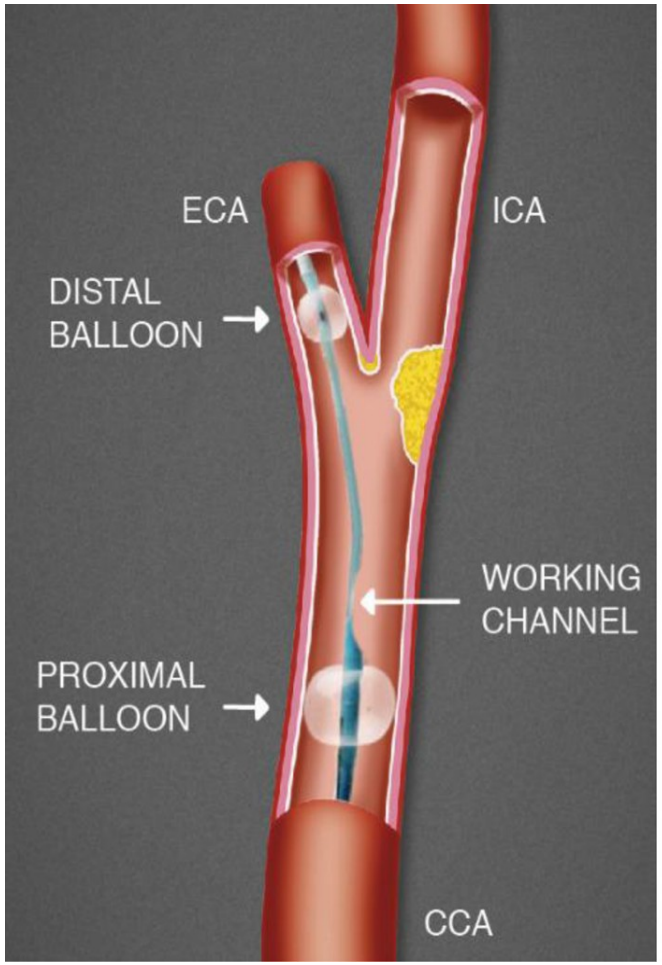
ICA, Internal carotid artery.
*3 cases of delayed retrieval of filter and one case of balloon wire kinking

Guard, or FilterWire filter embolic protection devices.

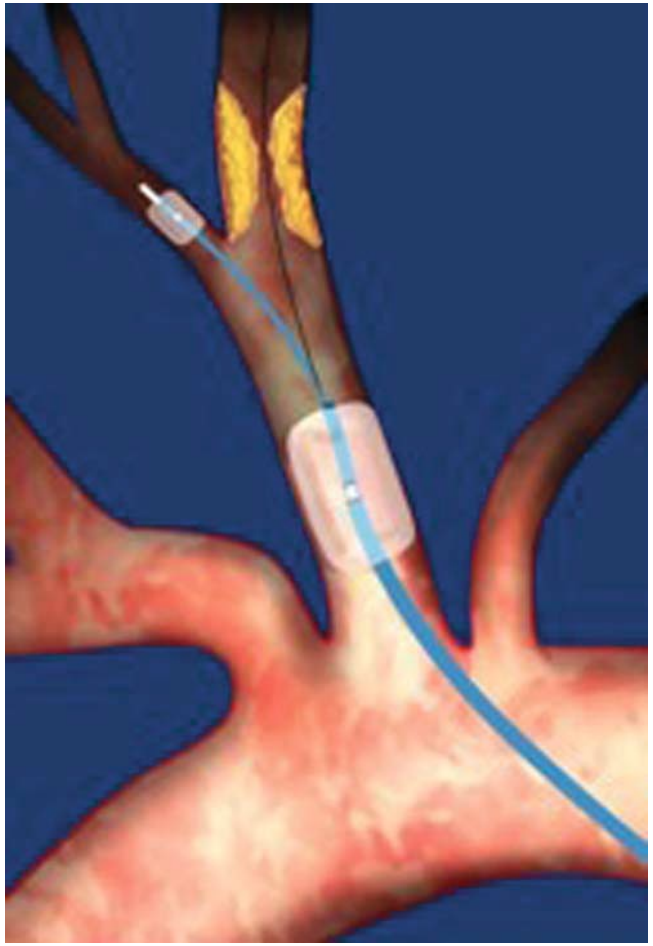
EPD-related technical difficulties were encountered, and although they appeared to have no effect on clinical outcome, vascular surgeons need to be prepared to handle these as they arise during CAS. In addition, familiarity with different types of EPDs may allow the surgeon to treat a broader clinical spectrum of patients with CAS. We prefer to use filter devices preferentially in most cases to avoid the 10% incidence of reversible neurologic compromise that occurs with balloon occlusion. However, we prefer balloon occlusion EPDs for critical stenoses that would be more difficult to cross with currently available filter systems without predilation. With such critical stenoses, it is less likely that the patients would not tolerate ICA occlusion. Thus, balloon and filter type EPDs have complimentary advantages and disadvantages that allow selection according to unique patient and lesion characteristics.

Proximal koruma

- Avantajları
  - Akım yönündeki değişiklik;
  - Lezyondan ilk geçişe gerek kalmaz
- 3 çalışma ve meta-analizde;
  - 30 günlük inme riski <%2...
- Dezavantajları
  - Nörolojik intolerans ~%2
  - Sistem çok daha komplike
  - İşlem süresi daha uzun
  - Bulky cihaz



Proximal Koruma



Device	Manufacturer	External carotid artery occlusion	Flow reversal
MICHI Neuroprotection System	Silk Road Medical (Sunnyvale, CA, USA)	N	Y

ARMOUR (2010)

- MO-MA cihazı güvenilirlik çalışması
- 25 merkezden 262 hasta...

- 30 günlük sonuçlar MACCE %2.7,
  İnme %2.3
  Mj inme %0.9

- Başarı; Cihaz başarısı (yerleşme, aspirasyon ve toplama)
  Teknik başarı (Cihaz başarısı + stentin yerleştirilmesi)
  Prosedür başarısı (Teknik başarı – MACCE – uzamış intolerans)

ARMOUR (2010)

- 25 merkezden 262 hasta...
- 1 aylık sonuçlar MACCE %2.7,
  İnme %2.3
  Mj inme %0.9

- Başarı;

