

Can Flow diverters be used in acute SAH



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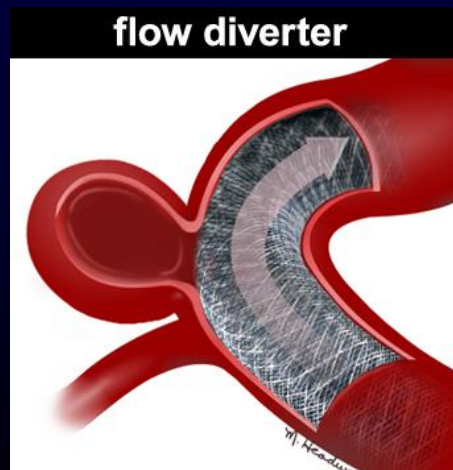
Dr. I Qtqish

Dr. M Khawladeh

Dr. S. Haddad

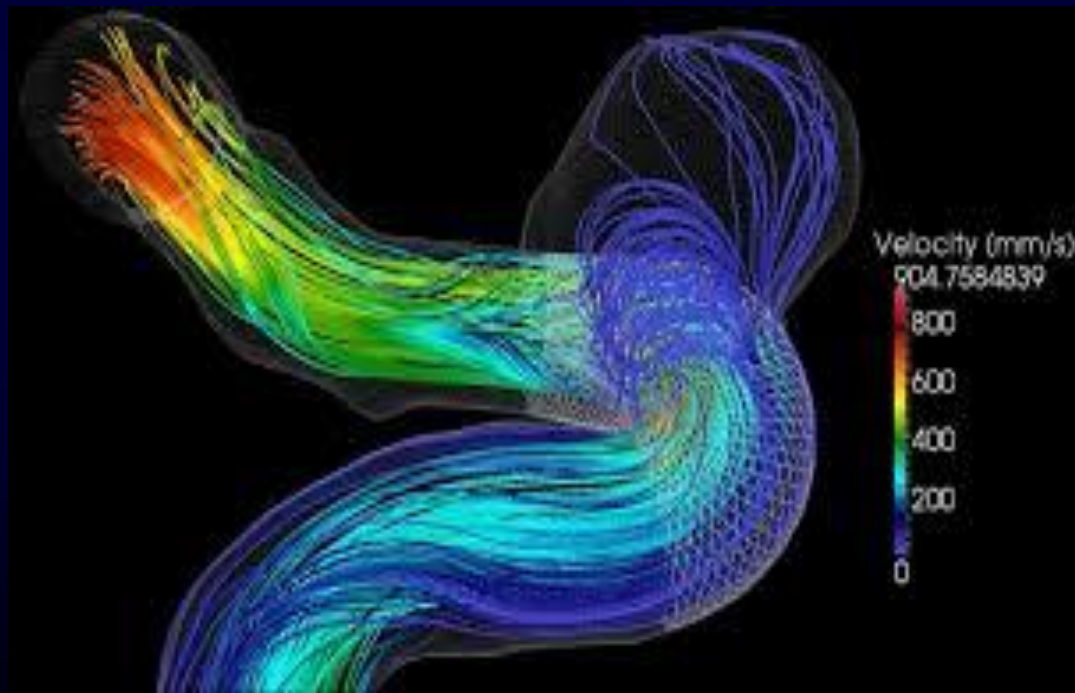
Dr. S Jfoot

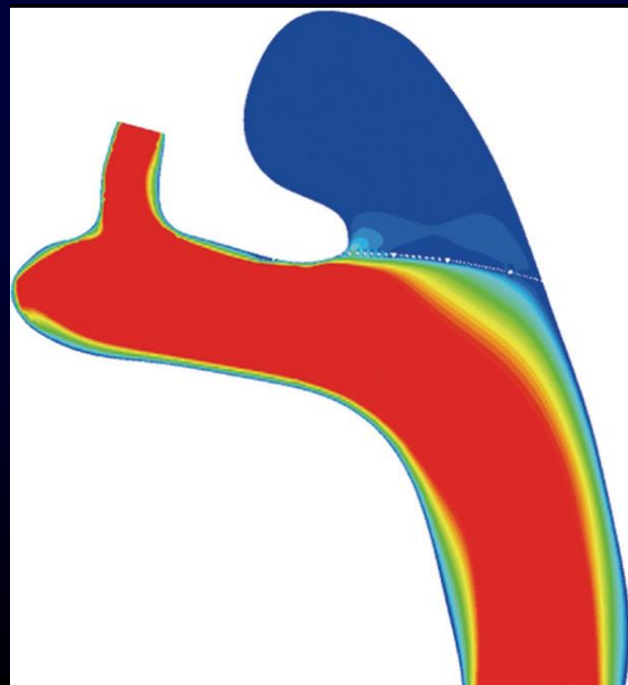
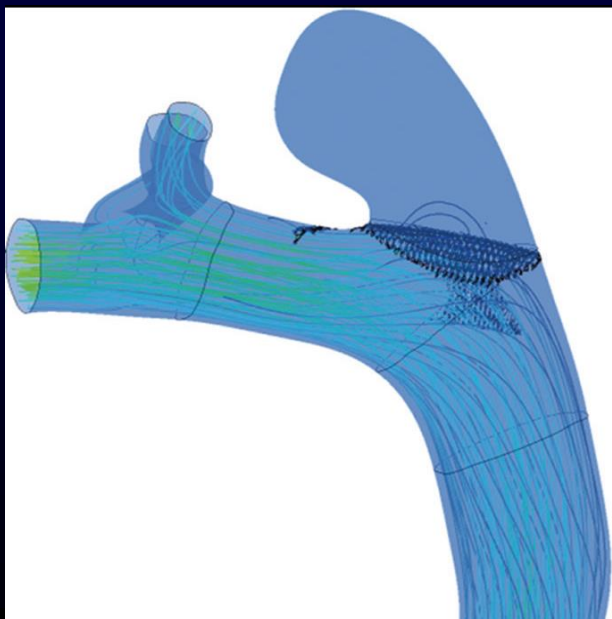
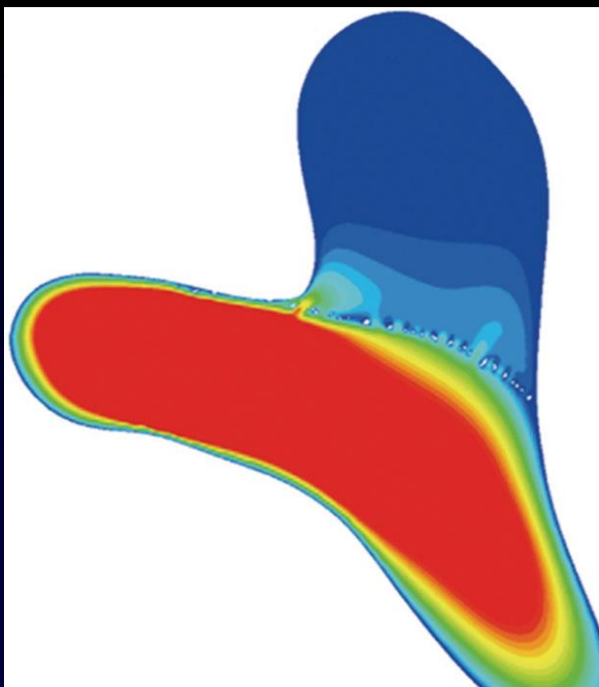
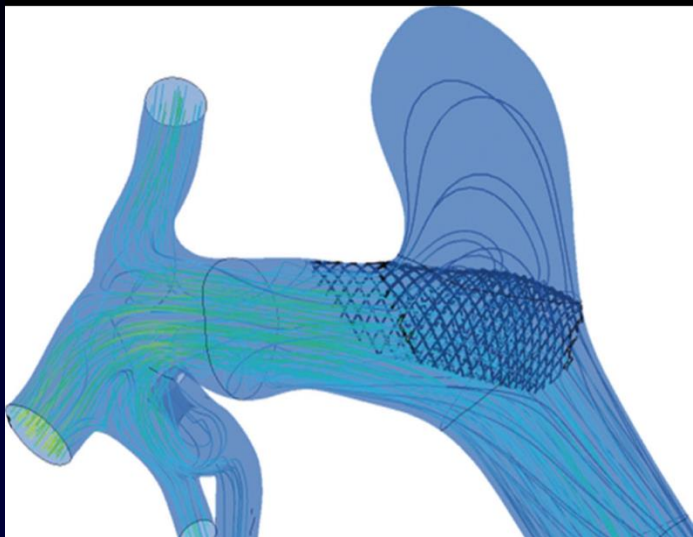
- Flow diverters represent a paradigm shift with the intervention carried out in the parent artery.
- Flow diverters were first tested in untreatable aneurysms or those that had failed previous endovascular therapy.
- Conceptually, flow diverters allow endoluminal reconstruction rather than endosaccular filling

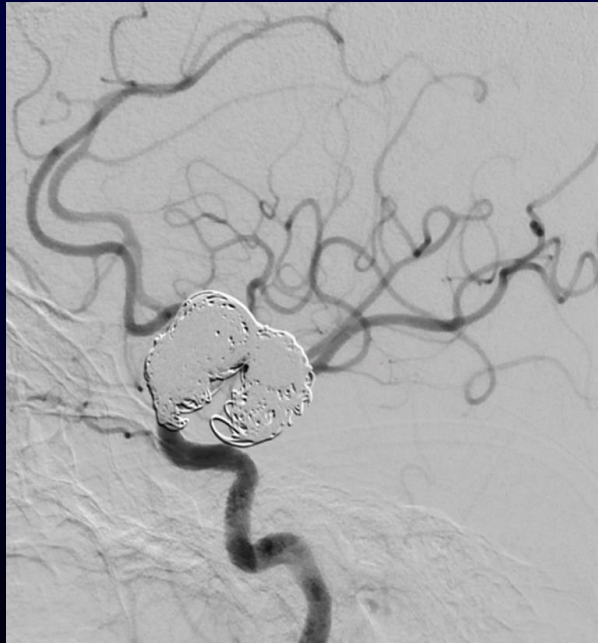


- It alter in-flow and out-flow jets, to induce aneurysm thrombosis.
Intrasaccular thrombosis ensues after device deployment.

-Subsequent neointimal **Overgrowth** covers the stent reconstructing the parent artery and eliminating the aneurysm/parent vessel interface







Thromboembolic complications with FD:

PUFS trial: Major ipsilateral stroke or neurologic death was 5.6%.

PITA study: Allowed medium and small aneurysms. Ischemic stroke occurred in (6.5%).

Endovascular Treatment of Intracranial Aneurysms With Flow Diverters

A Meta-Analysis

Waleed Brinjikji, MD; Mohammad H. Murad, MD, MPH; Giuseppe Lanzino, MD;
Harry J. Cloft, MD, PhD; David F. Kallmes, MD

Background and Purpose—Flow diverters are important tools in the treatment of intracranial aneurysms. However, their impact on aneurysmal occlusion rates, morbidity, mortality, and complication rates is not fully examined.

Methods—We conducted a systematic review of the literature searching multiple databases for reports on the treatment of intracranial aneurysms with flow-diverter devices. Random effects meta-analysis was used to pool outcomes of aneurysmal occlusion rates at 6 months, and procedure-related morbidity, mortality, and complications across studies.

Results—A total of 29 studies were included in this analysis, including 1451 patients with 1654 aneurysms. Aneurysmal complete occlusion rate was 76% (95% confidence interval [CI], 70%–81%). Procedure-related morbidity and mortality were 5% (95% CI, 4%–7%) and 4% (95% CI, 3%–6%), respectively. The rate of postoperative subarachnoid hemorrhage was 3% (95% CI, 2%–4%). Intraparenchymal hemorrhage rate was 3% (95% CI, 2%–4%). Perforator infarction rate was 3% (95% CI, 1%–5%), with significantly lower odds of perforator infarction among patients with anterior circulation aneurysms compared with those with posterior circulation aneurysms (odds ratio, 0.01; 95% CI, 0.00–0.08; $P<0.0001$). Ischemic stroke rate was 6% (95% CI, 4%–9%), with significantly lower odds of perforator infarction among patients with anterior circulation aneurysms compared with those with posterior circulation aneurysms (odds ratio, 0.15; 95% CI, 0.08–0.27; $P<0.0001$).

Conclusions—This meta-analysis suggests that treatment of intracranial aneurysms with flow-diverter devices is feasible and effective with high complete occlusion rates. However, the risk of procedure-related morbidity and mortality is not negligible. Patients with posterior circulation aneurysms are at higher risk of ischemic stroke, particularly perforator infarction. These findings should be considered when considering the best therapeutic option for intracranial aneurysms. (*Stroke*. 2013;44:442-447.)

Key Words: endovascular treatment ■ interventional neuroradiology ■ intracranial aneurysm
■ subarachnoid hemorrhage

No data to suggest the rate of complications in acute treatment of ruptured aneurysms with flow diverters.

Pipeline™ Flex Embolization Device Evolution

2008

Pipeline™
Embolization Device



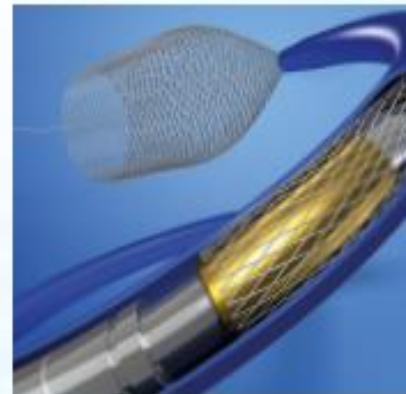
2012

Navien™ 5F/6F
Intracranial Support
Catheter



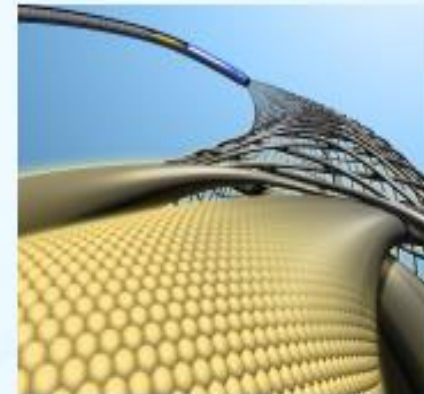
2014

Pipeline™ Flex
Embolization Device



2014

Pipeline™ Flex
Embolization
Device with Shield
Technology™



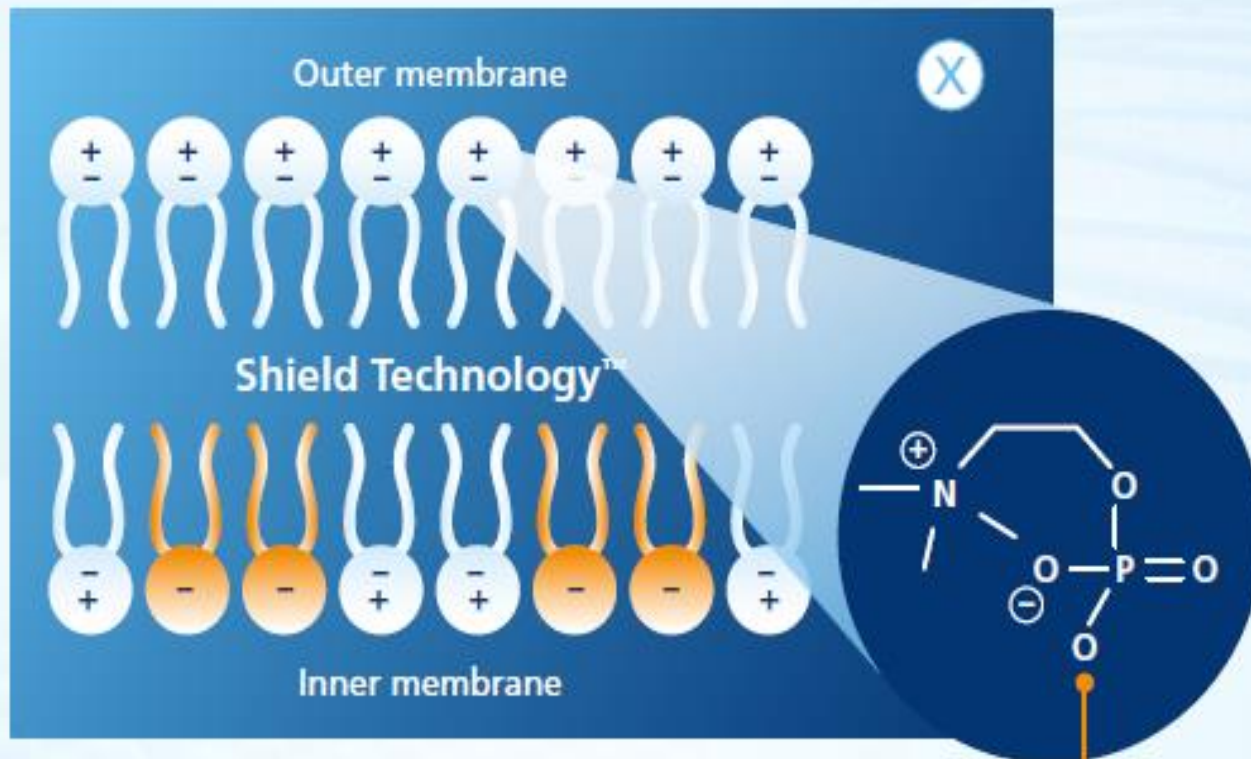
Shield Technology™
Innovation at the Surface

Shield Technology is a surface modification where a synthetic phosphorylcholine (PC) polymer is covalently bonded to the strands that make up the Pipeline device braid.

Shield Technology is designed to improve the hemocompatibility and deliverability of the Pipeline™ implant.

Shield Technology™

Innovation at the Surface



The phosphorylcholine
(PC) headgroup

Shield Technology™

Surface Modification vs. Coating

Method	Shield Technology™	PC Coating (Used on initial prototypes)
Mode of Action	Inert Polymer	Polymer±Drug
Thickness	<3 nanometers ¹¹ (0.01% of one braid strand)	> 500 nanometers ¹¹
Adhesion to the substrate	Chemical Bonding	Physical Encapsulation
Process	Chemical Reaction	Dipping, Spray or Brush

Why Improve Hemocompatibility?

Coils

*Guglielmi Detachable Coil embolization of cerebral aneurysms:
11 years ' Experience*

Yuichi Murayama, M.D., J Neurosurg 98:959–966, 2003



Coils
2003

COMPLICATIONS

With pre and post anti-coagulation and anti-platelet therapy, embolization complications have dropped, however, continue to be the most prevalent issue.

Why Improve Hemocompatibility?



**Aneurysm
Bridging Stents**

Aneurysm Bridging Stents

Stent-Supported Aneurysm Coiling: A Literature Survey of Treatment and Follow-Up

Shapiro, AJNR Am J Neuroradiol 33:159–63 Jan 2012

COMPLICATIONS

In the combined 39 articles with 1517 patients, the percent thromboembolic issues was high at close to 10%, leading to 0.6% death in overall cases.

Why Improve Hemocompatibility?

Flow Diverters

*International Retrospective Study of the Pipeline Embolization
Device: A Multicenter Aneurysm Treatment Study*

Kallmes AJNR Am J Neuroradiol Published October 29,
2014 as 10.3174/ajnr.A4111

COMPLICATIONS

Thromboembolic complications were most prevalent,
especially in large anterior circulation aneurysms or posterior
circulation aneurysms.



