Comparison of balloon versus filter protection in carotid artery stenting

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Background

Carotid artery stenting (CAS) has emerged as an alternative to carotid endarterectomy (CEA) for patients with high surgical risk. A distal embolic protection device (EPD) is regarded as an essential tool to avoid embolic complications during CAS.
Carotid endarterectomy performed by Neurosurgeons in Japan
Protected CAS using PercuSurge GuardWire, a balloon-type EPD, has been introduced into our hospital since 2002, and Angioguard XP, a filter-type EPD, has been approved in Japan since 2008.
Purpose

The purpose of this study is to compare clinical results of protected CAS with the use of GuardWire and that with Angioguard XP.

Balloon vs Filter protection
The GuardWire® Protection System (distal balloon protection)
Distal Filter Protection System

preserving ICA flow

Schema

AngioGuard XP
Patients (Okayama univ)

Carotid endarterectomy (CEA): 1998.10-
60 Pts. (53 men, 7 women)
45〜78 y/o (mean 67 y/o)

Protected carotid artery stenting (CAS): 2002.9-
209 Pts. (190 men, 19 women)
52〜88 y/o (mean 73 y/o)

PS GuardWire (GW group) 85 Pts. (-2007.11)
Angioguard XP (AG group) 99 Pts. (2007.11-)
recent cases with GW 25 Pts. (2008.9-)
CAS device change in OKAYAMA Univ.

No CAS devices approved officially in Japan

- PercuSurge GuardWire: 85 cases
- AngioGuard XP (Off Label): 99 cases
- AngioGuard XP: 25 cases

Timeline:

<table>
<thead>
<tr>
<th>Year</th>
<th>Device</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>02-09</td>
<td>SMART</td>
<td></td>
</tr>
<tr>
<td>04-05</td>
<td>PRECISE</td>
<td></td>
</tr>
<tr>
<td>06-08</td>
<td>PercuSurge GuardWire</td>
<td>85</td>
</tr>
<tr>
<td></td>
<td>AngioGuard XP</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>AngioGuard XP</td>
<td>25</td>
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</tbody>
</table>
Treatment results of CAS with the use of Angioguard XP compared with those of PercuSurge GuardWire
Results: Stroke or death within 30 days

GW group (n=110): 3 cases (2.7%)

hemorrhagic: 3
  (cerebral 2, abdominal 1)

AG group (n=99): 3 cases (3.0%)

ischemic: 2

hemorrhagic: 1
Neurological complications: GW group (n=110)

Intracerebral hemorrhage (POD 5) → D
Intracerebral hemorrhage (POD 7) → SD
Multiple organ failure after intra-operative abdominal wall hemorrhage → D
No perioperative ischemic stroke
(2 transient ischemic complications)
Neurological complications: AG group (n=99)

Intracerebral hemorrhage (POD 0) → D

2 ischemic complications → MD

(due to emboli during procedure)

Limitation of Angioguard XP’s capture capability

the debris may go away through or around the filter bascket. ?
78 y.o. male: repeated TIA (minor stroke)
Right mild hemiparesis
78y.o. male: repeated TIA (minor stroke)
CAS device and complications

Hyperperfusion hemorrhage

MOF

Hyperperfusion hemorrhage

Hyperperfusion hemorrhage

Ischemic stroke: 2

AngioGuard XP

(Off Label)

PercuSurge GuardWire

SMART

PRECISE

02 03 04 05 06 07 08 09 10
Evaluation of Plaque by MRI (MPRAGE)

For CAS high risk (vulnerable) plaque, balloon protection is superior to filter protection. CEA is preferable, if possible.