Cihaz başarısı	%98.2
Teknik başarı	%94.6
Prosedür başarısı	%93.6

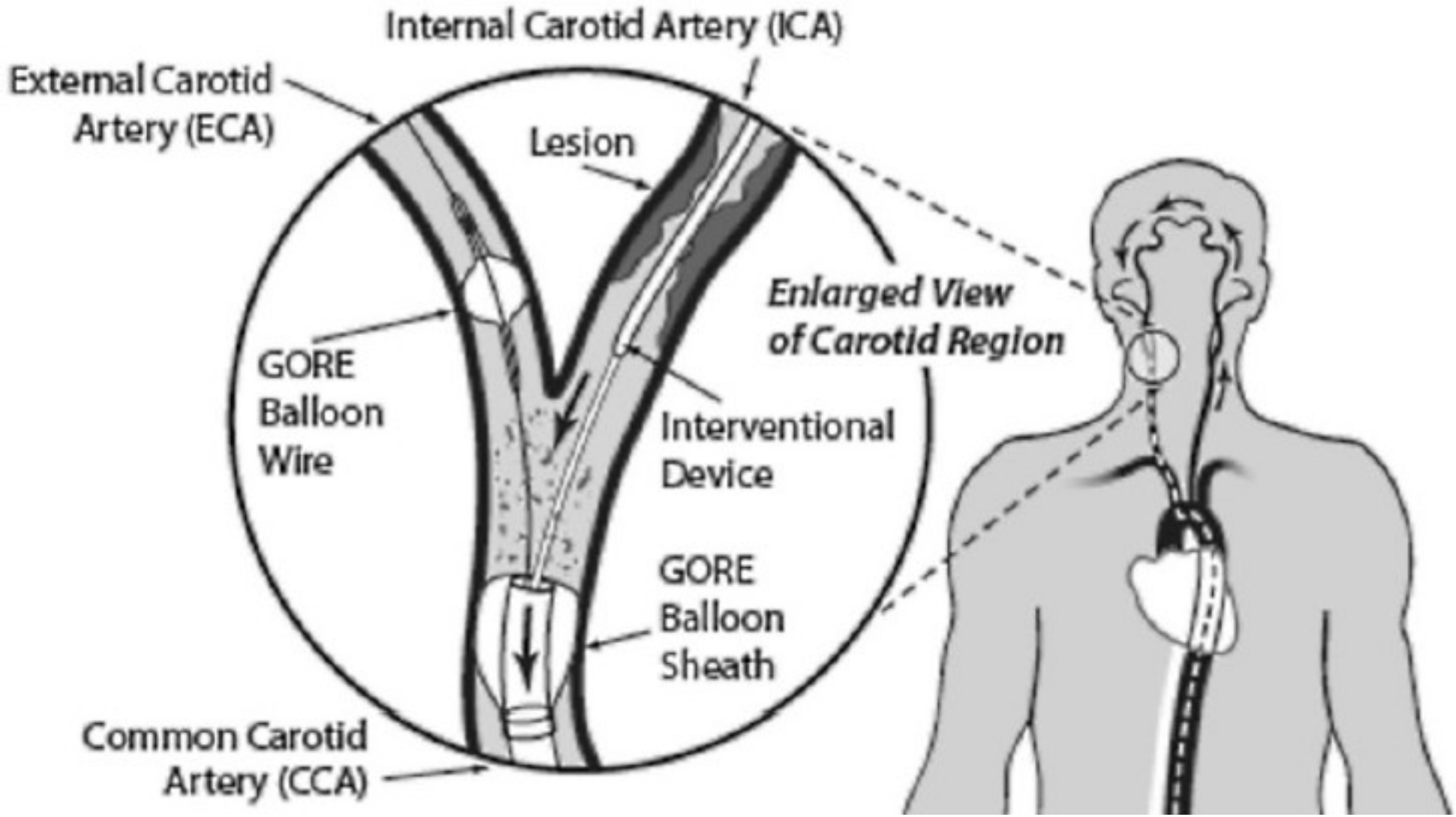
ARMOUR (2010)

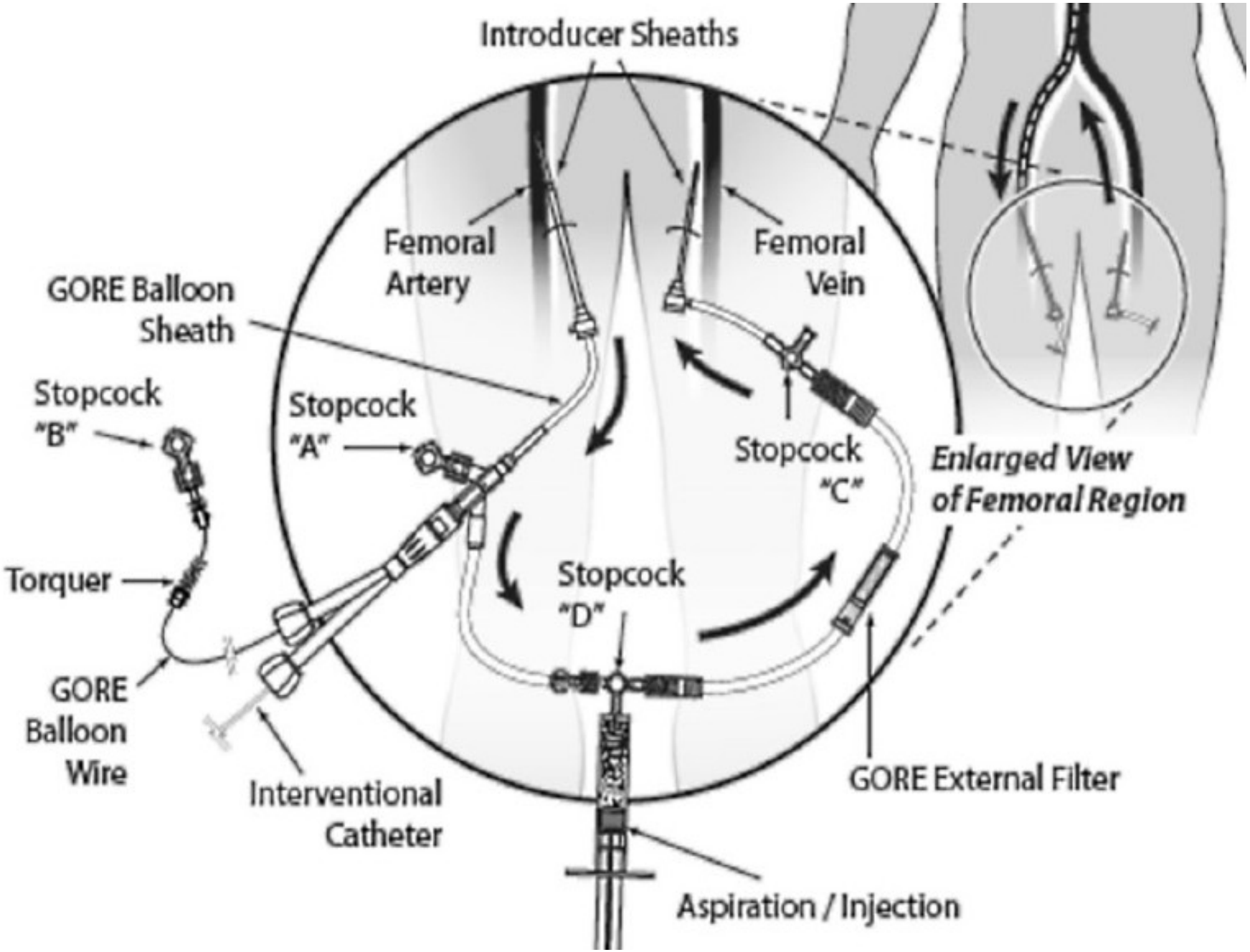
- 25 merkezden 262 hasta...
- 1 aylık sonuçlar MACCE %2.7,
  İnme %2.3
  Mj inme %0.9