Flow Diverters
2014

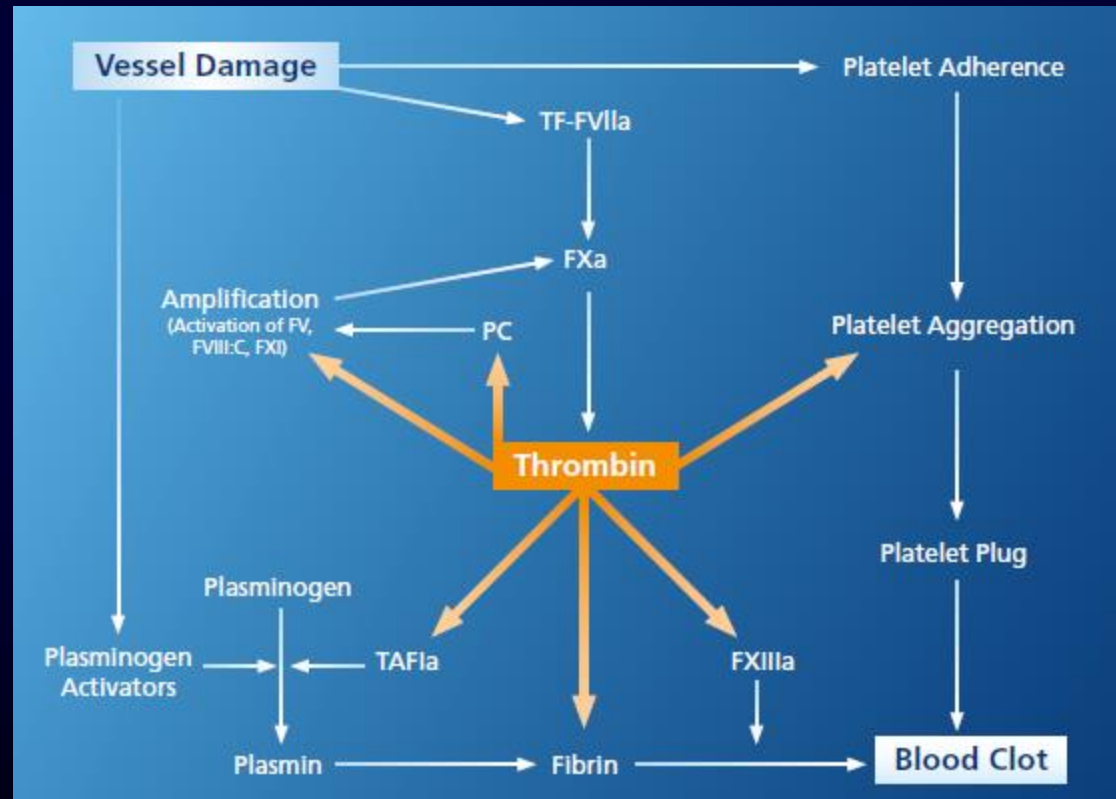
Improving Hemocompatibility

The Role of Thrombin

Thrombin

One of the central enzymes in blood coagulation.

The rate of thrombin formation and the total amount of thrombin formed can be considered to be a reflection of the potential coagulation activity in plasma.



What is the **Thrombogram?**

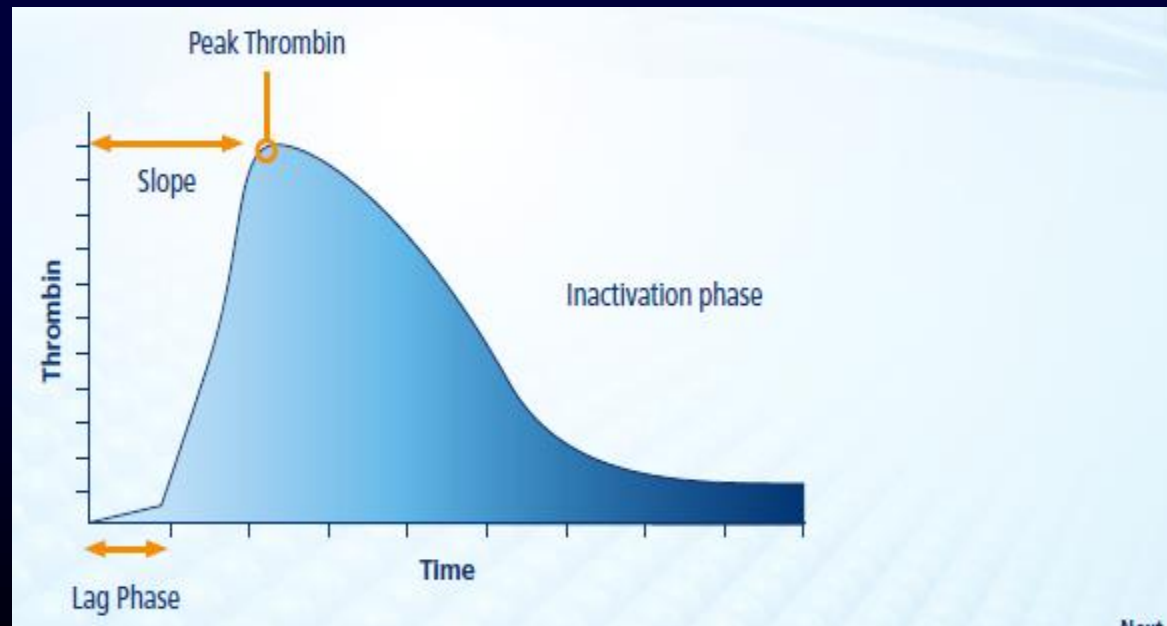
Fluorescent assay comparing Peak Thrombin (nM) using freeze dried human platelets and plasma.

Measures the fluorescence generated by thrombin cleavage of a fluorogenic substrate over time upon activation of the coagulation cascade by different materials

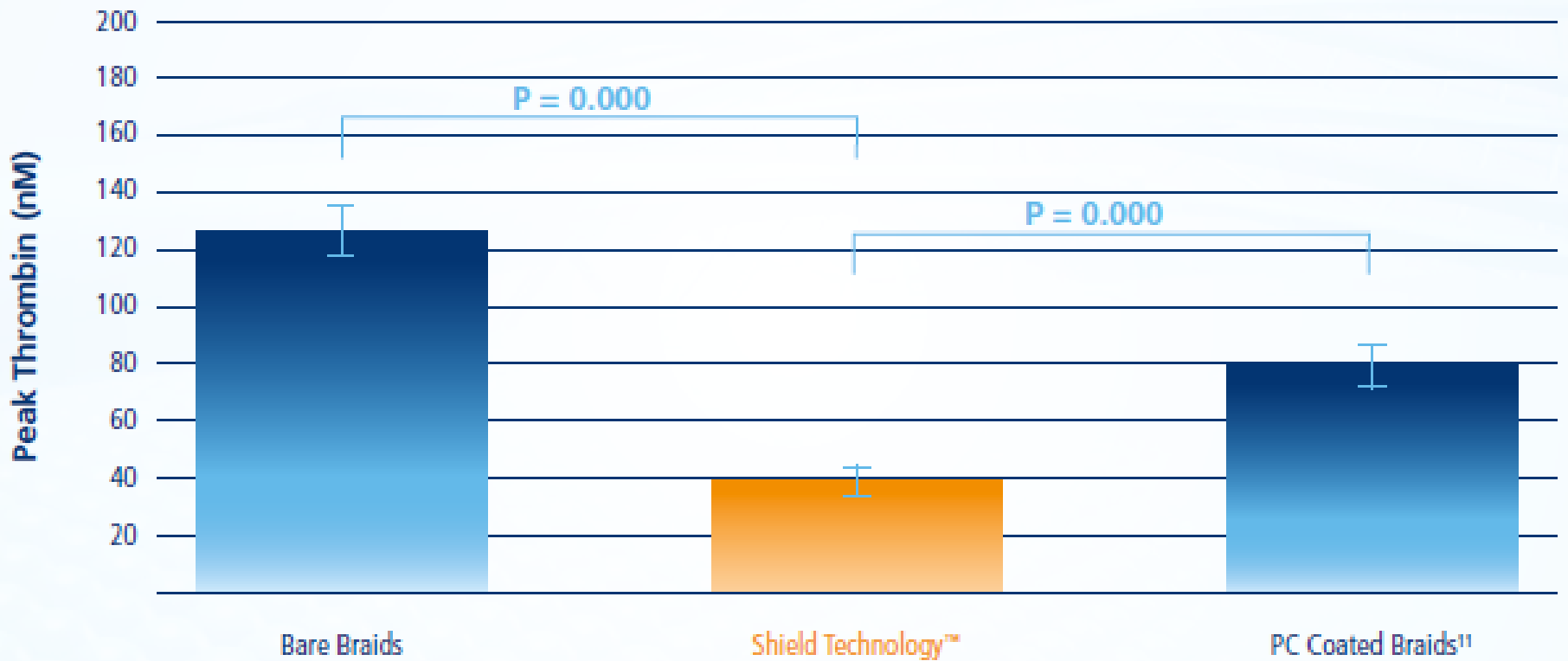
What is the Thrombogram?

Repeatable, validated and used clinically

More sensitive to differences than PTT (industry standard)



Peak Thrombin (N=15)



*Note: PC coatings used on initial prototypes are similar to EVAHEART LVAD, Endeavor and BiodivYsio Stents .

Materials

Between January 2016 – May 20th 2016

10 patients treated with pipe line shield as primary treatment with no pre loading for antiplatelets.

Age: 34-76 years.

Sex : M: F 6:4

Materials

Presentation:

8 patients with acute SAH

2 patients with acute symptomatic large aneurysms

Location of aneurysm:

Acom A : 3

MCA: 3

paraophthalmic: 1

Pcom: 1

ICA: 2

Date of treatment form SAH: 3-10 days

Diameter range: 2.5mm-25.0 mm

The protocol

The decision for treatment of acute SAH or symptomatic aneurysms with FD was discussed for each case by the ethical committee of the department and hospital.

Special consent form for using FD without antiplatelets pre loading was also obtained.

The protocol

- The patient is loaded with ~5000 IU of Heparin depending on body weight. (70 IU / kg) after the catheter was placed across the aneurysm neck.
- ACT was obtained when available, to each ~ 150
- Heparin was infused hourly at a rate of 1000 IU /hr. Also depending on ACT level.
- Elevation of blood pressure to range of 130-140 mmhg after deployment of the FD.

The protocol

- after deployment of FD , patient was kept on table with control angiogram Q 15 min to evaluate for thrombosis or clotts within the FD.
- After 2 hours , the patient was transferred to the ICU with the sheath in Femoral artery in place.
- Patients were awakened after 2 hours if angio showed no abnormality.

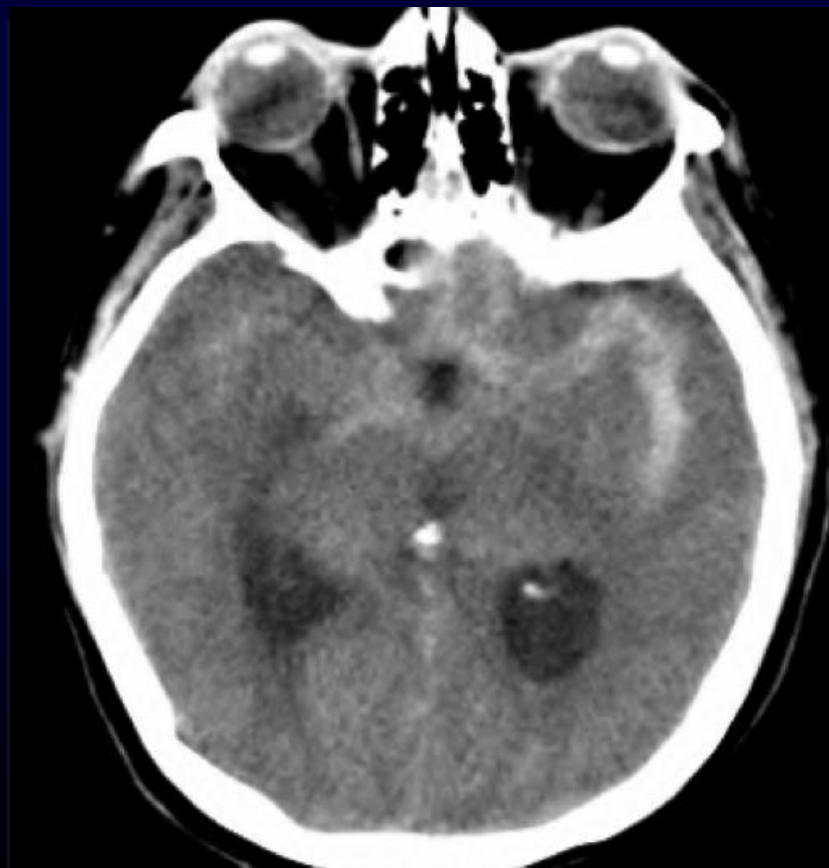
The protocol

- patients kept on full dose heparinization of 1000IU /Hr IV for 12 hours.
- Patients started on clexane according to weight after 4 hours in ICU
- No antiplatelets therapy given.
- Brain MRI obtained at 48 hours if patients are not symptomatic.
- Cerebral CT and CTA at 12 weeks was requested.
- Control angiogram at 8-12 weeks.

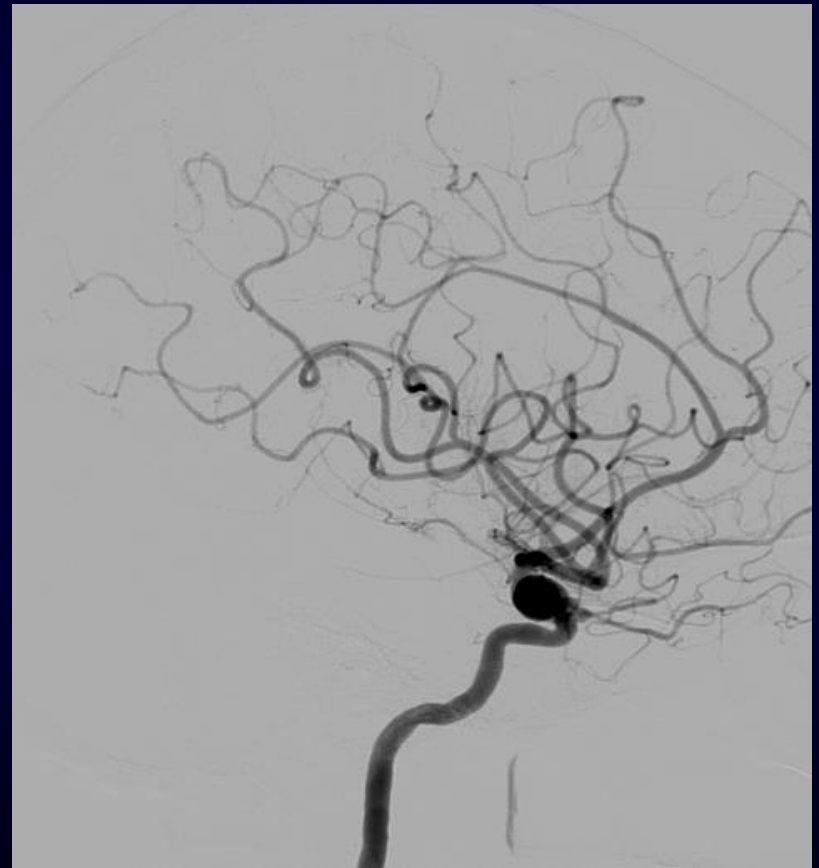
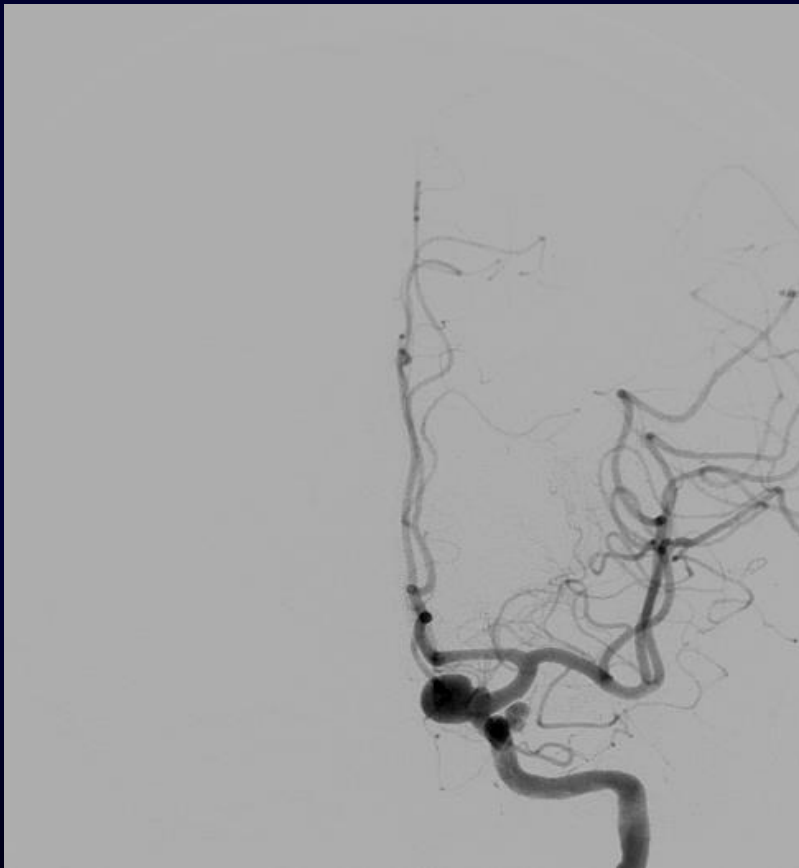
The protocol

- Patients were shifted from clexane to antiplatelets after 2nd week.
- Cerebral CT and CTA during the first week was requested in 3 patient