High intensity in the plaque: necrotic core with intraplaque hemorrhage

CAS high risk (vulnerable) plaque!
A case with a vulnerable plaque
Debris in the aspirated blood
Selective EPD system by MRI

Reasons of the use of GuardWire in recent 25 selected cases (2008.9-: filter era)

- Vulnerable plaque on MRI: 18
- Subacute stage after onset: 3
- Tortuous ICA: 3
- In-stent thrombosis (after 1st CAS): 1
CAS device and complications

PercuSurge GuardWire

SMART

02 03 04 05 06 07 08 09 10

AngioGuard XP

02 03 04 05 06 07 08

02 03 04 05 06 07 08

PRECISe

No complications

Hyperperfusion hemorrhage

MOF

Hyperperfusion hemorrhage

Ischemic stroke: 2

Hyperperfusion hemorrhage

Hyperperfusion hemorrhage

Hyperperfusion hemorrhage
Staged angioplasty to prevent hyperperfusion

SPECT

Pre  baseline  Diamox
Staged angioplasty to prevent hyperperfusion

2.5 mm balloon

1 month later

Pre

After PTA

After CAS
Staged CAS

Yoshimura et al. Staged angioplasty for carotid artery stenosis to prevent postoperative hyperperfusion (Neurosurgery 2009)
Conclusion

• Hemorrhagic complications were causes of disability in our series in the era of GuardWire balloon protection.

• Hyperperfusion hemorrhage may prevent by using staged CAS in selected cases (impaired cerebral blood flow).
• Thromboembolic events were more frequently encountered in patients undergoing CAS with the use of Angioguard XP filter protection.

• Selection of EPD based on plaque imaging by MRI may be useful to achieve more sufficient results.
Protected CAS: standard procedures

- local anesthesia
- systemic heparinization
- guiding catheter: 6Fr. Shuttle® sheath
- edaravone, atropine, catecholamine, if needed
- distal embolic protection (PS Guardwire™ or Angioguard XP™)
- pre-dilatation, stent deployment (Precise®), post-dilatation
- debris aspiration, if needed
Pre-pre-PTA to enable the passage of a filter device
Intraluminal thrombus: proximal protection before filter deployment
Adjunctive techniques for CAS with the use of Angioguard XP

- extremely severe stenosis → pre-PTA (2 cases)
- concomitant intraluminal thrombus → proximal protection before filter deployment (2 cases)
- slow or no flow → blood aspiration before capture of the filter (6 cases)
Tortuous ICA
Conclusion

• Appropriate selection of patients and devices may be necessary to achieve more sufficient results.
Captured debris
考察：Protection deviceの比較

• 実験的にfilter deviceを比較 (Müller-Hülsbeck, J Endovasc Ther 2002)
  ➢ Angioguardが注入量の4.4%と最も多く取り逃がした

• Balloonとfilterとの比較 (1) (Kim, Korean J Radiol 2007)
  ➢ 術後DWI陽性率、塞栓性合併症発生率は同等

• Balloonとfilterとの比較 (2) (Zahn, J Am Coll Cardiol 2005)
  ➢ Balloonがより難しい病変に使用されていたが、周術期のイベントには差はなし

• 臨床的にfilter deviceを比較 (Hart, J Vasc Surg 2006)
  ➢ 低エコー輝度病変ではopen-cell-type stentあるいはconcentric-type filterの使用で合併症多い
考察: Patient selection for CAS

- 術前plaque imageと塞栓性合併症 (柏木, JNET 2008)
  - 狭窄長25 mm以上かつT1強調像でhigh、あるいはT2強調像でlowのplaqueを有する例で、有意に塞栓性合併症が多い

- フィルター内debris発生の因子 (Sprouse, J Vasc Surg 2005)
  - 高血圧、脂質代謝異常、9 mm以上のステント径、CAS施行中の神経症状発現などがdebris発生と関連
頸動脈狭窄症の診断・治療プロセス

頸動脈狭窄症（無症候、一過性虚血発作(TIA)、軽症脳梗塞）

血行再建の適応

なし

内科治療
薬剤投与

内科治療

あり

外科治療
CEA, CAS

外科治療

CEA手術リスク判定

CEA手術リスク判定

CAS

CAS

関連検査

MRI, MRA

脳血流SPECT

CTA

頚部エコー

脳内病変確認（脳梗塞や他の脳疾患）

狭窄の有無、粥腫の性状の判別

粥腫の性状の判別（MRI）、石灰化の確認（CT）

アクセスルートの確認

過灌流症候群のリスク判定

無症候性例では適応の判定の一助

最終診断、治療適応決定

アクセスルートの最終確認

ただしCAS高リスクなら
86 y.o. male: repeated TIA

Contra-lateral IC occlusion
Abdominal CT