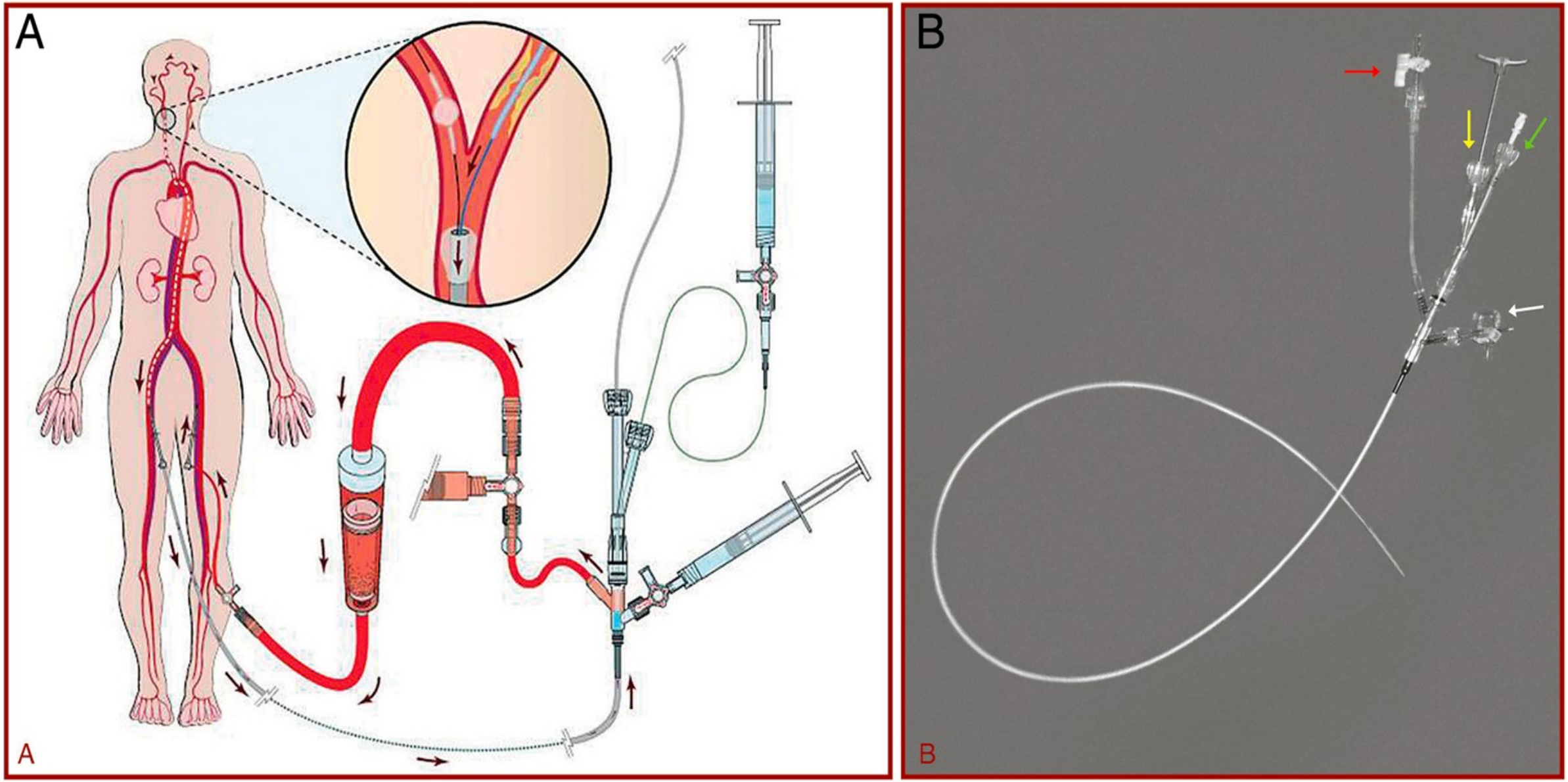
- Başarı; Cihaz başarısı %98.2
  Teknik başarı %94.6
  Prosedür başarısı %93.6

- Total süre; 38.5±21 dk
- Akım kesim süresi; 6.71±3.8 dk.

- İntolerans %13 (31h)
- Uzamış intolerans; %0.9 (2h)
  (>20dk süren intolerans...)


Internal Carotid Artery (ICA)
External Carotid Artery (ECA)
Lesion
Enlarged View of Carotid Region
GORE Balloon Wire
Interventional Device
GORE Balloon Sheath
Common Carotid Artery (CCA)


Introducer Sheaths
Femoral Artery
Femoral Vein
GORE Balloon Sheath
Stopcock "B"
Stopcock "A"
Stopcock "C"
Stopcock "D"
Torquer
GORE Balloon Wire
Interventional Catheter
GORE External Filter
Aspiration / Injection
Enlarged View of Femoral Region


A
A
B
B

Gore flow reversal

- Nikas ve ark; 2012
  - Çok merkezli EU kayıt ç.
  - 122 hasta (%28 semptomatik)
  - 9 ayrı stent çeşidi kullanılmış
  - İlk 24 saat ve 30 günlük MAE değerlendirilmiş
    - 1 hastada aşırı tortiyozite
    - 2 hastada intolerans nedeni ile kullanılamamış

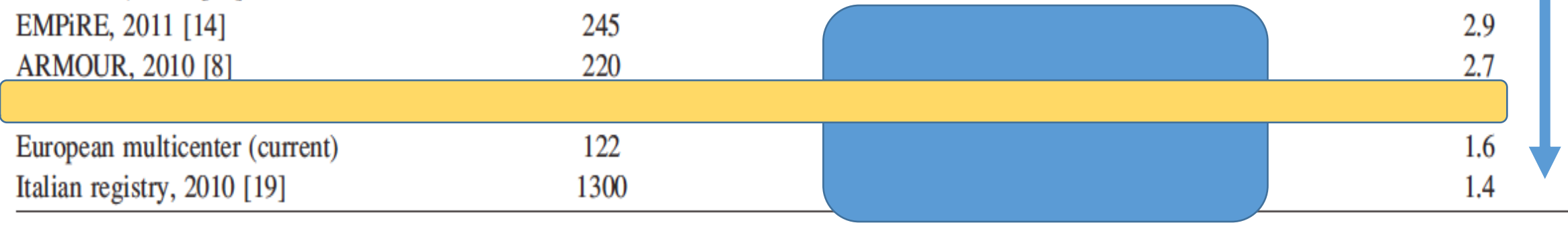
Event	All patients ($n = 122$)	Symptomatic patients ($n = 34$)	Asymptomatic patients ($n = 88$)
Within 24 hr of CAS			
MAEs	2 (1.6)	0	2 (2.3)
Death	0	0	0
Major stroke	1 (0.8)	0	1 (1.1)
Minor stroke	1 (0.8)	0	1 (1.1)
MI	0	0	0
Visual/speech disturbance	0	0	0
Amaurosis fugax	0	0	0
TIA	1 (0.8)	0	1 (1.1)
Within 30 days of CAS			
MAEs	2 (1.6)	0	2 (2.3)
Death	0	0	0
Major stroke	1 (0.8)	0	1 (1.1)
Minor stroke	1 (0.8)	0	1 (1.1)
MI	0	0	0
Visual/speech disturbance	0	0	0
Amaurosis fugax	0	0	0
TIA	2 (1.6)	1 (2.9)	1 (1.1)

[a]Values are number (percent) of patients in each group.

Distal koruma mı / Flow reversal mı ?