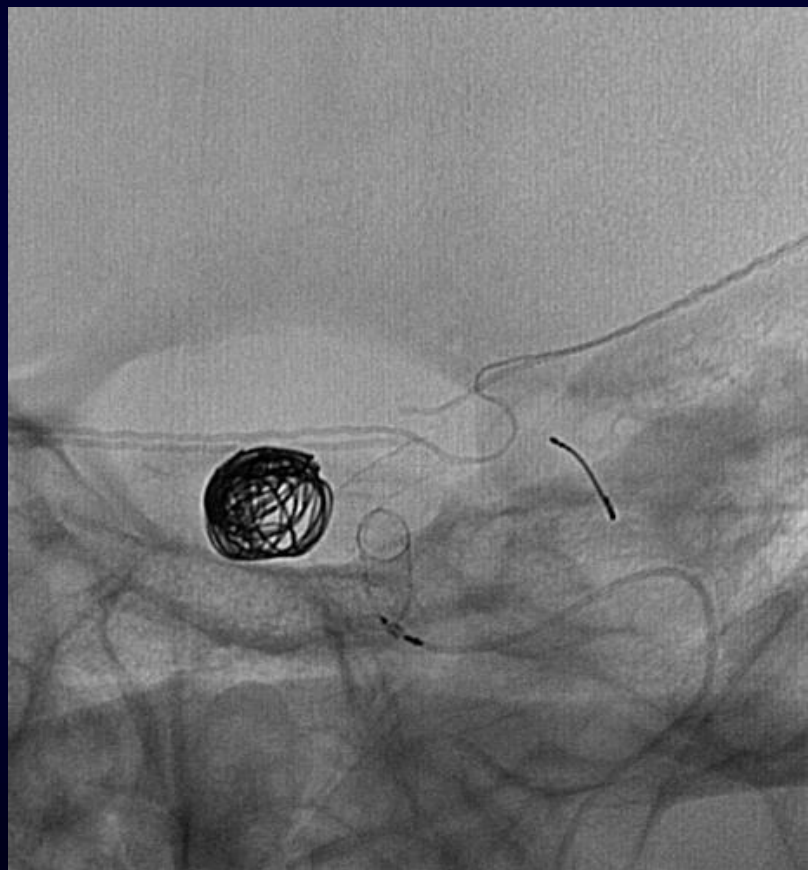
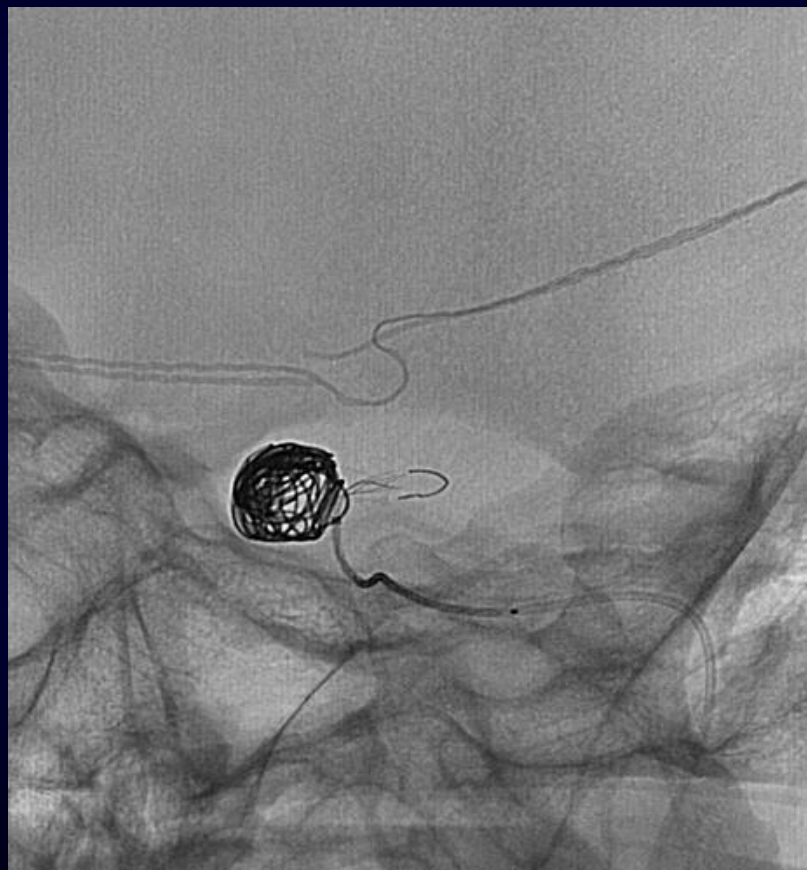
Ibtisam



44 years old Female pt., presented with SAH

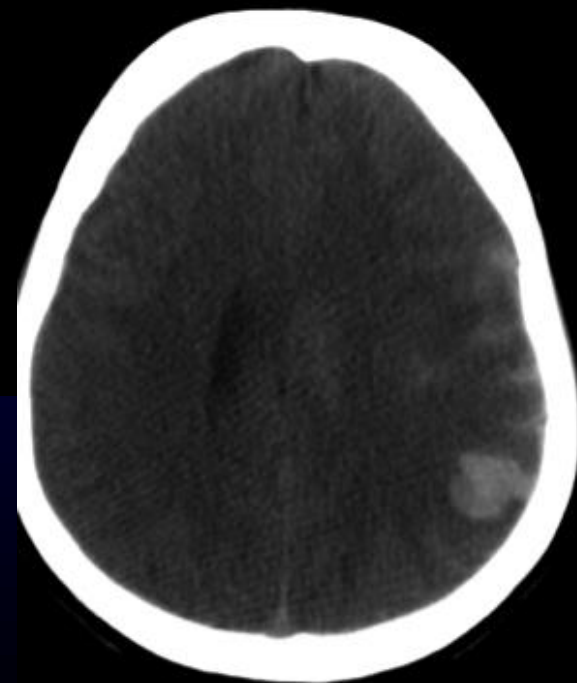
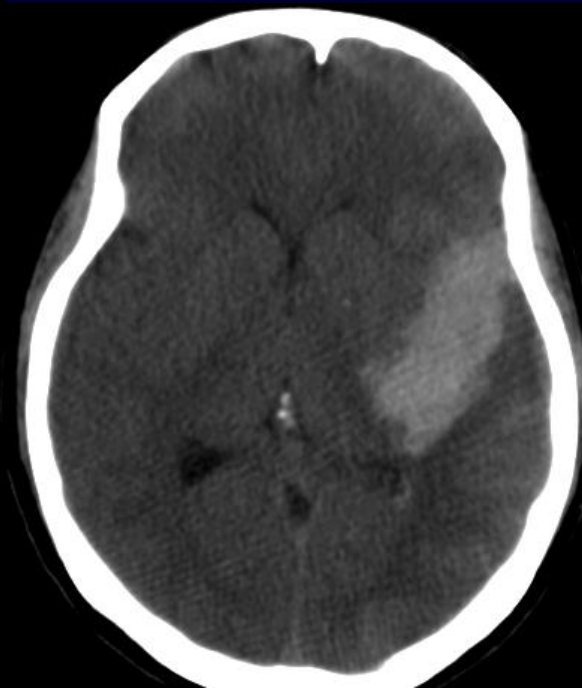




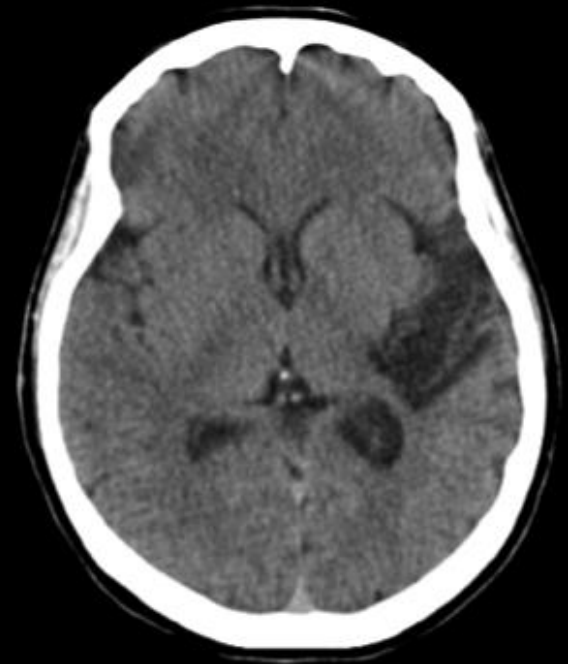




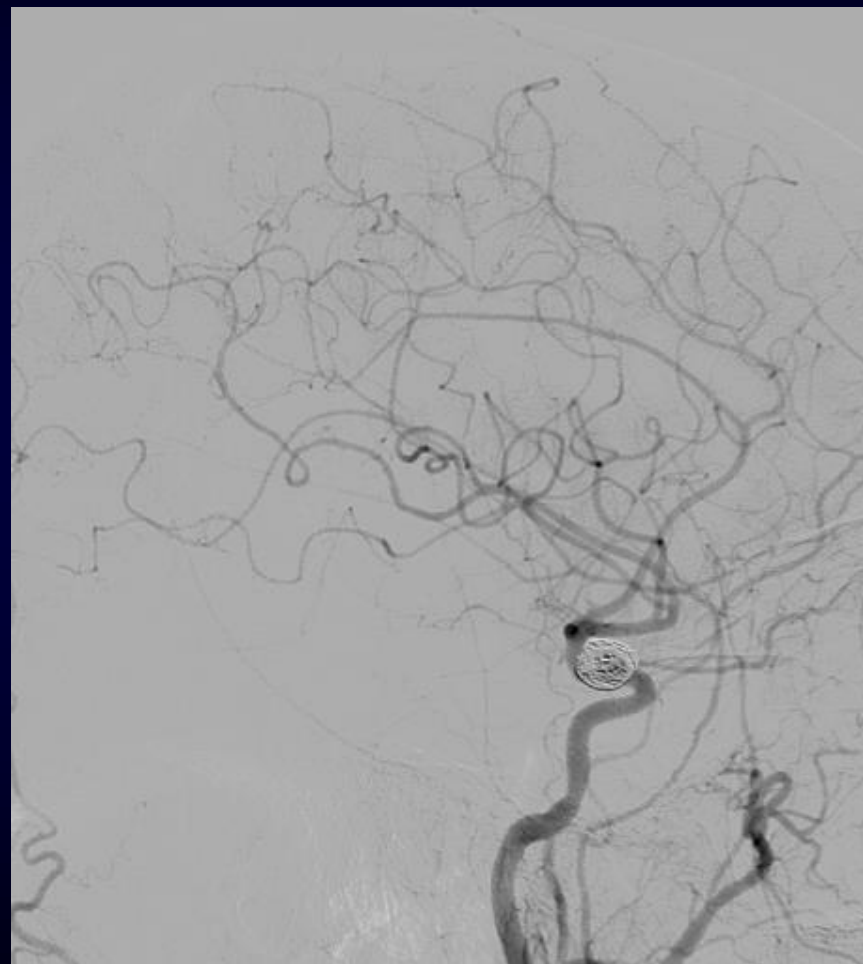
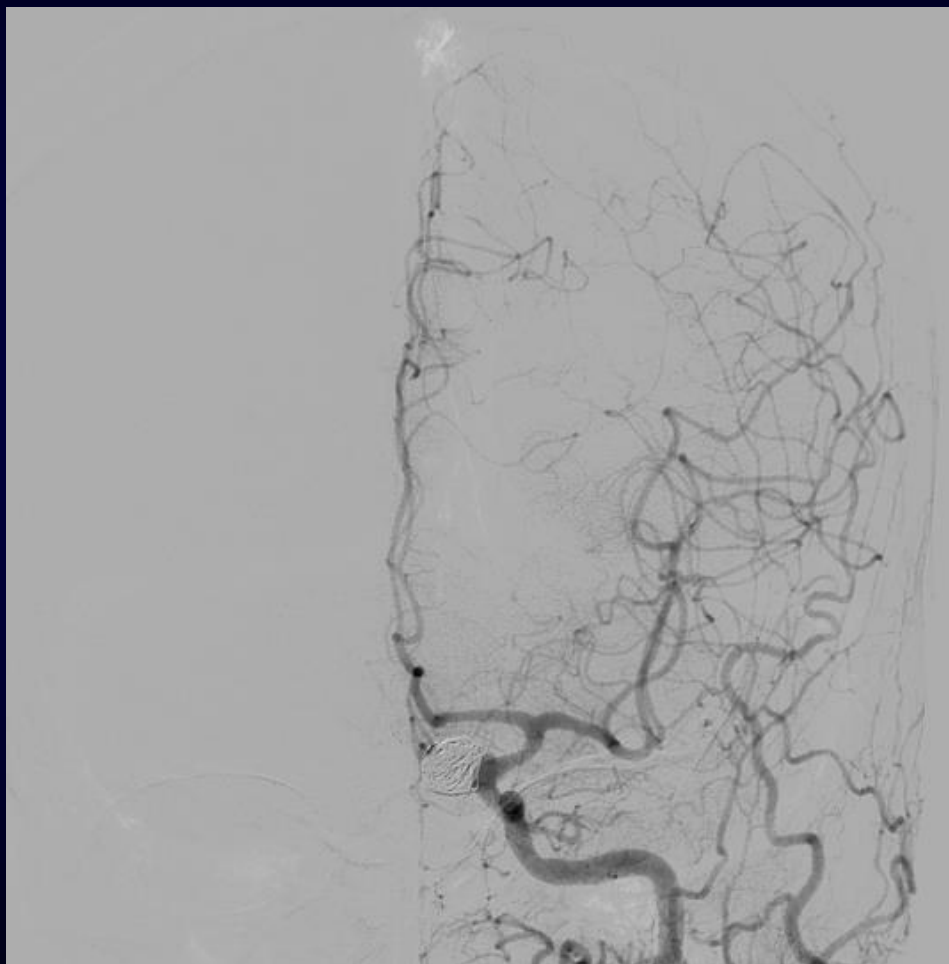
6 hours later

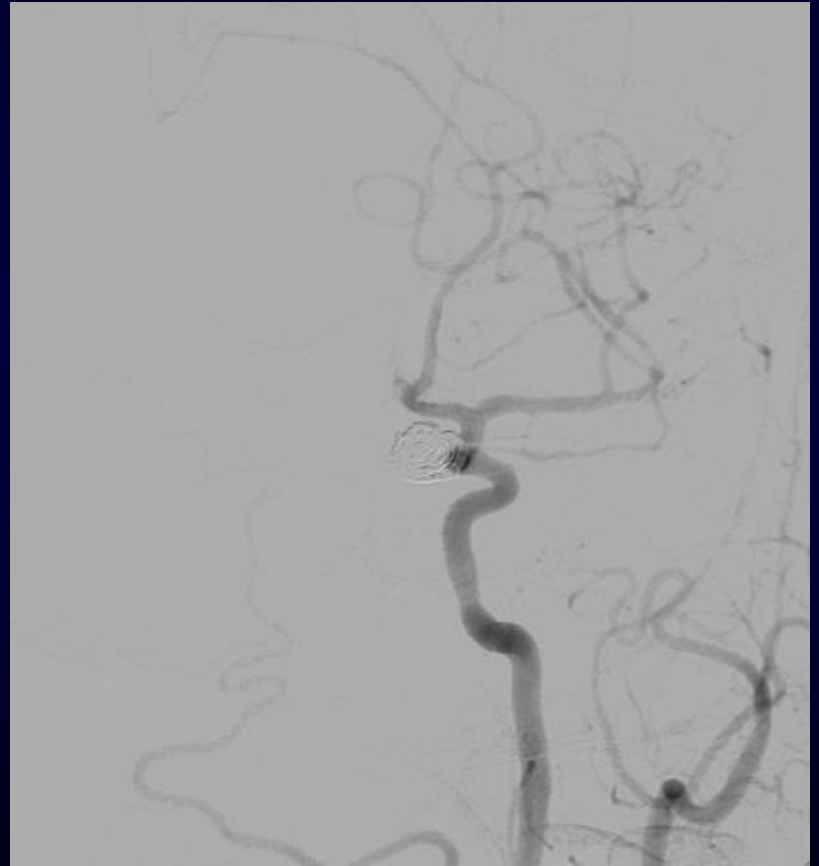
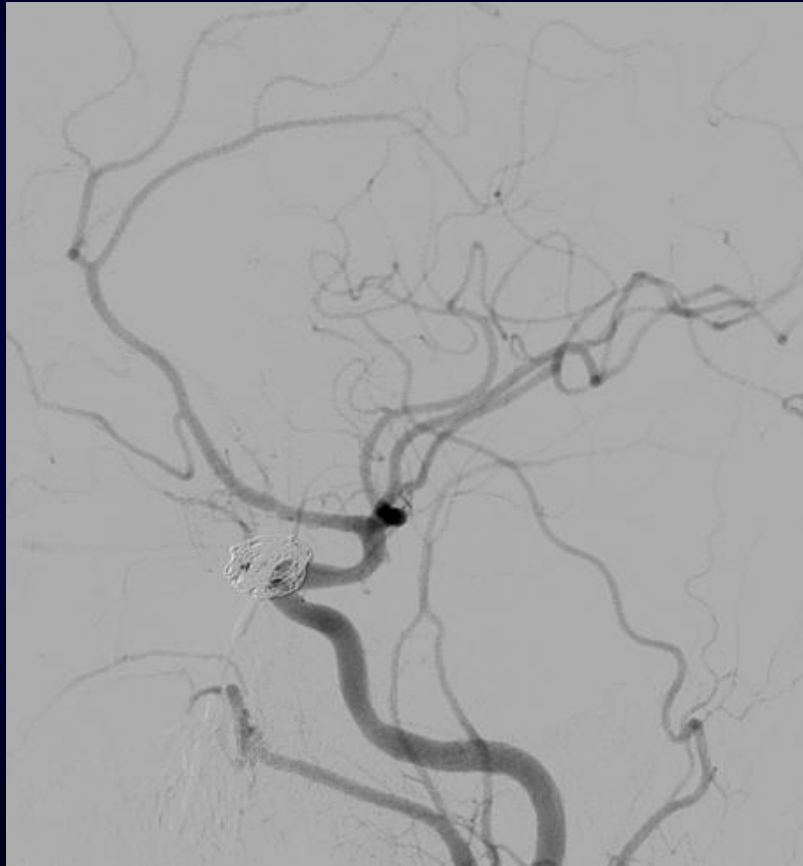


2 days post EVD



3 months F/U





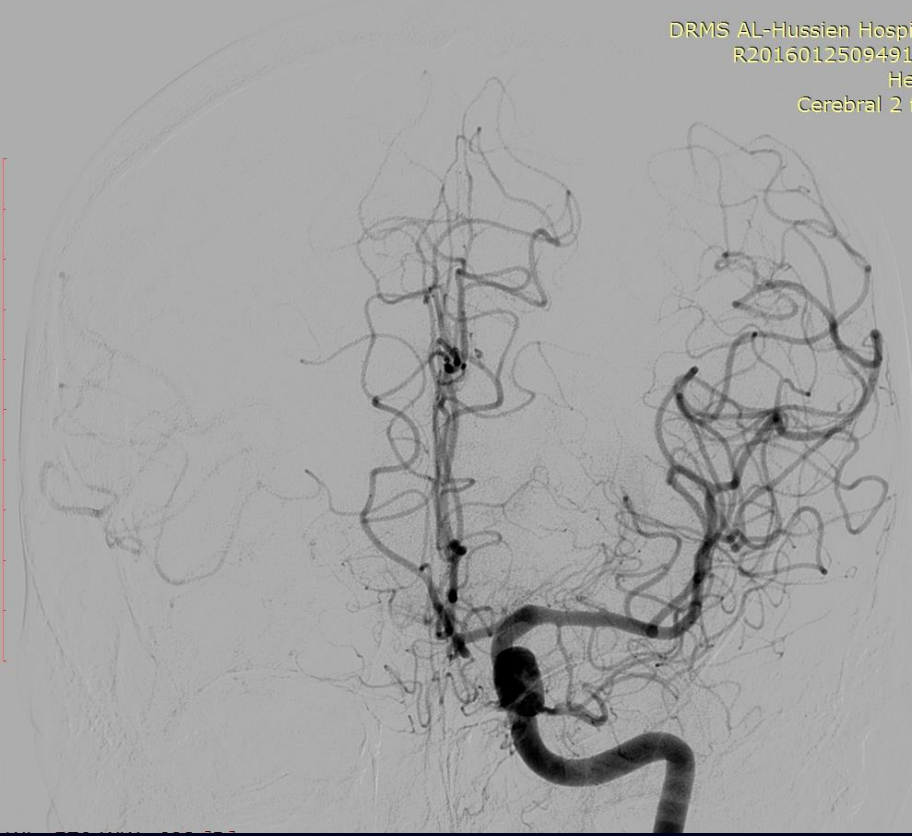
37 year old male patient referred from peripheral hospital diagnosed as S.A.H