TABLE V. Stroke/Death Rates Within 30 Days of CAS Using an EPD in Recent Large Studies

Study, year	No. of patients	EPD used[a]	Stroke/death rate (%)[b]
CREATE, 2010 [23]	160	SpideRX	5.6
MAVErIC, 2010 [22]	498	GuardWire	5.2
CREST, 2010 [1]	1262[c]	RX Accunet	4.8
Ielasi et al, 2010 [24]	490	Various[d]	3.7
EMPiRE, 2011 [14]	245		2.9
ARMOUR, 2010 [8]	220		2.7
European multicenter (current)	122		1.6
Italian registry, 2010 [19]	1300		1.4



Distal koruma mı / Flow reversal mı ?

Flow Reversal Versus Filter Protection
A Pilot Carotid Artery Stenting Randomized Trial

Luis Henrique de Castro-Afonso, MD; Lucas Giansante Abud, MD;
Jaicer Gonçalves Rolo, MD; Antônio Carlos dos Santos, MD, PhD; Lívia de Oliveira, MD;
Clara Monteiro Antunes Barreira, MD; Tonicarlo Rodrigues Velasco, MD, PhD;
Octávio Marques Pontes-Neto, MD, PhD; Daniel Giansante Abud, MD, PhD

- Afonso ve ark; (Brezilya-2013)
  - 40 hasta flow r. / distal f. gruplarına ayrılmış (21/19)
  - Demografik özellikler benzer
  - Tek merkezli, randomize, open label, prospektif...

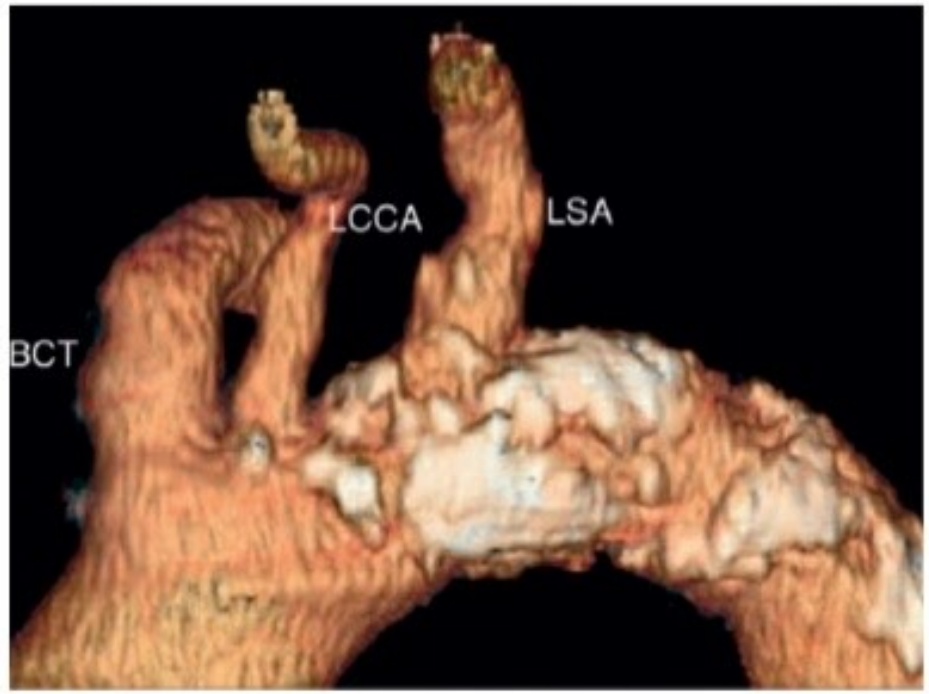
Table 2. Baseline Characteristics of Patients per Group Assigned

Clinical, Radiological, and Procedural Data	Total (N=40)	Flow-Reversal Group (n=21)	Filter Group (n=19)	*P* Value
Mean procedural time, min	19.74 (10.61–33.58; SD±5.17)	22.41 (16.61–33.58; SD±4.68)	16.78 (10.61–22.91; SD±4.00)	<0.001
Mean protection time, min	4.88 (2.83–7.55; SD±1.21)	4.49 (2.83–7.55; SD±1.44)	5.32 (4.26–6.98; SD±0.71)	0.02

Table 3. Primary End Points Obtained

New Ischemic Brain Lesions on DWI-MRI Between 6 and 24 h After Procedure	Total (N=40)	Flow-Reversal Group (n=21)	Filter Group (n=19)	Odds Ratio (95% CI)	*P* Value
Incidence, n (%)	13 (32.5)	10 (47.6)	3 (15.8)	4,85 (1.08–21.76)	0.03
Number (mean)	1.72 (0–18; SD±3.98)	2.61 (0–18; SD±5.13)	0.73 (0–5; SD±1.75)	…	0.05
Mean diameter (mm)	1.56 (0.0–9.5; SD±2.49)	2.23 (0.0–9.5; SD±2.77)	0.81 (0.0–6.4; SD±1.96)	…	0.05
Incidence of ipsilateral lesions, n (%)	7 (46.1)	7 (70.0)	0 (0.0)	…	0.07
Incidence of bilateral lesions, n (%)	6 (53.9)	3 (30.0)	3 (100)	…	0.07

CI indicates confidence interval; and DWI-MRI, diffusion-weighted magnetic resonance image.



Example of an aortic arch with high emboligenic-risk.

extense, irregular and calcified plaque in the aortic wall

Table 4. Secondary End Points Obtained for Clinical Assessments

	Total (N=40)	Flow-Reversal Group (n=21)	Filter Group (n=19)	*P* Value
Clinical Assessment at 24 h				
Stroke, n (%)	0	0	0	NA
Symptomatic myocardial infarct, n (%)	0	0	0	NA
Death, n (%)	0	0	0	NA
TIA, n (%)	0	0	0	NA
NIHSS, mean (median)	1.60; 1.0 (0–8; SD±2.03)	1.52; 1.0 (0–7; SD±1.86)	1.68; 1.0 (0–8; SD±2.26)	0.93
Clinical assessment at 3-mo follow-up				
Stroke, n (%)	0	0	0	NA
Symptomatic myocardial infarct, n (%)	0	0	0	NA
Death, n (%)	0	0	0	NA
TIA, n (%)	2 (5.0)	1 (4.8)	1 (5.3)	NA
NIHSS, mean (median)	1.35; 1.0 (0–8; SD±1.89)	1.24; 1.0 (0–6; SD±1.67)	1.42; 1.0 (0–8; SD±2.14)	0.91
mRS, mean (median)	1.57; 2.0 (0–4; SD±1.31)	1.57; 1.0 (0–4; SD±1.32)	1.58; 2.0 (0–4; SD±1.34)	0.95

CI indicates confidence interval; mRS, modified Rankin Scale; NA, not applicable; NIHSS, National Institutes of Health Stroke Scale; and TIA, transient ischemic attack.

Catheterization and Cardiovascular Interventions 00:00–00 (2016)

Original Studies

Proximal Balloon Occlusion versus Distal Filter Protection in Carotid Artery Stenting: A Meta-Analysis and Review of the Literature

Jad Omran,[1*] MD, Ehtisham Mahmud,[2] MD, Christopher J. White,[3] MD, Herbert D. Aronow,[4] MD, MPH, Douglas E. Drachman,[5] MD, William Gray,[6] MD, Obai Abdullah,[1] MD, Mazen Abu-Fadel,[7] MD, Belal Firwana,[8] MD, Gergory Mishkel,[9] MD, and Ashraf S. Al-Dadah,[9] MD

- Tarama kaynakları;
  - Medline,
  - Embase
  - Cochrane
- Anahtar kelimeler;
  - Karotis darlığı
  - K. Koruma cihazları
  - Proximal balon ok.
  - Distal filtre kor. vb.

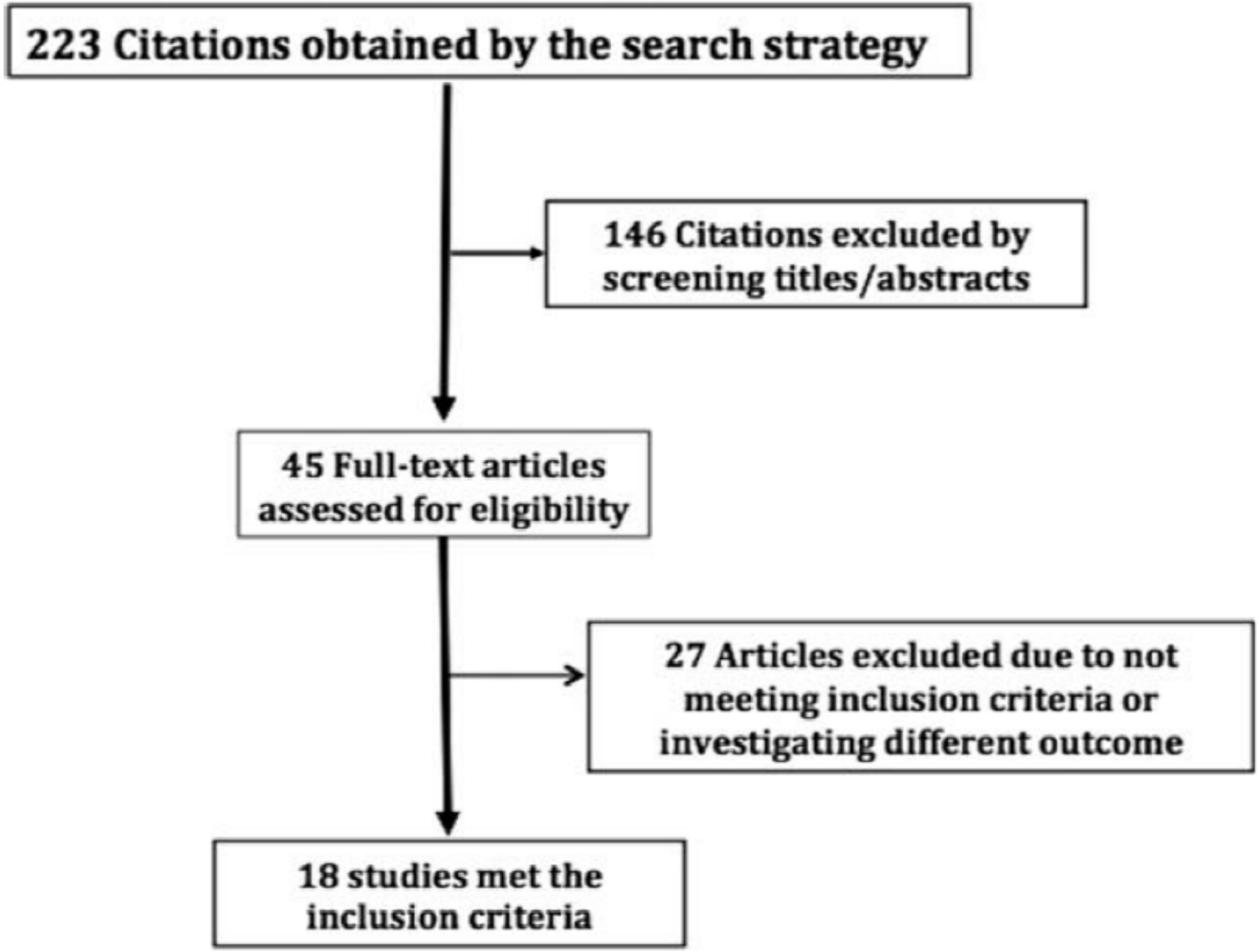
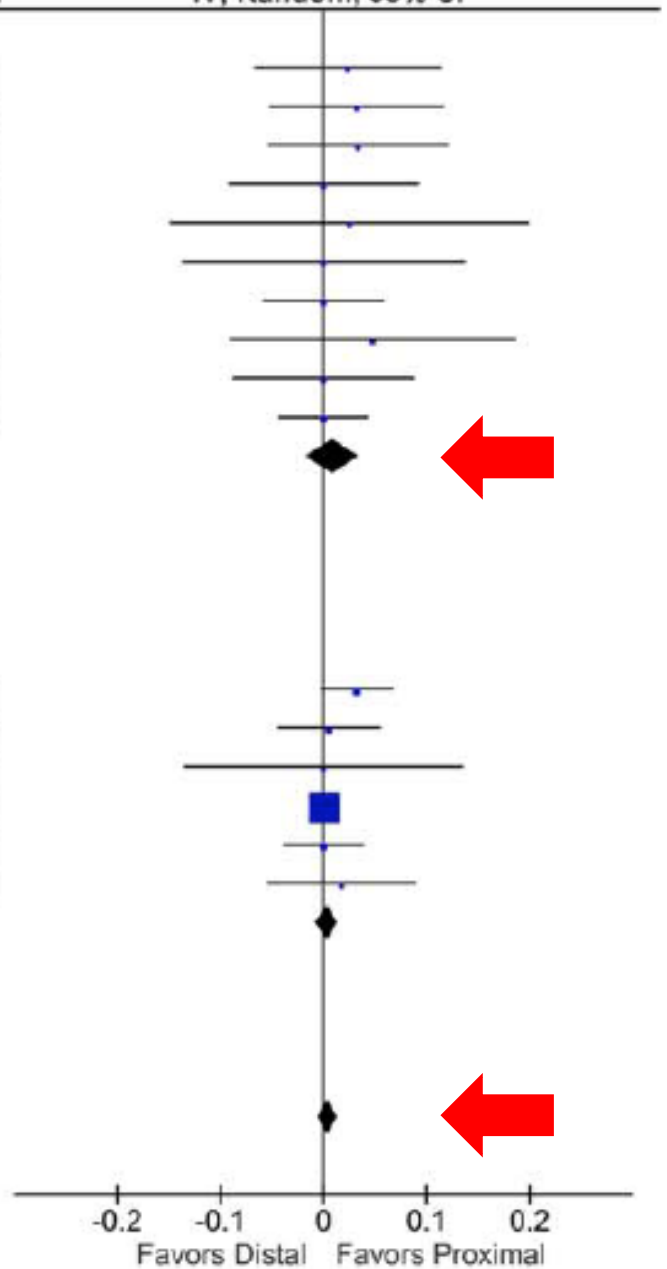


Fig. 1. Identification of studies selection process.