Im: 6/13
Se: 3

SARI IBRAHEEM KHAL
97910471

DRMS AL-Hussien Hospi
R2016012509491
He
Cerebral 2



Im: 6/13
Se: 3

SARI IBRAHEEM KHAL
97910471

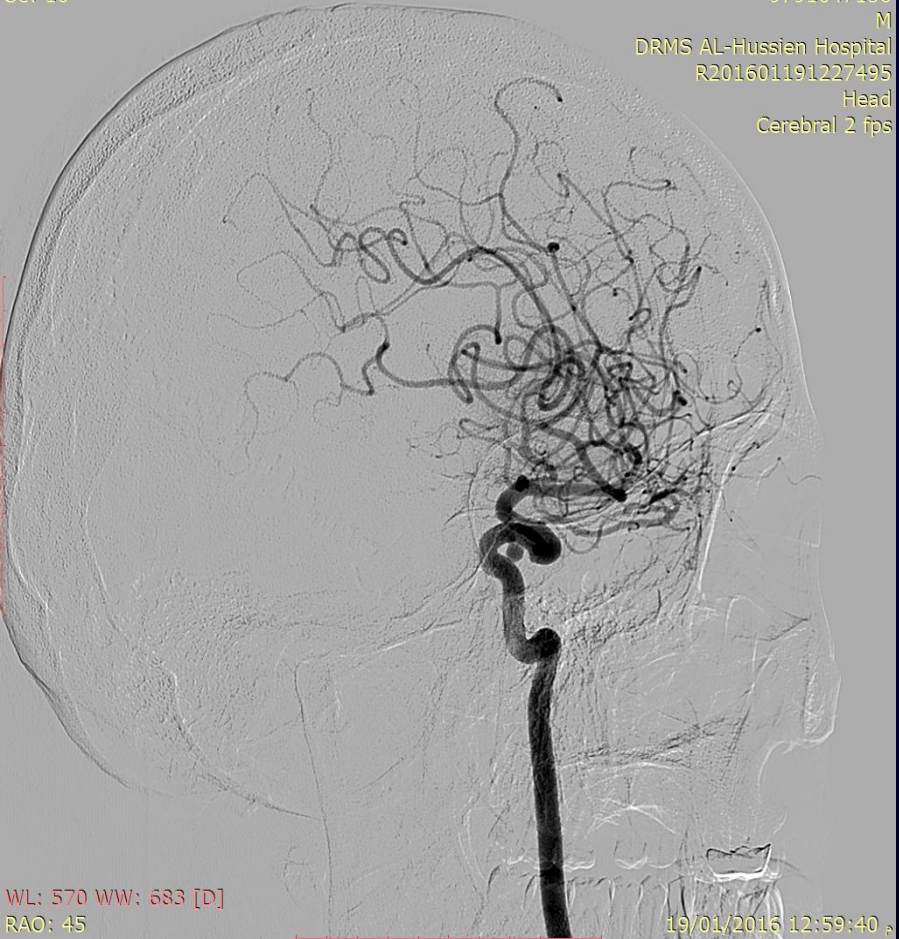
DRMS AL-Hussien Hospi
R2016012509491
He
Cerebral 2



WL: 570 WW: 683 [D]

Im: 6/14
Se: 10

SARI IBRAHEEM KHALED
9791047156
M
DRMS AL-Hussien Hospital
R201601191227495
Head
Cerebral 2 fps



WL: 570 WW: 683 [D]
RAO: 45

19/01/2016 12:59:40

Im: 7/11
Se: 11

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9791047156
M
DRMS AL-Hussien Hospital
R201601191227495
Head
Cerebral 2 fps



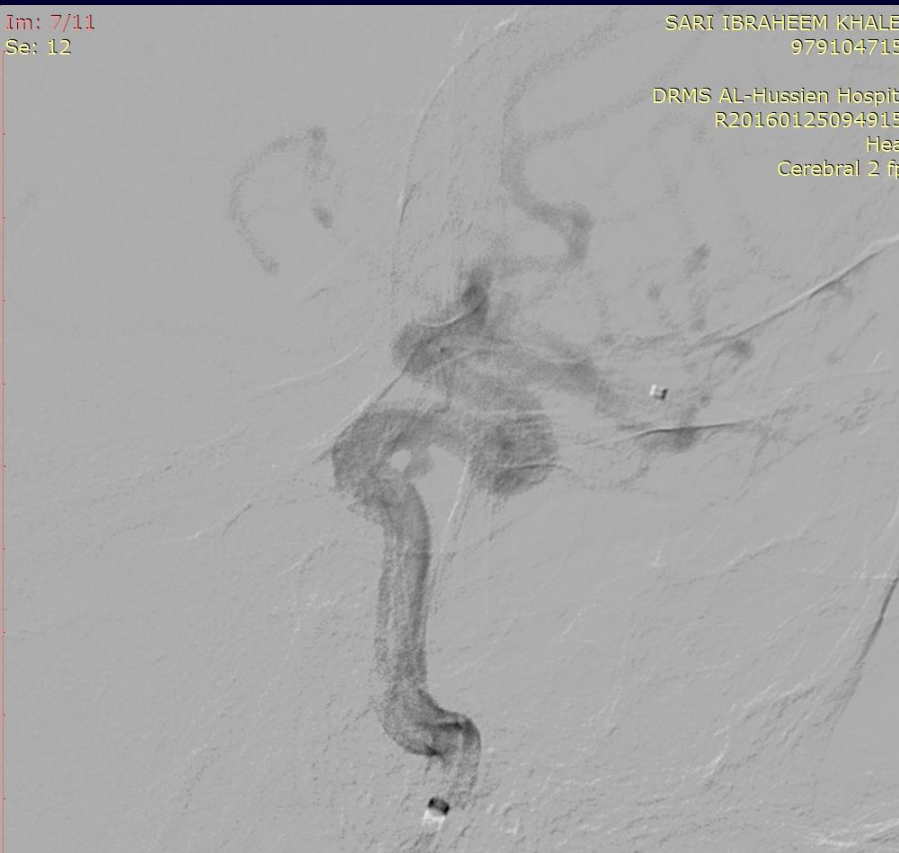
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RAO: 45

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Im: 7/11
Se: 12

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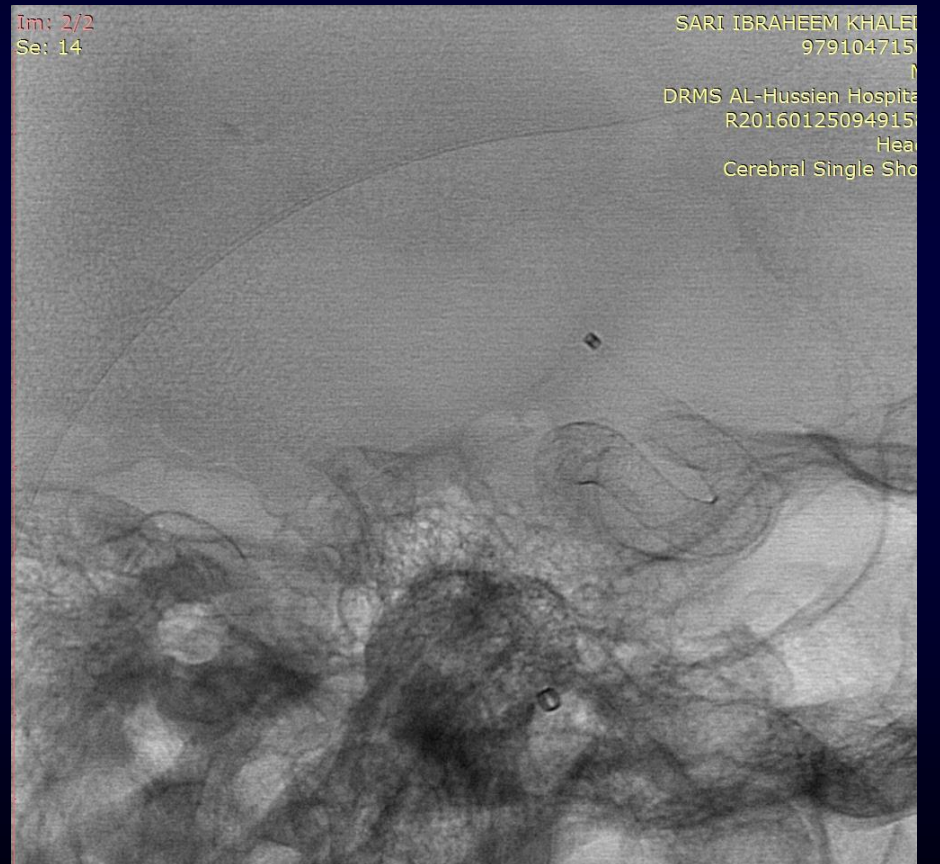
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R20160125094915
Hea
Cerebral 2 ft

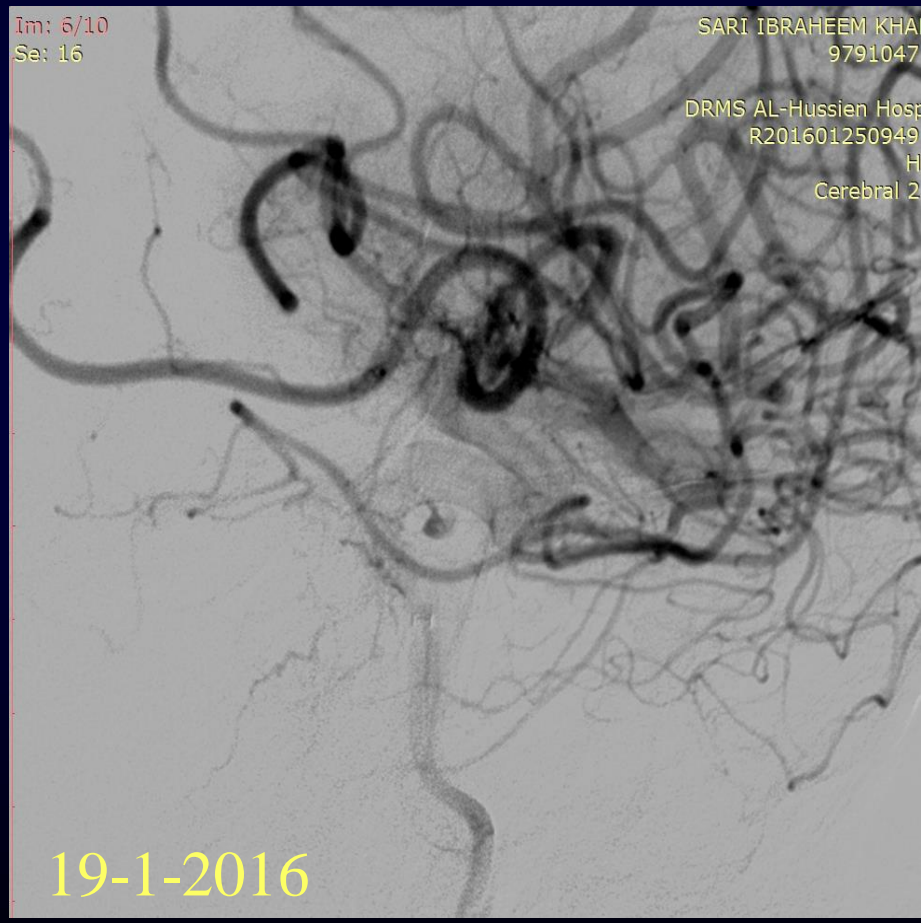
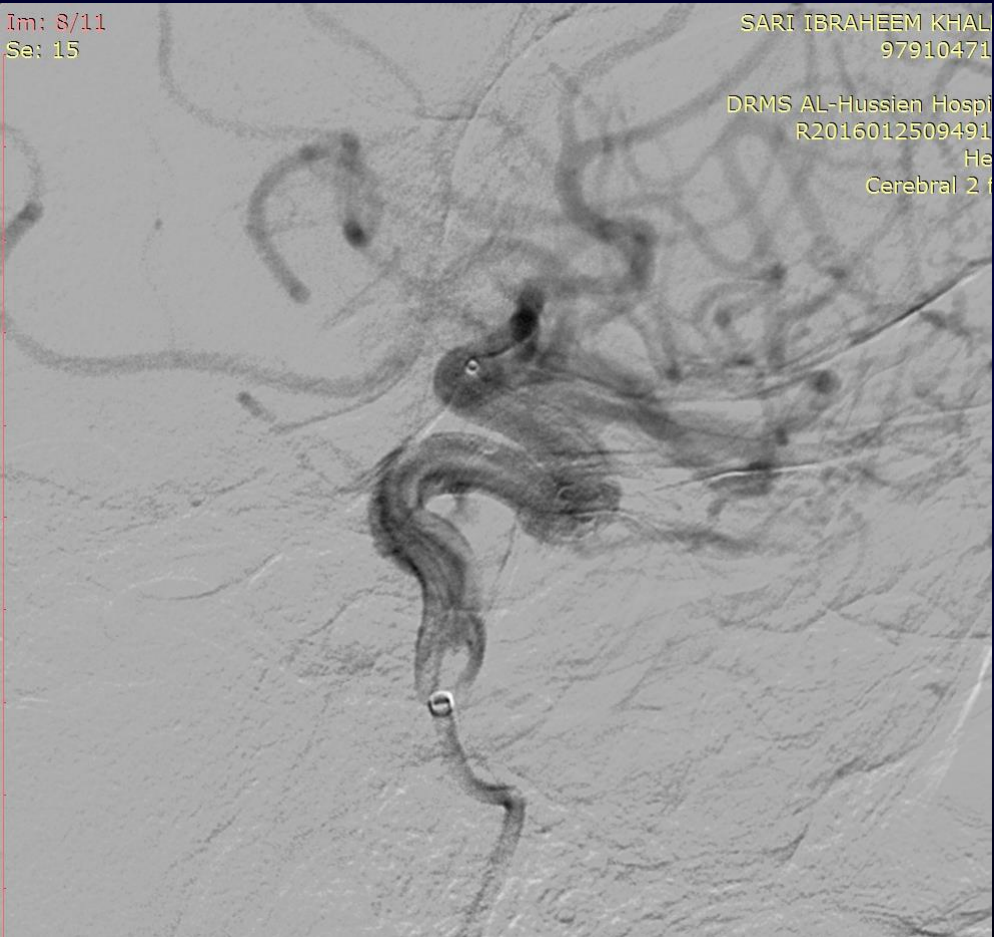


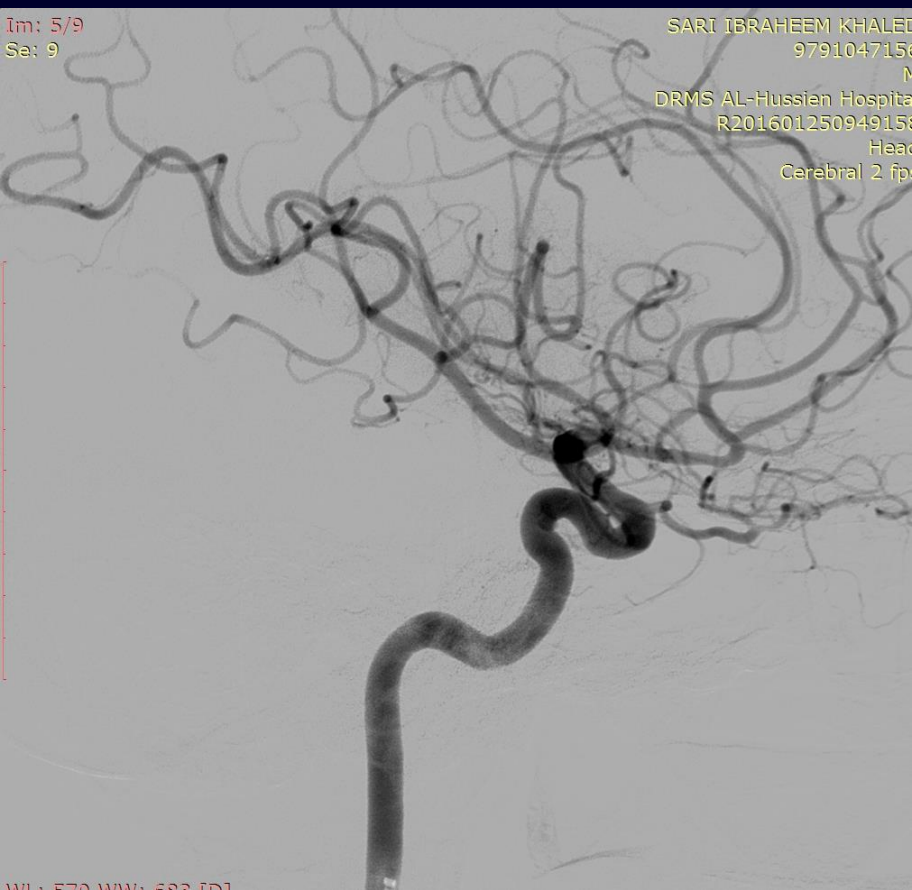
Im: 2/2
Se: 14

SARI IBRAHEEM KHALE
979104715

DRMS AL-Hussien Hospita
R20160125094915
Hea
Cerebral Single Sho





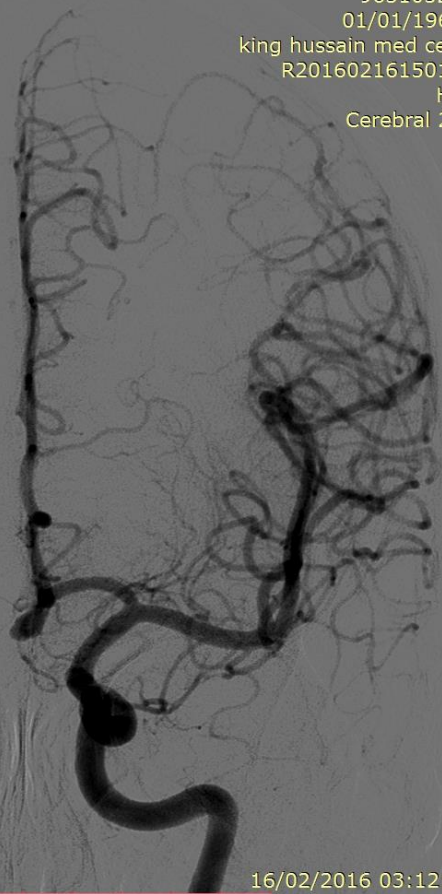


25-3-2016

53 year old male patient know to have
hypertension referred from peripheral
hospital diagnosed S.A.H

Im: 5/10
Se: 10

MOHAMD MAHMOUD AWAD
9631032172
01/01/1963 M
king hussain med center
R201602161501057
Head
Cerebral 2 fps



WL: 570 WW: 683 [D]
RAO: 1 CRA: 31

16/02/2016 03:12:46

Im: 4/9
Se: 11

MOHAMD MAHMOUD AWAD
9631032172
01/01/1963 M
king hussain med center
R201602161501057
Head
Cerebral 2 fps