A

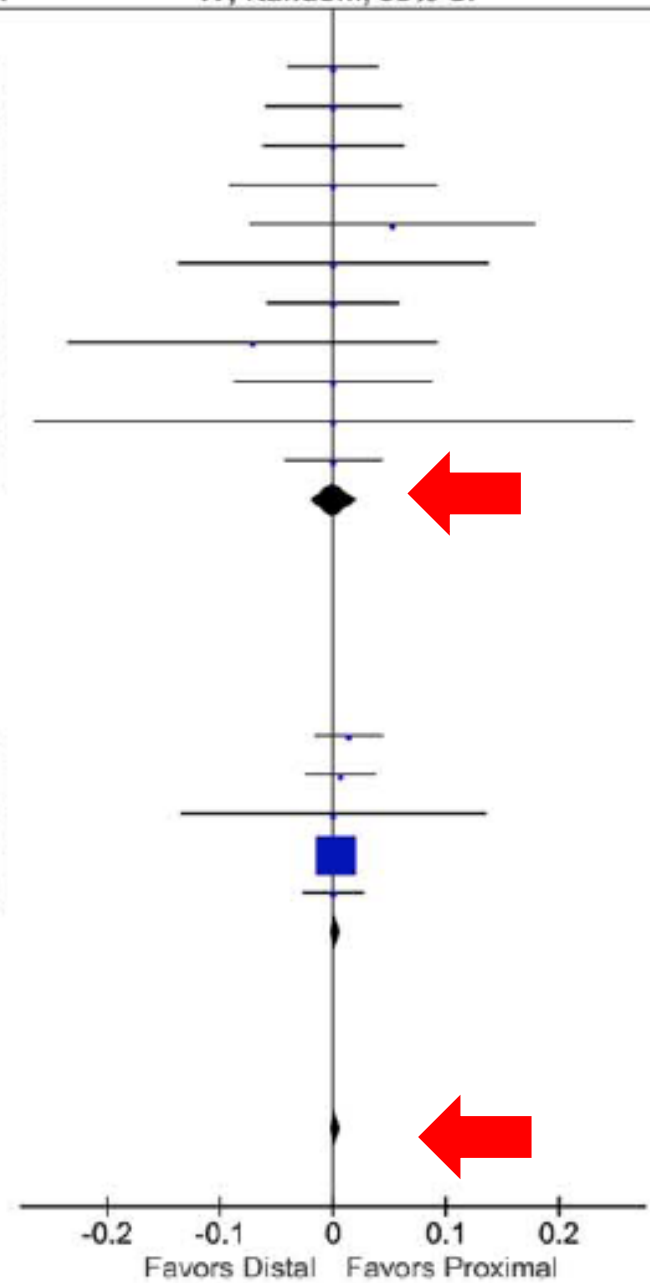
Study or Subgroup	Distal Filter Protection Events	Total	Proximal Baloon Occlusion Events	Total	Weight	Risk Difference IV, Random, 95% CI
2.2.1 Randomized						
Akkaya 2014	3	46	2	48	1.2%	0.02 [-0.07, 0.11]
Bijuklic 2012	1	31	0	31	1.3%	0.03 [-0.05, 0.12]
Cano 2013	1	30	0	30	1.2%	0.03 [-0.05, 0.12]
Castro-Afonso 2013	0	19	0	21	1.1%	0.00 [-0.09, 0.09]
El-Koussy 2007	2	19	2	25	0.3%	0.03 [-0.15, 0.20]
Grego 2002	0	13	0	13	0.5%	0.00 [-0.14, 0.14]
Leal 2012	0	33	0	31	2.7%	0.00 [-0.06, 0.06]
Montorsi 2011	1	21	0	14	0.5%	0.05 [-0.09, 0.19]
Schmidt 2004	0	21	0	21	1.2%	0.00 [-0.09, 0.09]
Tatli 2013	0	40	0	48	5.0%	0.00 [-0.04, 0.04]
Subtotal (95% CI)		**273**		**282**	**15.1%**	**0.01 [-0.02, 0.03]**
Total events	8		4			
Heterogeneity: Tau² = 0.00; Chi² = 1.36, df = 9 (P = 1.00); I² = 0%						
Test for overall effect: Z = 0.74 (P = 0.46)						
2.2.2 Observational						
Brewster 2011	7	216	0	53	7.7%	0.03 [-0.00, 0.07]
Fernandez 2014	9	208	3	79	3.8%	0.01 [-0.05, 0.06]
Flach 2007	0	23	0	10	0.5%	0.00 [-0.14, 0.14]
Giri 2015	33	2032	8	508	64.9%	0.00 [-0.01, 0.01]
Mokin 2014	1	70	1	70	6.2%	0.00 [-0.04, 0.04]
Powel 2006	2	42	3	99	1.8%	0.02 [-0.06, 0.09]
Subtotal (95% CI)		**2591**		**819**	**84.9%**	**0.00 [-0.01, 0.01]**
Total events	52		15			
Heterogeneity: Tau² = 0.00; Chi² = 2.99, df = 5 (P = 0.70); I² = 0%						
Test for overall effect: Z = 0.72 (P = 0.47)						
Total (95% CI)		**2864**		**1101**	**100.0%**	**0.00 [-0.01, 0.01]**
Total events	60		19			
Heterogeneity: Tau² = 0.00; Chi² = 4.50, df = 15 (P = 1.00); I² = 0%						