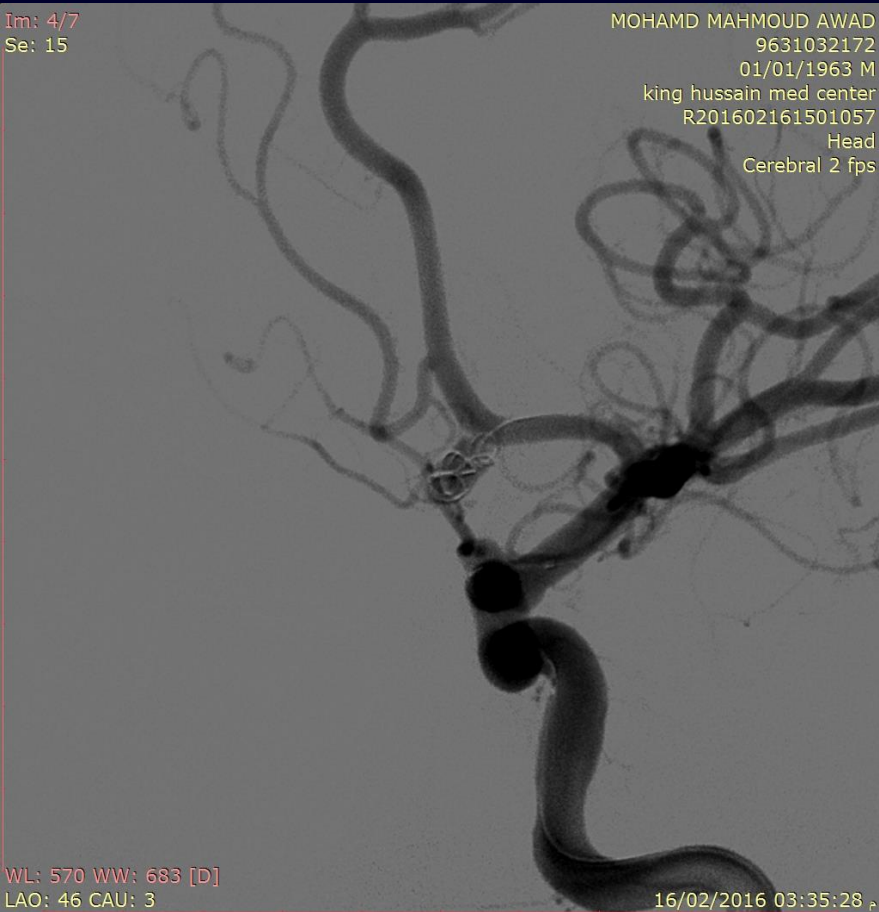


WL: 570 WW: 683 [D]
LAO: 28 CRA: 11

16/02/2016 03:13:07

Im: 4/7
Se: 15

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9631032172
01/01/1963 M
king hussain med center
R201602161501057
Head
Cerebral 2 fps

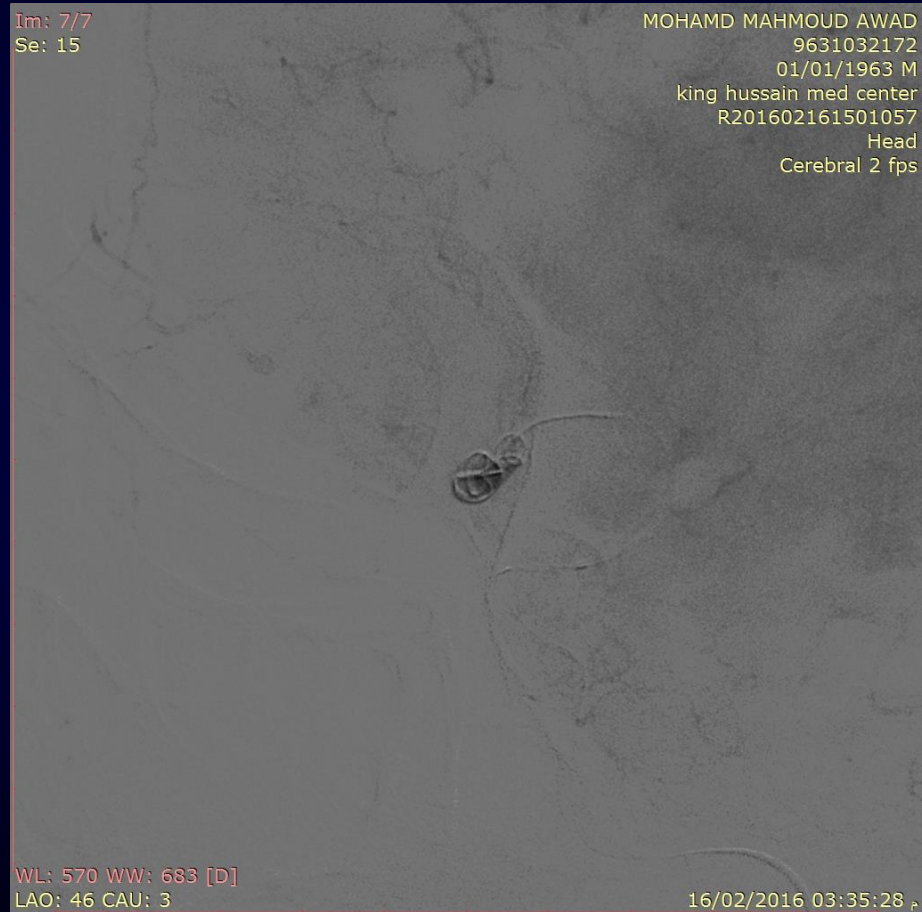


WL: 570 WW: 683 [D]
LAO: 46 CAU: 3

16/02/2016 03:35:28 p

Im: 7/7
Se: 15

MOHAMD MAHMOUD AWAD
9631032172
01/01/1963 M
king hussain med center
R201602161501057
Head
Cerebral 2 fps



WL: 570 WW: 683 [D]
LAO: 46 CAU: 3

16/02/2016 03:35:28 p

Im: 7/9
Se: 18

MOHAMD MAHMOUD AWAD
9631032172
01/01/1963 M
king hussain med center
R201602161501057
Head
Cerebral 2 fps

WL: 570 WW: 683 [D]
LAO: 46 CAU: 3

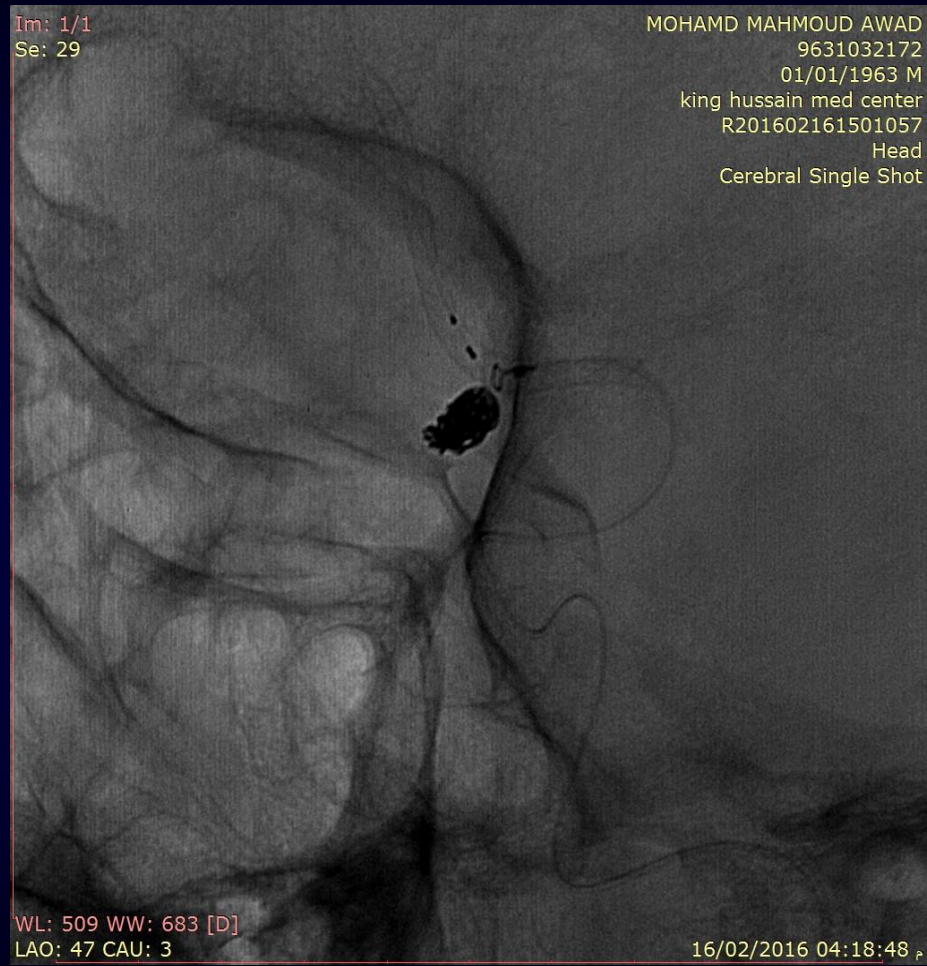
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Im: 7/9
Se: 18

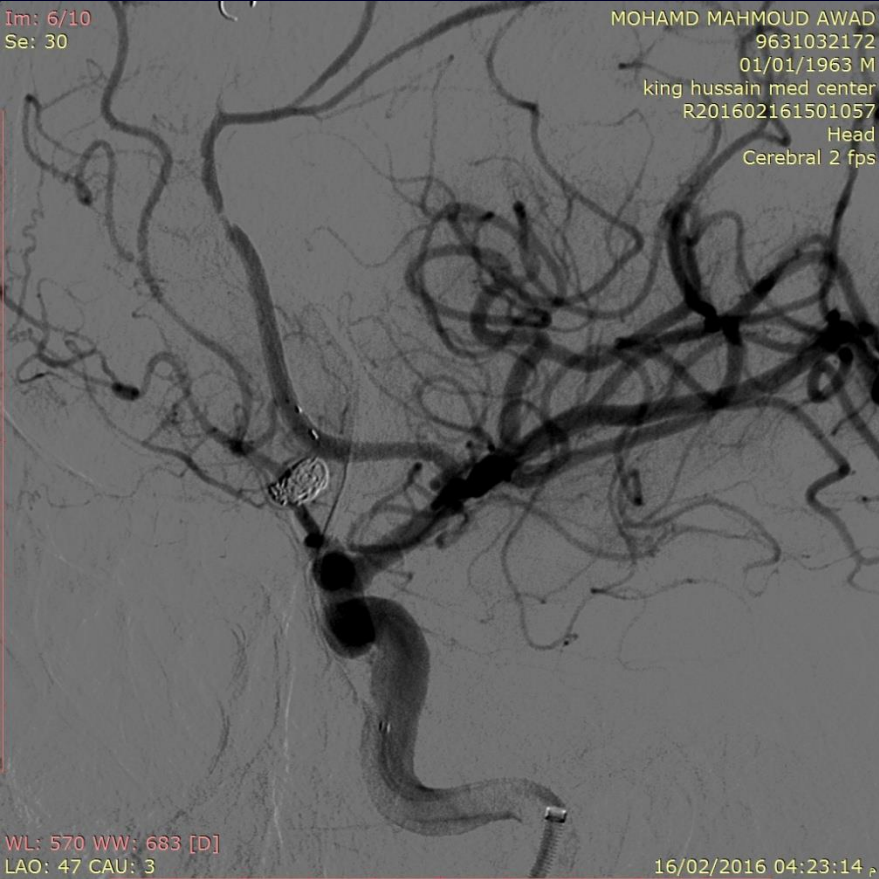
MOHAMD MAHMOUD AWAD
9631032172
01/01/1963 M
king hussain med center
R201602161501057
Head
Cerebral 2 fps

WL: 570 WW: 683 [D]
LAO: 46 CAU: 3

16/02/2016 03:51:42 p



Wire dislocated



Im: 3/10
Se: 40

MOHAMD MAHMOUD AWAD
9631032172
01/01/1963 M
king hussain med center
R201602161501057
Head
Cerebral 2 fps

WL: 570 WW: 683 [D]
LAO: 47 CAU: 3

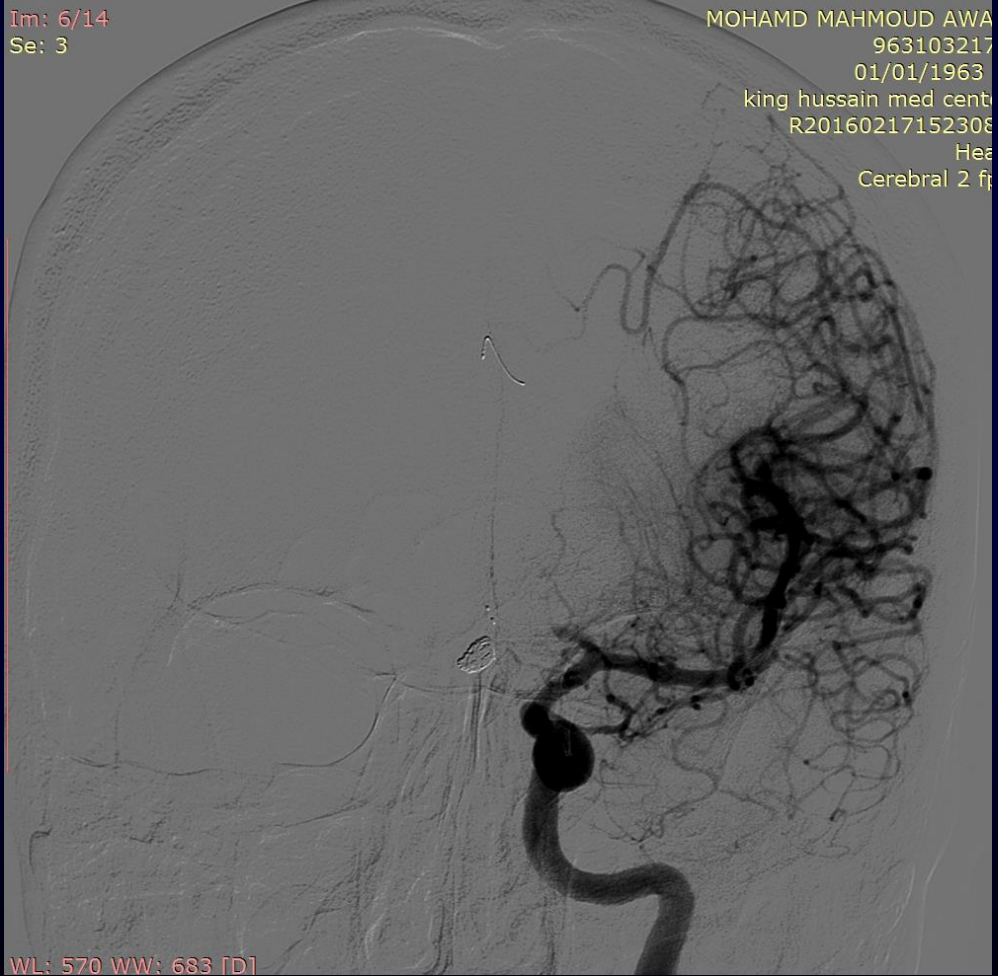
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Final angiogram after 2 hours

1 week post procedure

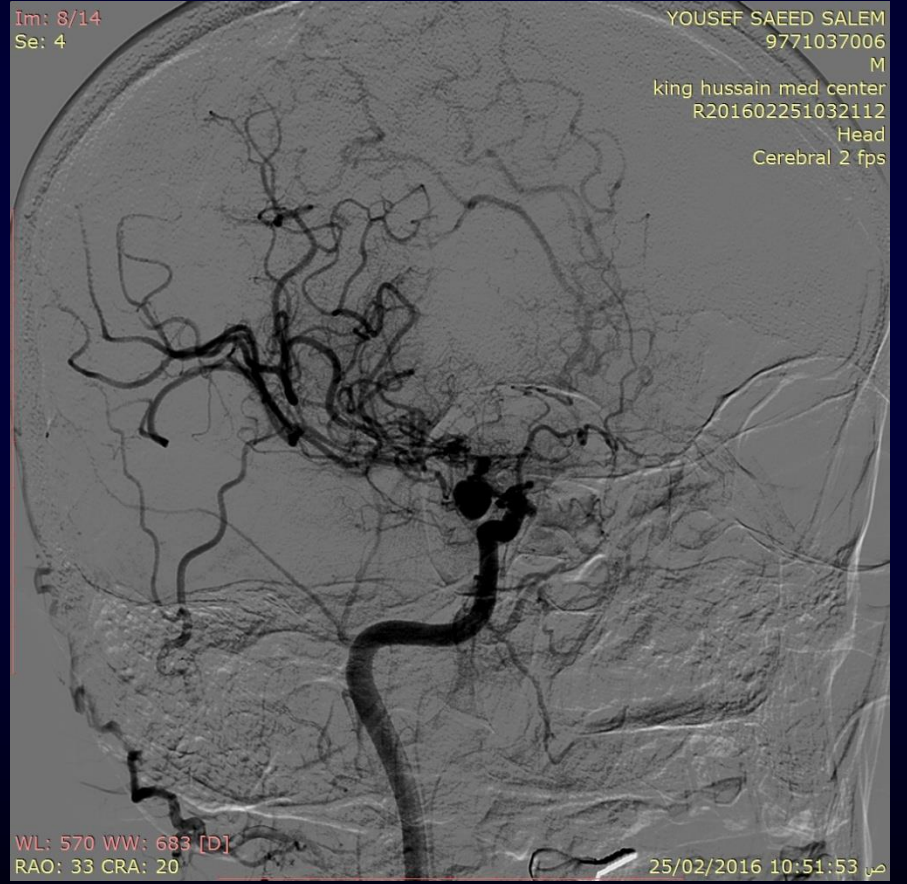
Im: 6/14
Se: 3

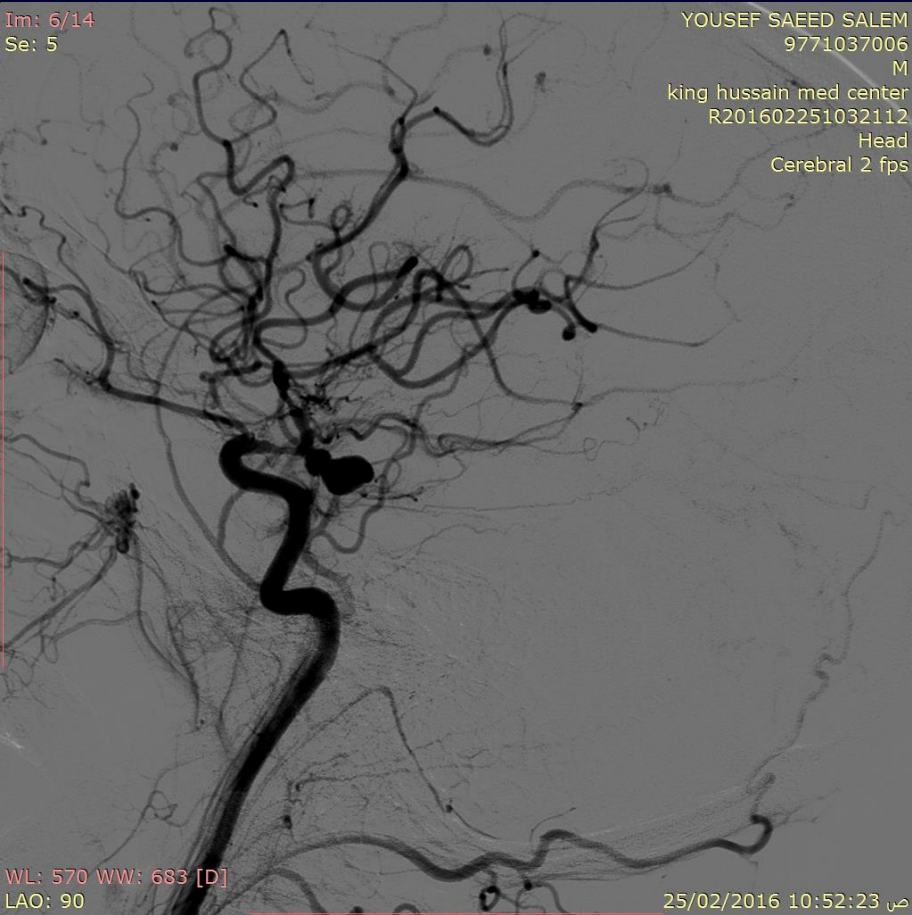
MOHAMD MAHMOUD AWA
963103217
01/01/1963
king hussain med cent
R20160217152308
Hea
Cerebral 2 ft

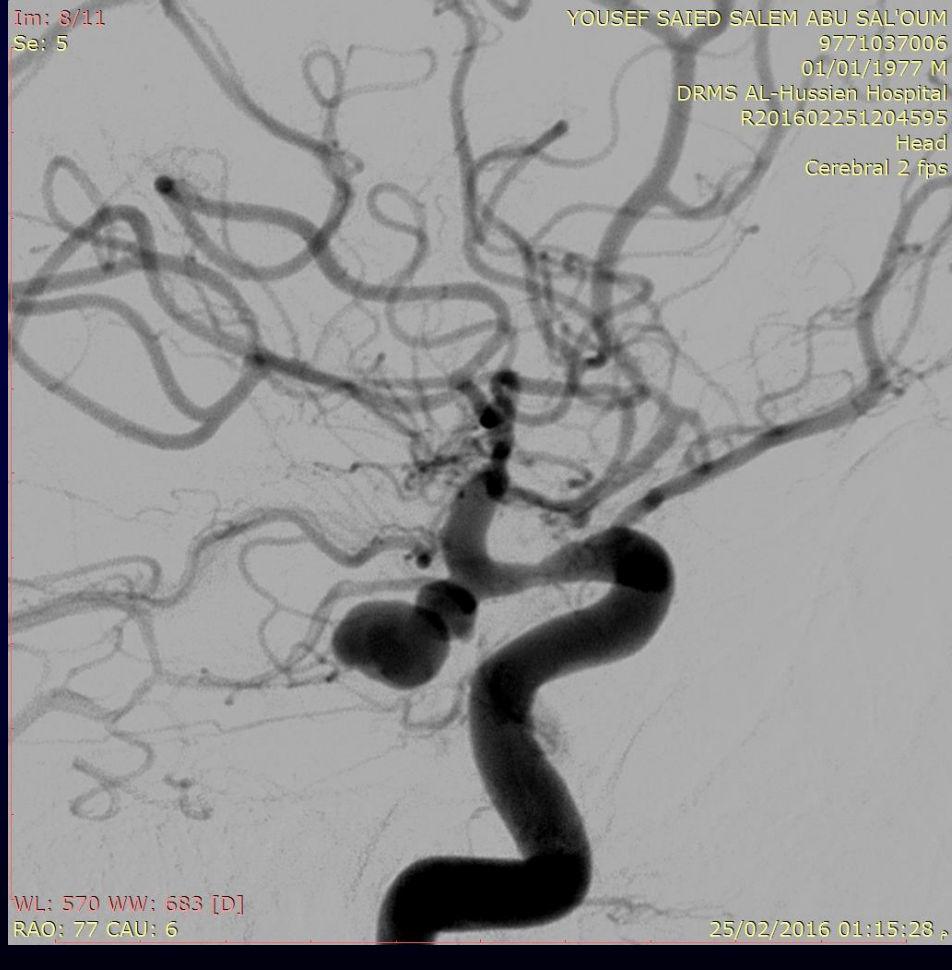


WL: 570 WW: 683 [D]

39 year old male patient referred from
private hospital diagnosed S.A.H







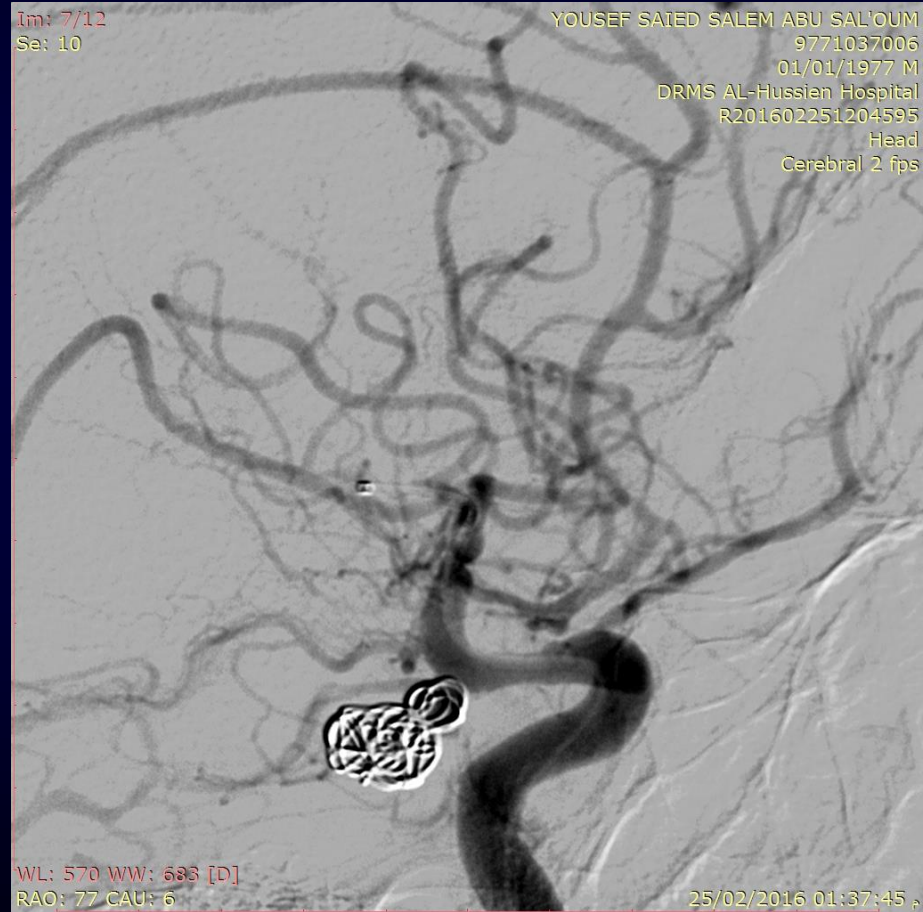
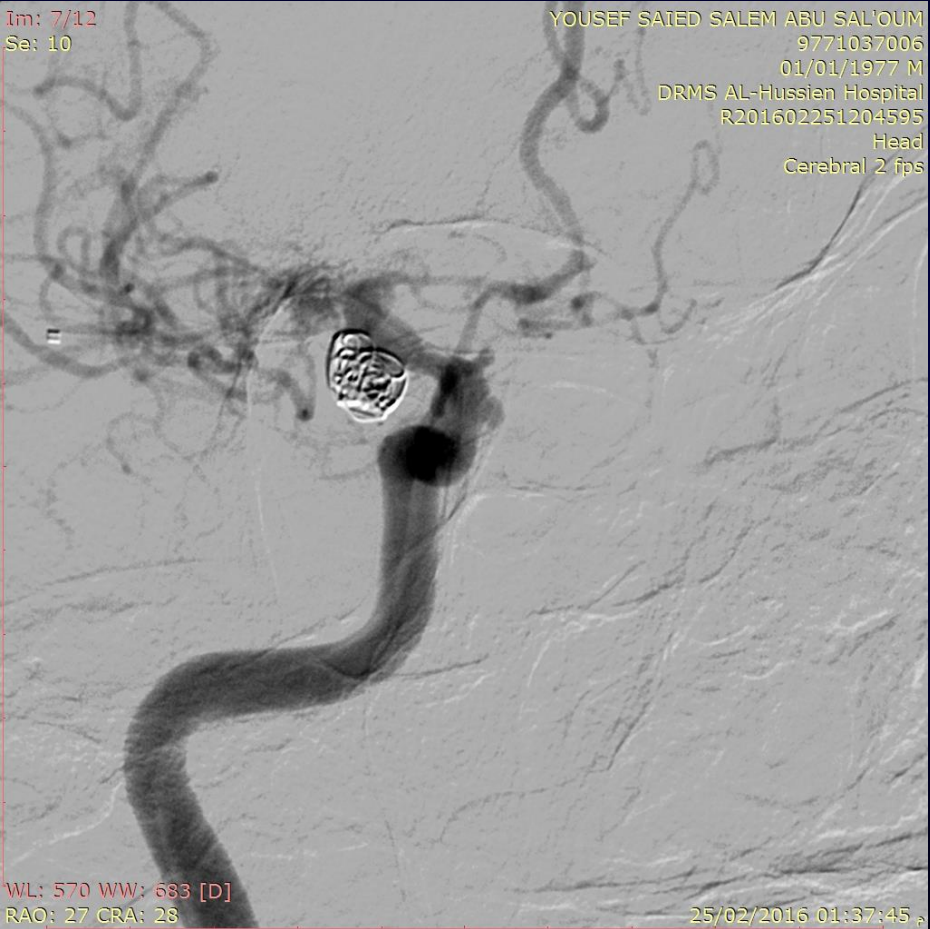
Im: 1/2 Im: 2/2 Im: 1/ Im: 2/ Im: 1/2 Im: 2/2
Se: 7 Se: 7 Se: 8 Se: 8 Se: 9 Se: 9

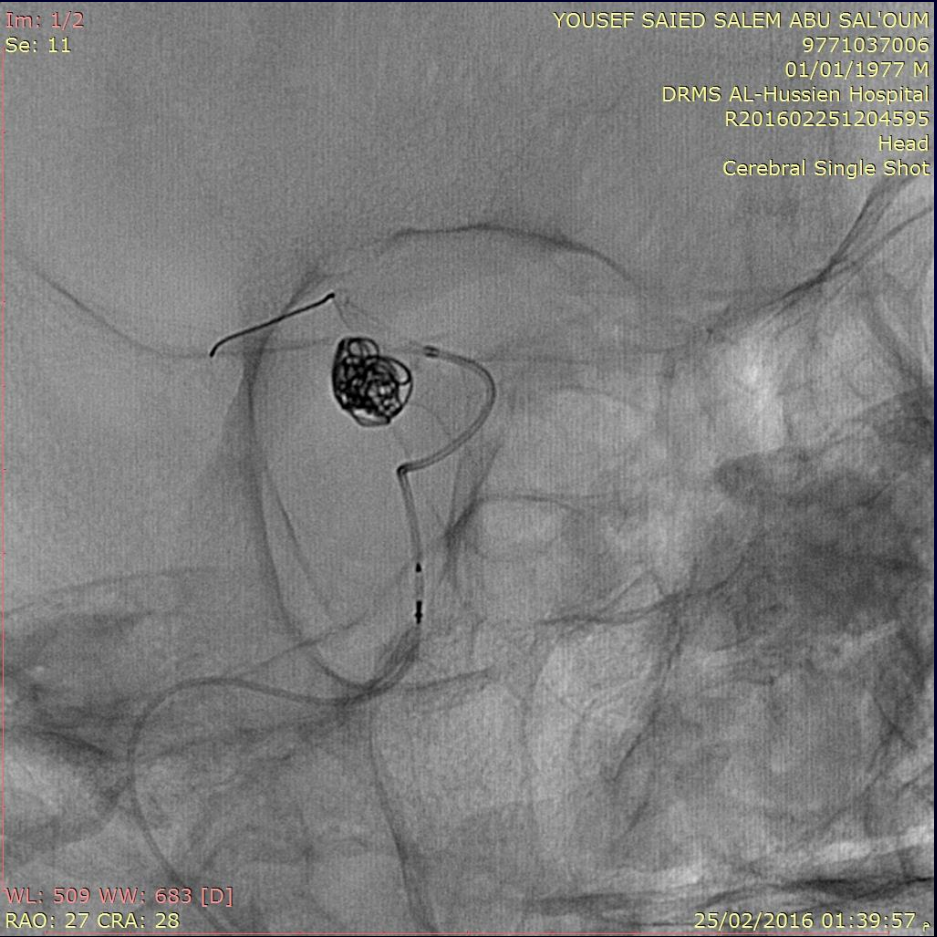
YUSEF SAIED SALEM ABU S
9771
01/01/
DRMS AL-Hussien
R201602251
Cerebral Sing

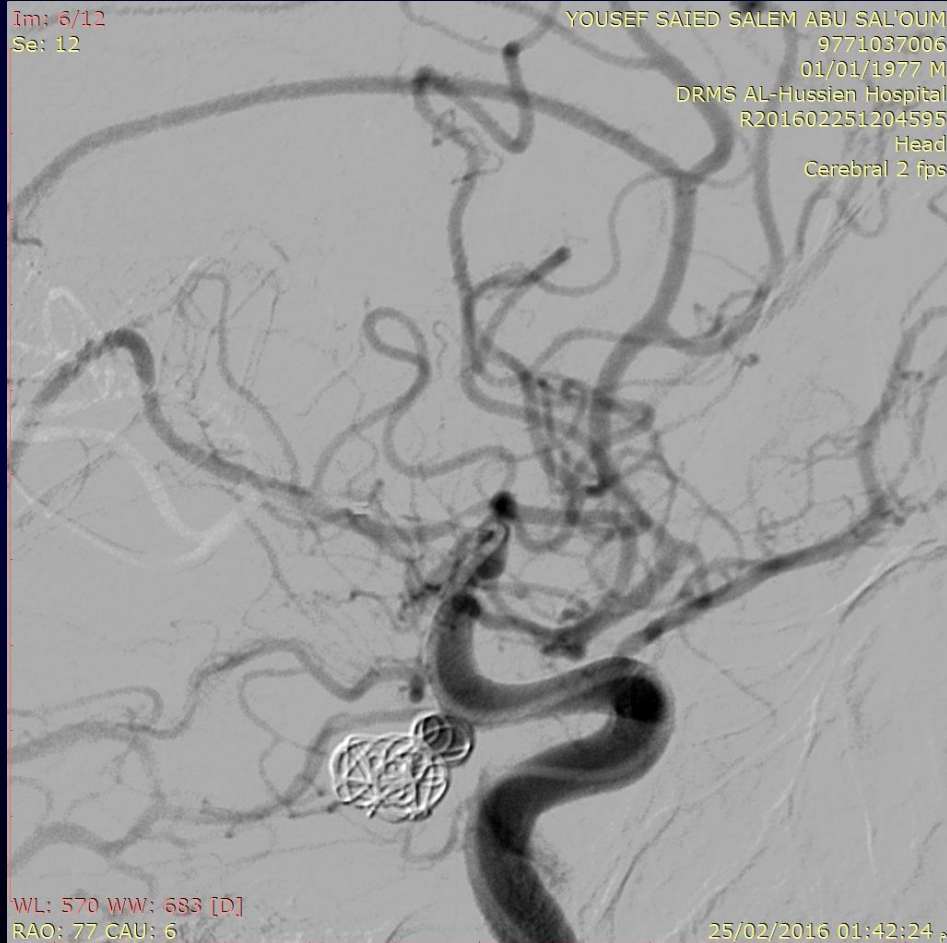
WL: 509
RAO: 27

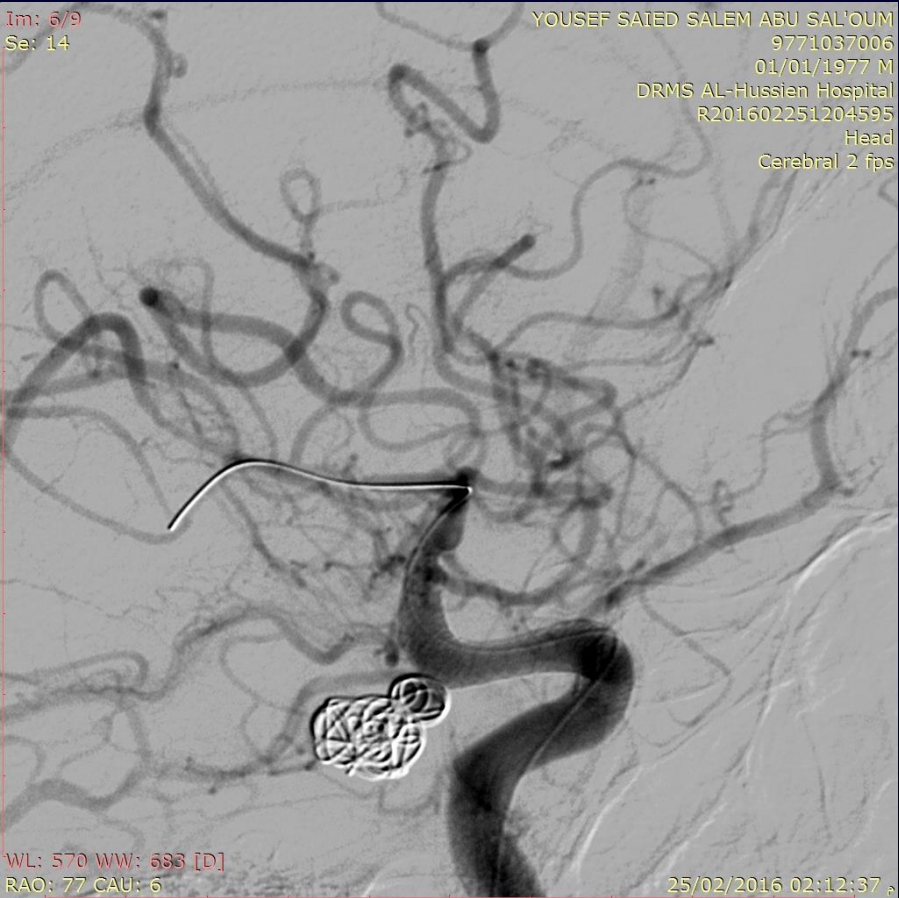
WL: 50 WL: 50 WL: 50 WL: 50 WL: 509 WW: 683 [D]
RAO: 77 RAO: 2 RAO: 7 RAO: 27 RAO: 77 CAU: 6