İskemik inme açısından anlamlı fark yok

B

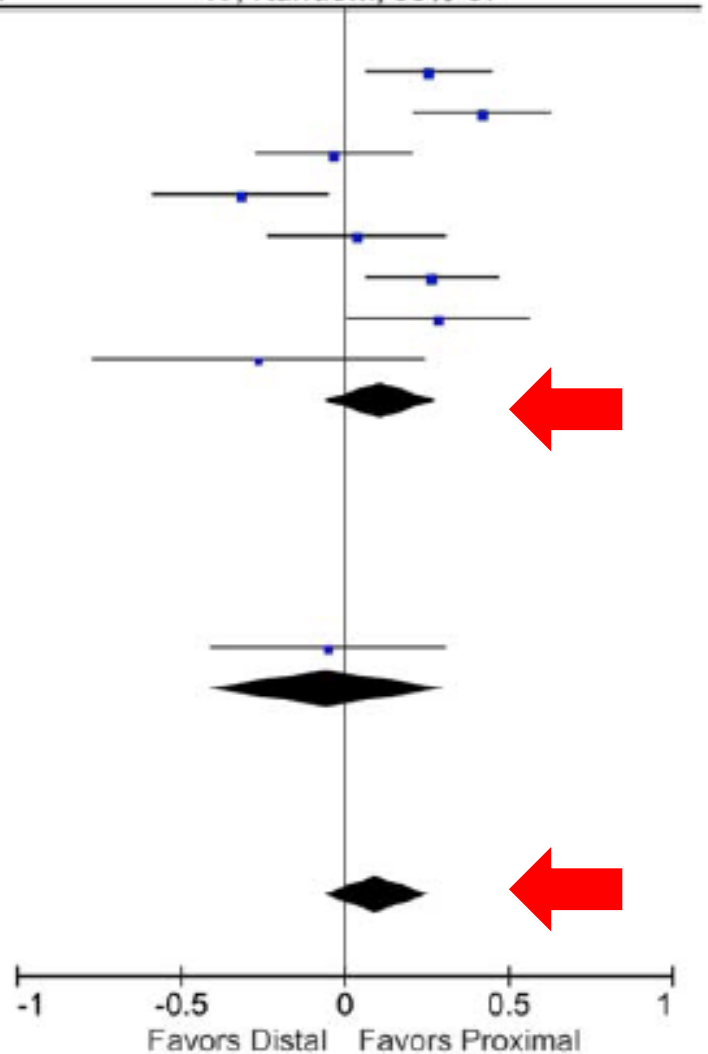
Study or Subgroup	Distal Filter Protection Events	Total	Proximal Baloon Occlusion Events	Total	Weight	Risk Difference IV, Random, 95% CI
2.6.1 Randomized						
Akkaya 2014	0	46	0	48	1.2%	0.00 [-0.04, 0.04]
Bijuklic 2012	0	31	0	31	0.6%	0.00 [-0.06, 0.06]
Cano 2013	0	30	0	30	0.5%	0.00 [-0.06, 0.06]
Castro-Afonso 2013	0	19	0	21	0.2%	0.00 [-0.09, 0.09]
El-Koussy 2007	1	19	0	25	0.1%	0.05 [-0.07, 0.18]
Grego 2002	0	13	0	13	0.1%	0.00 [-0.14, 0.14]
Leal 2012	0	33	0	31	0.6%	0.00 [-0.06, 0.06]
Montorsi 2011	0	21	1	14	0.1%	-0.07 [-0.24, 0.09]
Schmidt 2004	0	21	0	21	0.3%	0.00 [-0.09, 0.09]
Taha 2009	0	4	0	34	0.0%	0.00 [-0.27, 0.27]
Tatli 2013	0	40	0	48	1.1%	0.00 [-0.04, 0.04]
Subtotal (95% CI)		**277**		**316**	**4.8%**	**0.00 [-0.02, 0.02]**
Total events	1		1			
Heterogeneity: Tau² = 0.00; Chi² = 1.39, df = 10 (P = 1.00); I² = 0%						
Test for overall effect: Z = 0.02 (P = 0.98)						
2.6.2 Observational						
Brewster 2011	3	216	0	53	2.2%	0.01 [-0.02, 0.04]
Fernandez 2014	4	208	1	79	2.1%	0.01 [-0.02, 0.04]
Flach 2007	0	23	0	10	0.1%	0.00 [-0.14, 0.14]
Giri 2015	9	2032	1	508	88.1%	0.00 [-0.00, 0.01]
Mokin 2014	0	70	0	70	2.7%	0.00 [-0.03, 0.03]
Subtotal (95% CI)		**2549**		**720**	**95.2%**	**0.00 [-0.00, 0.01]**
Total events	16		2			
Heterogeneity: Tau² = 0.00; Chi² = 0.62, df = 4 (P = 0.96); I² = 0%						
Test for overall effect: Z = 1.16 (P = 0.25)						
Total (95% CI)		**2826**		**1036**	**100.0%**	**0.00 [-0.00, 0.01]**
Total events	17		3			
Heterogeneity: Tau² = 0.00; Chi² = 2.06, df = 15 (P = 1.00); I² = 0%						



Mortalite açısından anlamlı fark yok

C

Study or Subgroup	Distal Filter Protection Events	Total	Proximal Baloon Occlusion Events	Total	Weight	Risk Difference IV, Random, 95% CI
2.3.1 Randomized						
Akkaya 2014	30	46	19	48	13.3%	0.26 [0.06, 0.45]
Bijuklic 2012	27	31	14	31	12.8%	0.42 [0.21, 0.63]
Cano 2013	19	30	20	30	12.0%	-0.03 [-0.27, 0.21]
Castro-Afonso 2013	3	19	10	21	11.3%	-0.32 [-0.59, -0.05]
El-Koussy 2007	6	19	7	25	11.2%	0.04 [-0.24, 0.31]
Leal 2012	13	33	4	31	13.0%	0.26 [0.06, 0.47]
Montorsi 2011	9	21	2	14	11.0%	0.29 [0.01, 0.57]
Taha 2009	2	4	26	34	6.3%	-0.26 [-0.78, 0.25]
Subtotal (95% CI)		**203**		**234**	**90.9%**	**0.11 [-0.06, 0.28]**
Total events	109		102			
Heterogeneity: Tau² = 0.04; Chi² = 26.54, df = 7 (P = 0.0004); I² = 74%						
Test for overall effect: Z = 1.24 (P = 0.21)						
2.3.2 Observational						
Flach 2007	8	23	4	10	9.1%	-0.05 [-0.41, 0.31]
Subtotal (95% CI)		**23**		**10**	**9.1%**	**-0.05 [-0.41, 0.31]**
Total events	8		4			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.28 (P = 0.78)						
Total (95% CI)		**226**		**244**	**100.0%**	**0.10 [-0.07, 0.26]**
Total events	117		106			
Heterogeneity: Tau² = 0.04; Chi² = 27.73, df = 8 (P = 0.0005); I² = 71%						
Test for overall effect: Z = 1.16 (P = 0.24)						
Test for subgroup differences: Chi² = 0.63, df = 1 (P = 0.43), I² = 0%						



Yeni serebral lezyonlar açısından anlamlı fark yok

D

Study or Subgroup	Distal Filter Protection Events	Total	Proximal Baloon Occlusion Events	Total	Weight	Risk Difference IV, Random, 95% CI
2.4.1 Randomized						
Akkaya 2014	3	46	2	48	26.0%	0.02 [-0.07, 0.11]
Bijuklic 2012	9	31	2	31	9.8%	0.23 [0.04, 0.41]
Cano 2013	11	30	8	30	6.4%	0.10 [-0.13, 0.33]
Castro-Afonso 2013	3	19	3	21	7.0%	0.02 [-0.21, 0.24]
El-Koussy 2007	1	19	5	25	9.5%	-0.15 [-0.33, 0.04]
Leal 2012	2	33	0	31	24.0%	0.06 [-0.04, 0.16]
Taha 2009	1	4	11	34	1.9%	-0.07 [-0.53, 0.38]
Subtotal (95% CI)		**182**		**220**	**84.5%**	**0.04 [-0.03, 0.12]**
Total events	30		31			
Heterogeneity: Tau² = 0.00; Chi² = 8.74, df = 6 (P = 0.19); I² = 31%						
Test for overall effect: Z = 1.08 (P = 0.28)						
2.4.2 Observational						
Flach 2007	0	23	0	10	15.5%	0.00 [-0.14, 0.14]
Subtotal (95% CI)		**23**		**10**	**15.5%**	**0.00 [-0.14, 0.14]**
Total events	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.00 (P = 1.00)						
Total (95% CI)		**205**		**230**	**100.0%**	**0.04 [-0.03, 0.10]**
Total events	30		31			
Heterogeneity: Tau² = 0.00; Chi² = 9.05, df = 7 (P = 0.25); I² = 23%						
Test for overall effect: Z = 1.10 (P = 0.27)						
Test for subgroup differences: Chi² = 0.27, df = 1 (P = 0.60), I² = 0%						