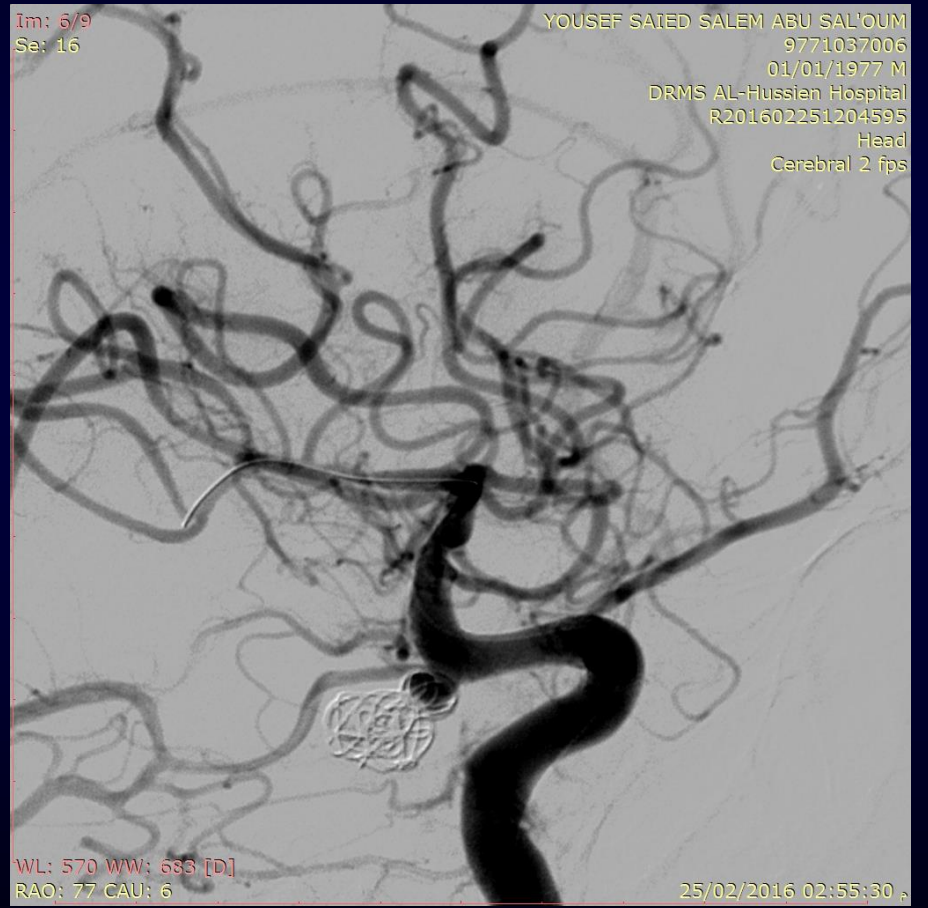
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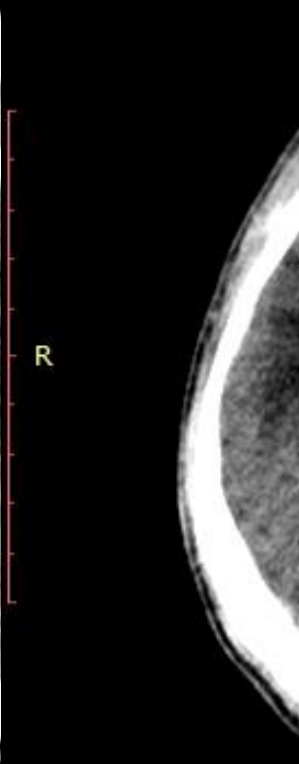
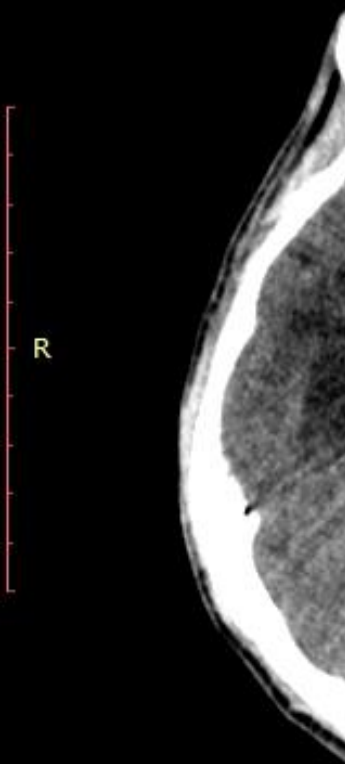


After 5 weeks patient complain of sever
headache

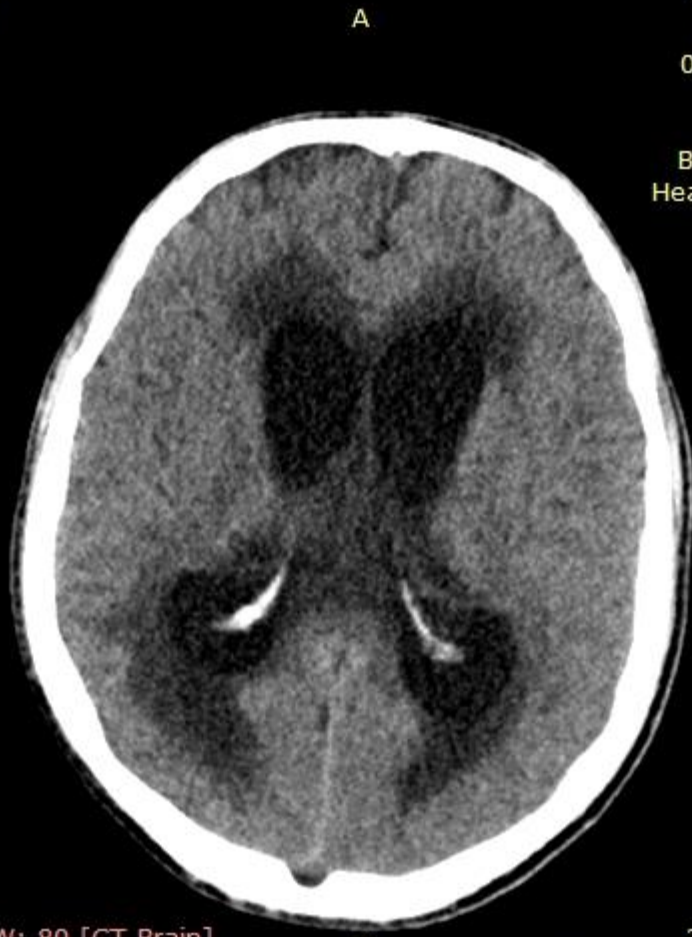
Im: 11/31
Se: 2

Im: 12/31
Se: 2

YOSEF SAED
9771037006
01/01/1977 M
KHMC



Im: 18/31
Se: 2



YOSEF SAED
9771037006
01/01/1977 M
KHMC
1739696
Brain CT Scan
Head 5.0 H31s

WL: 40 WW: 80 [CT Br
T: 5.0mm L: 138.5mm

WL: 40 WW: 80 [CT
T: 5.0mm L: 143.5m

WL: 40 WW: 80 [CT Brain]
T: 5.0mm L: 173.5mm

248mA 120kV
24/03/2016 07:52:56

Im: 13/23
Se: 4

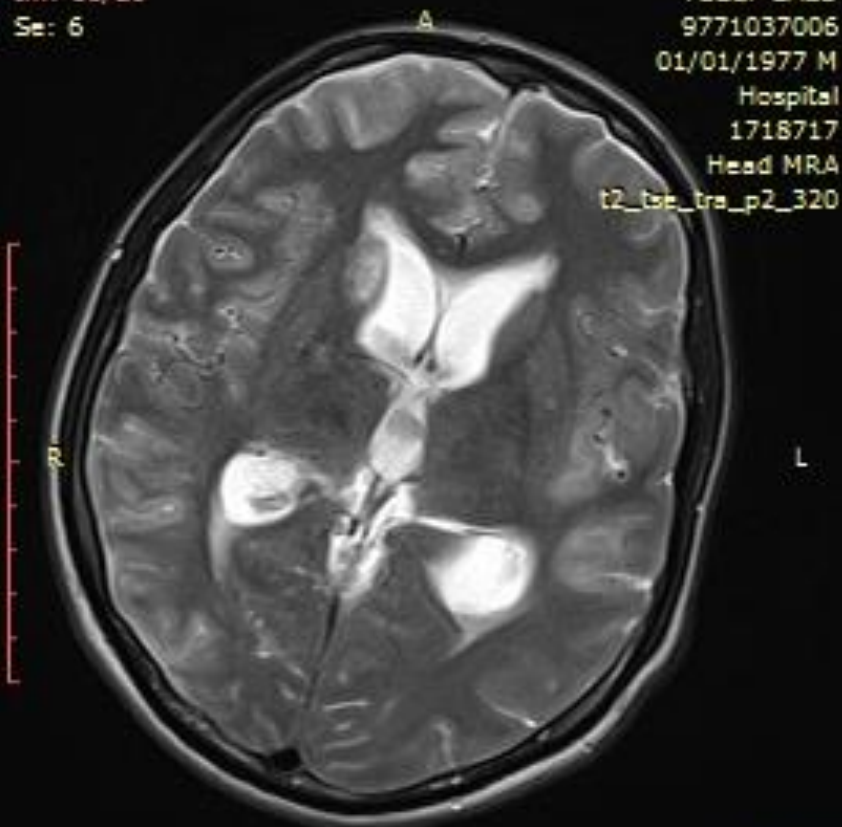
YOSEF SAED
9771037006
01/01/1977 M
Hospital
1718717
Head MRA
t2_tirm_tra_dark-fluid



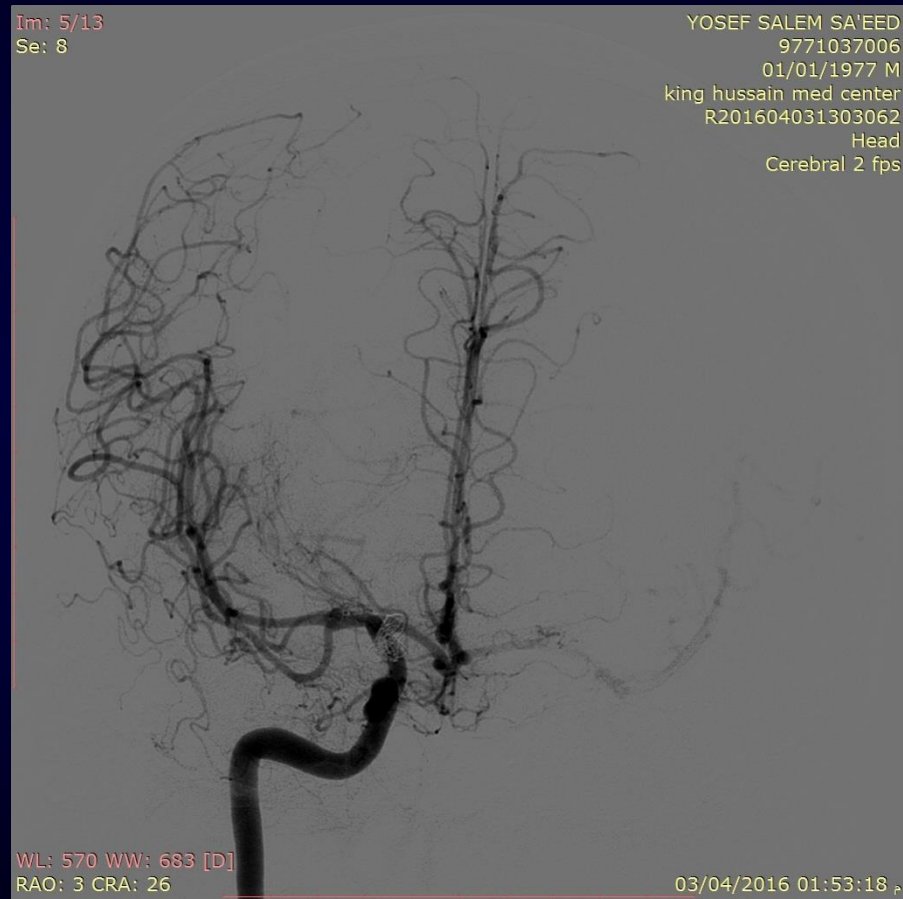
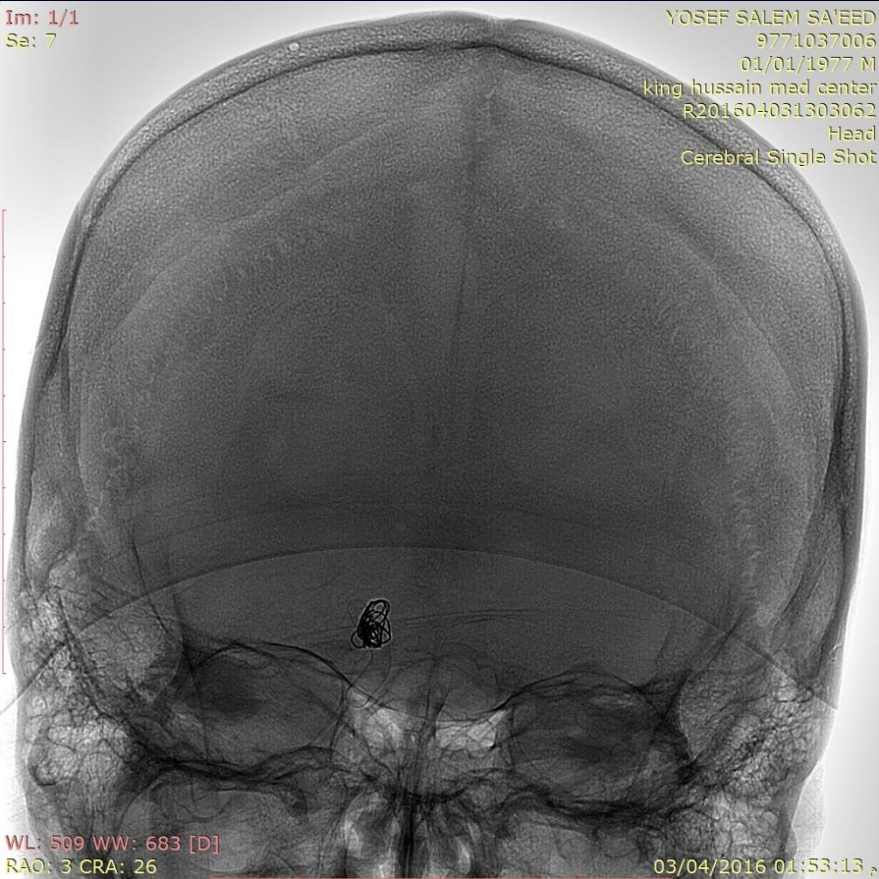
WL: 449 WW: 933 [D]
T: 5.0mm L: 79.5mm
FS: 1.5
TR: 9000.0 TE: 92.0
01/03/2016 10:31:41 ص

Im: 11/20
Se: 6

YOSEF SAED
9771037006
01/01/1977 M
Hospital
1718717
Head MRA
t2_tse_tra_p2_320



WL: 625 WW: 1326 [D]
T: 5.0mm L: 75.9mm
FS: 1.5
TR: 4500.0 TE: 100.0
01/03/2016 10:35:51 ص

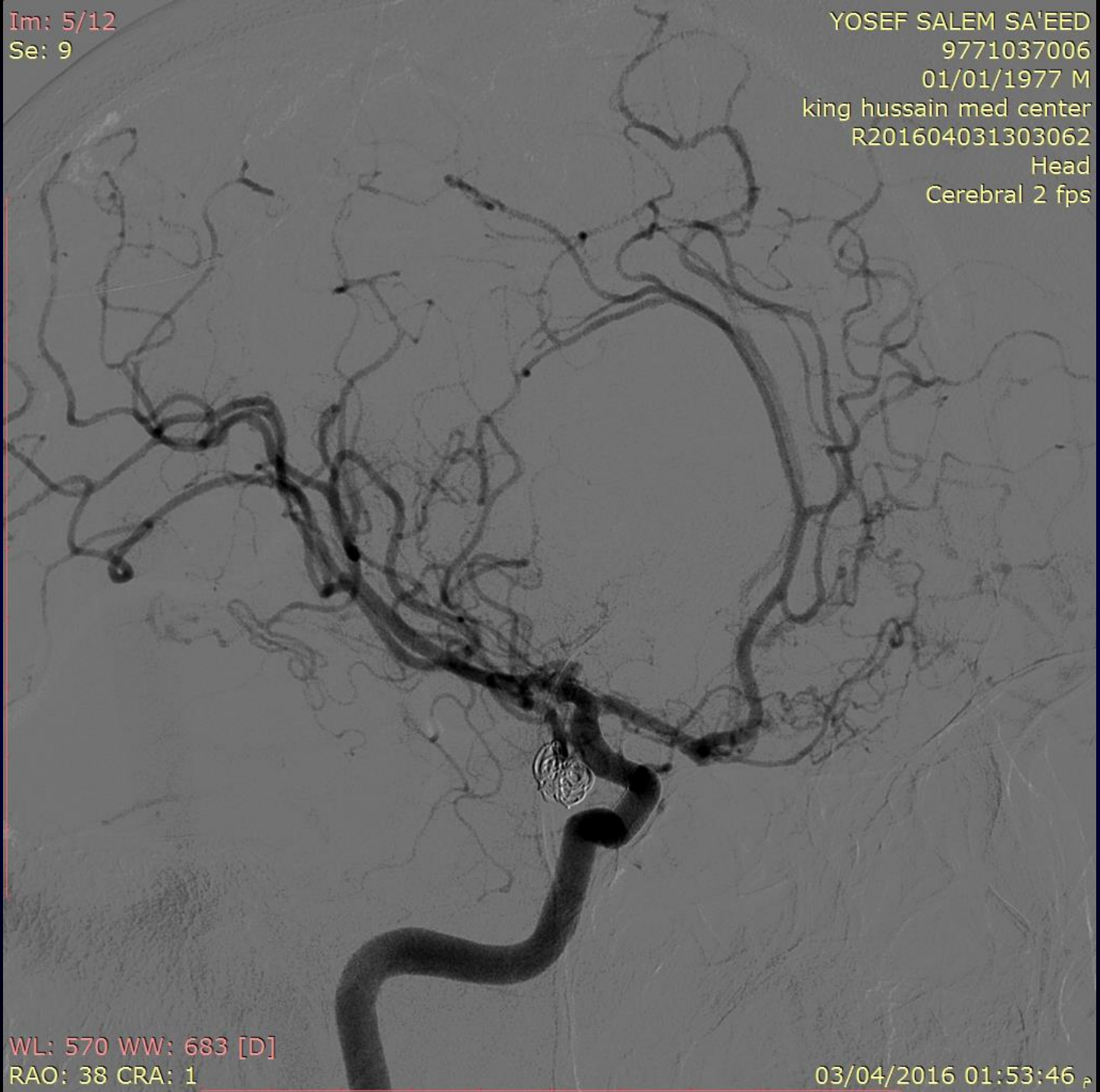


Im: 5/12
Se: 9

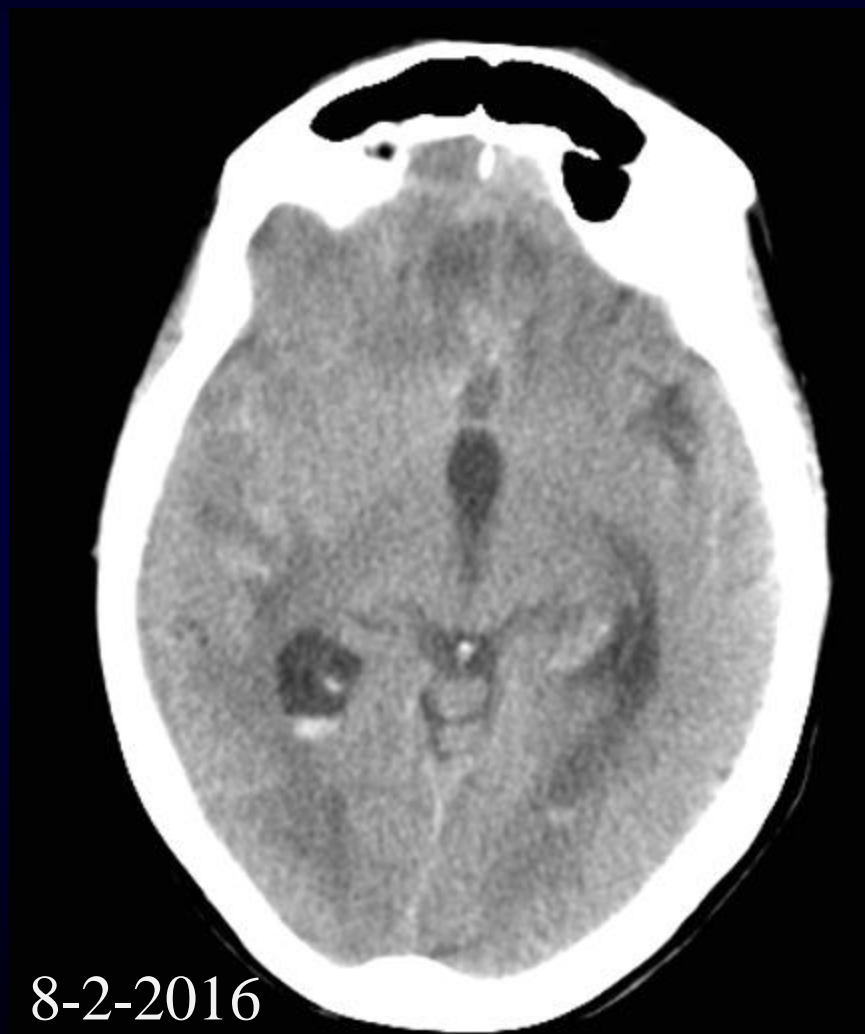
YOSEF SALEM SA'EED
9771037006
01/01/1977 M
king hussain med center
R201604031303062
Head
Cerebral 2 fps