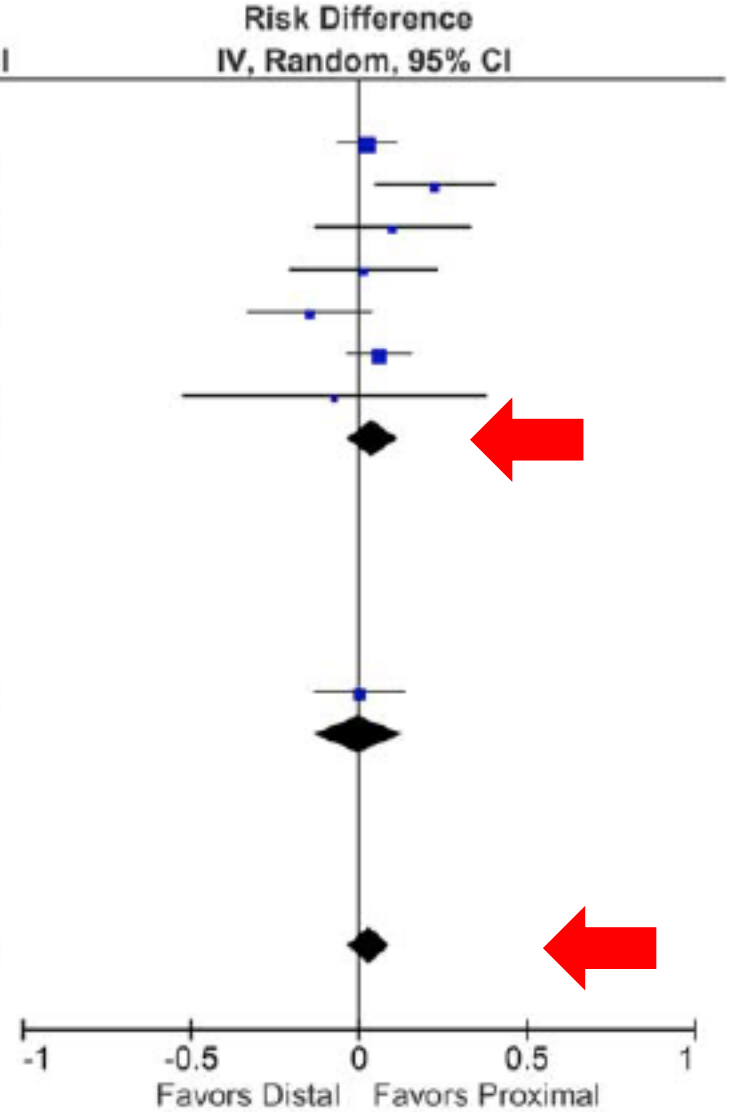


Fig. 2. Continued

Kontrlateral lezyonlar açısından anlamlı fark yok

Özetle;

- Çalışmaların ve meta-analizlerin sonuçları birbirleri ile tam tutarlılık göstermemektedir.
  - Her ne kadar çalışmaların tümünde klinik fayda gösterilememiş olsa da; koruma cihazları emboli sayısını , hacmini azaltmakta, sonlanım noktalarını etkilemektedir.
  - Meta-analizde belirgin fark gösterilememiş olsa da proximal koruma cihazları en azından teorik olarak daha olumlu bir klinik sonlanım eğilimi izlemektedir.

  - Hangi cihazın en faydalı olacağına;
    - damarın tortüyozitesi,
    - darlığın ciddiyeti,
    - trombüs yükü,
    - kontrlateral dolaşımın / vertebrobasiller sistemin yeterliliği
    - Operatörün cihaza aşinalığı

doğrultusunda karar verilmelidir...

- ***Teşekkürler***

CONCLUSION

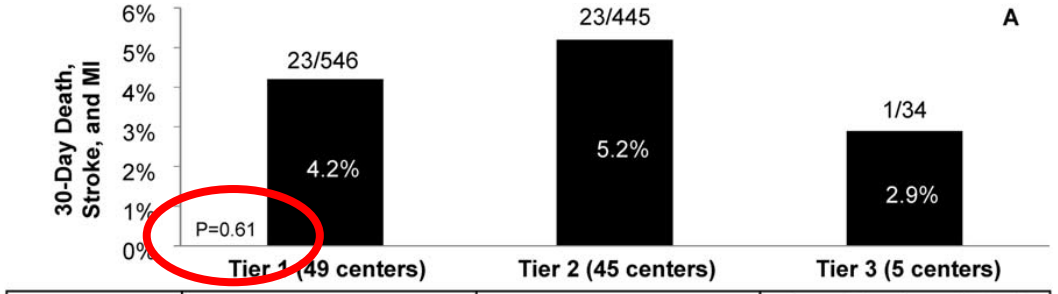
Our meta-analysis demonstrated no difference in clinical outcomes between D-EPD and P-EPD during CAS. While this finding should reinforce the importance of operator's comfort and experience with the use of either device, in fact individual patient characteristics may still dictate use of one style of EPD over the other. Furthermore, emerging data on direct access CAS using P-EPD, double-filtration, meshed-covered stents may change some of these conclusions.

Review den

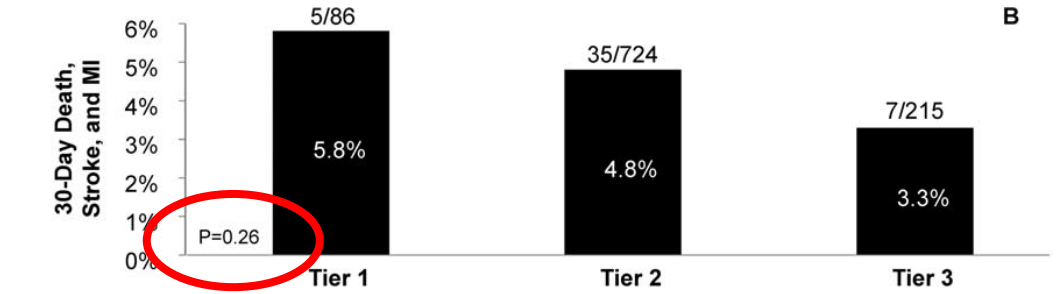
- Although there are no large-scale randomized multi- center trials assessing the value of protection devices, nevertheless protection devices have been associated with a lower risk of stroke during CAS in some smaller/retrospective studies. In a meta-analysis by Touze et al., EPD yielded significant reduction in the
- Proximal versus Distal Protection 7 metaanaliz
- occurrence of stroke or death following CAS [34]. Garg et al. have also observed that the risk of peri- procedural stroke was lower with the use of EPD [35].

Deneyim ne kadar etkili ?

- CABANA (2014)
  - 1097 hasta (%67 asemptomatik)
  - CAS (wallstent) + EPD (FilterWireEZ)
  - %97.1 teknik başarı +
  - İlk 30 günlük MAE değerlendirilmiş
    - Asemptomatik + semptomatik : %4.6...



Center Experience Tier Definition	Center PI performed ≥75 CAS procedures; ≥15 with Carotid Wallstent + FilterWire EZ	Center PI performed ≥40 CAS procedures with any carotid stent + EPD	Center PI performed 25 - 40 procedures with any carotid stent + EPD, ≥13 as the primary operator



Physician Experience	≥5 procedures with Carotid Wallstent + FilterWire EZ	<5 procedures with Carotid Wallstent + FilterWire EZ or ≥3 procedures/month with any device as primary operator	0 procedures with Carotid Wallstent + FilterWire EZ or ≤2 procedures/month with any device as primary operator
Device Module Training	Optional	Required	Required
Proctoring	None required	3 live cases	3 live cases