WL: 570 WW: 683 [D]
RAO: 38 CRA: 1

03/04/2016 01:53:46

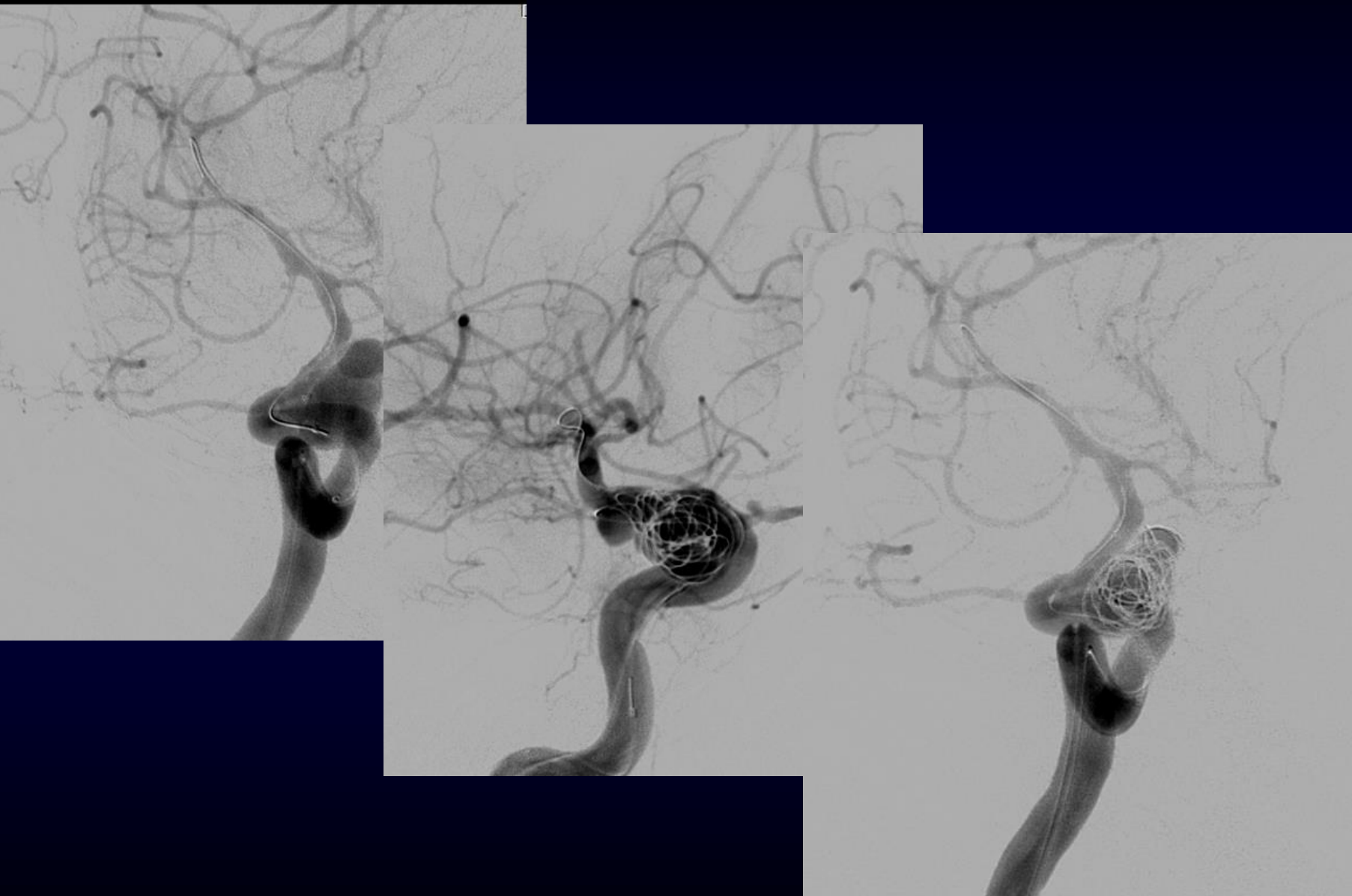


Case 4



8-2-2016

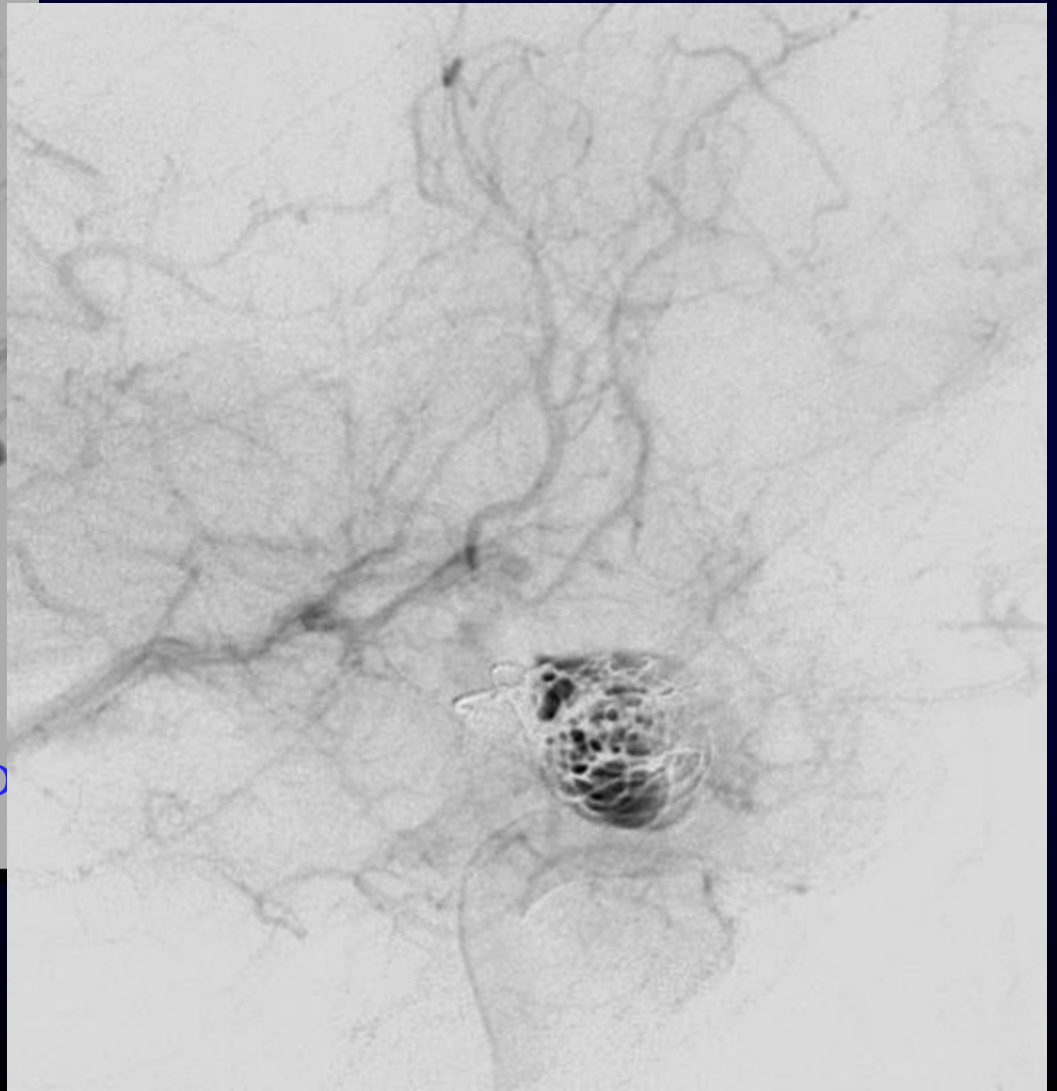
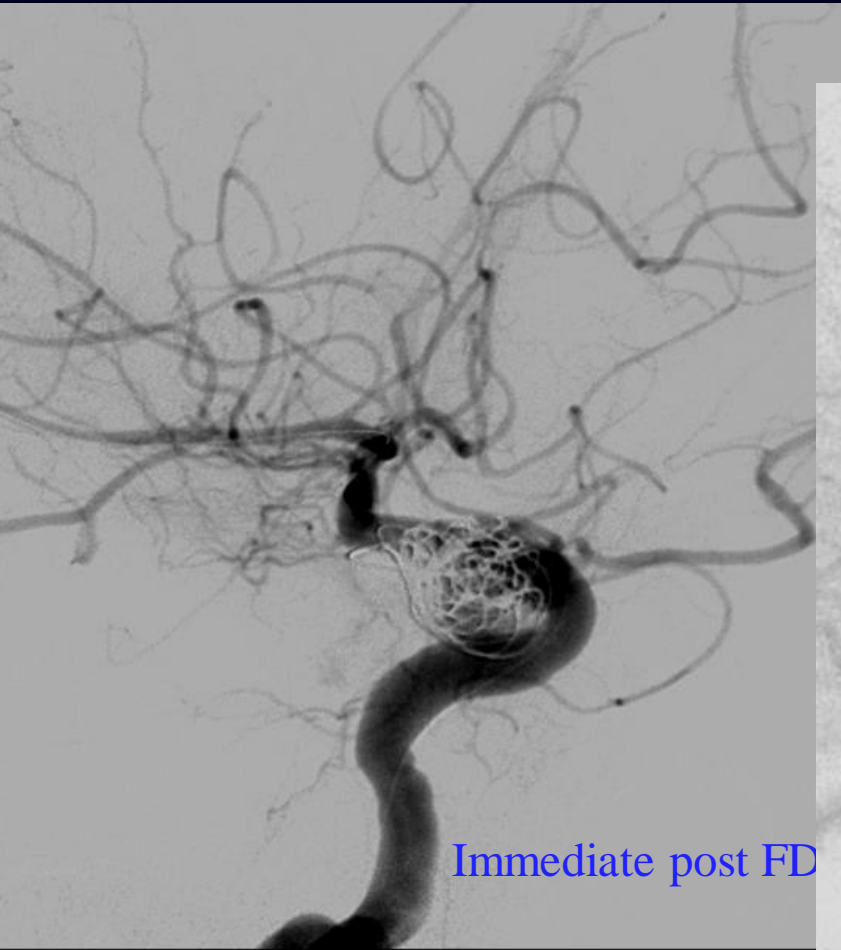
Case 4



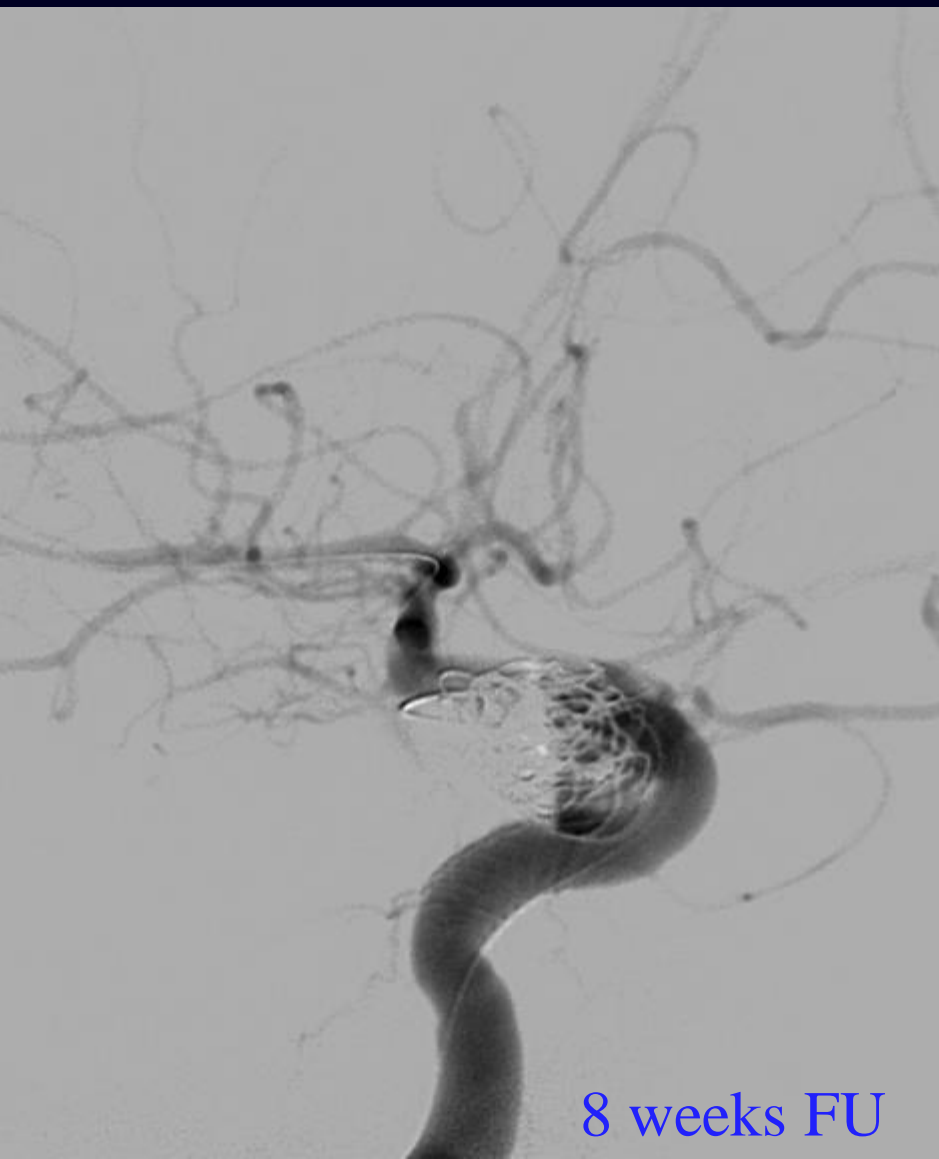
Case 4



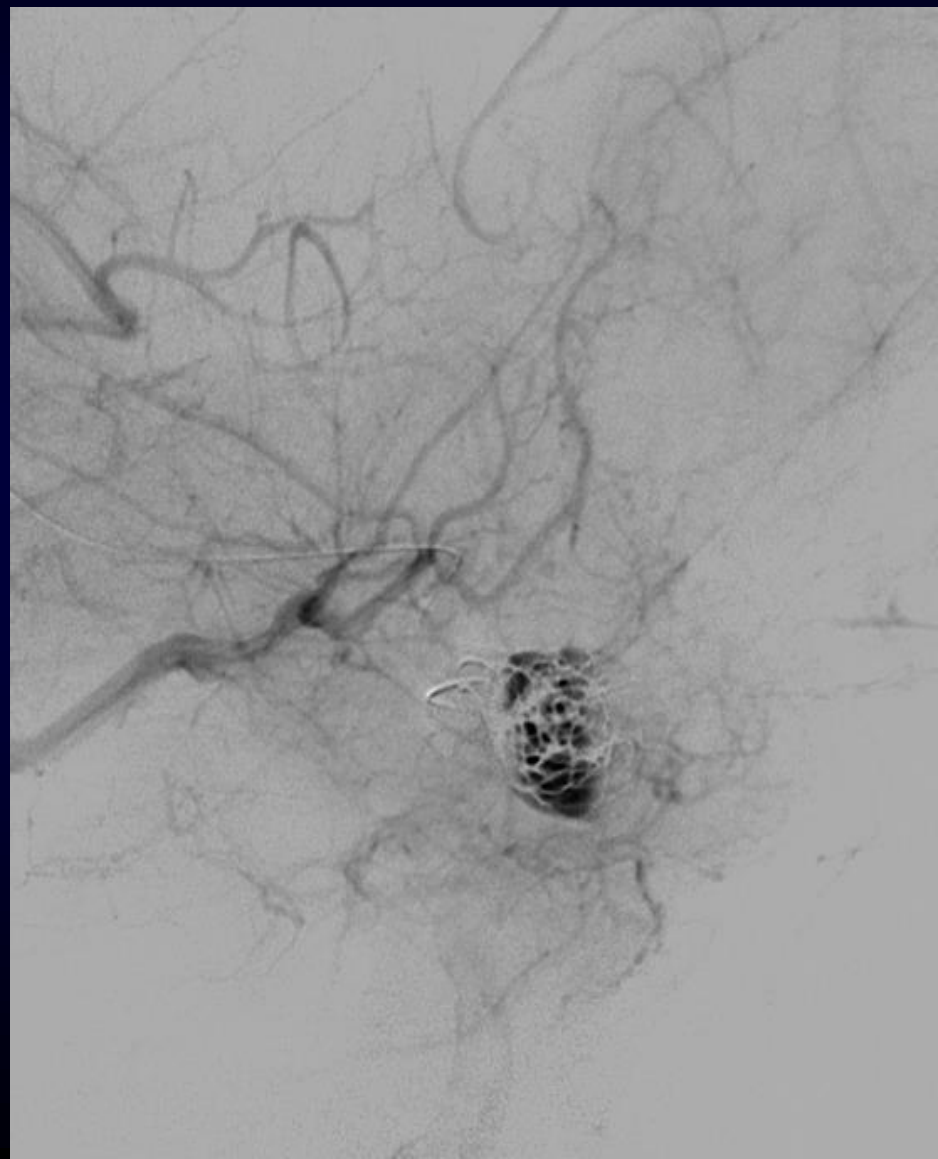
Case 4



Case 4



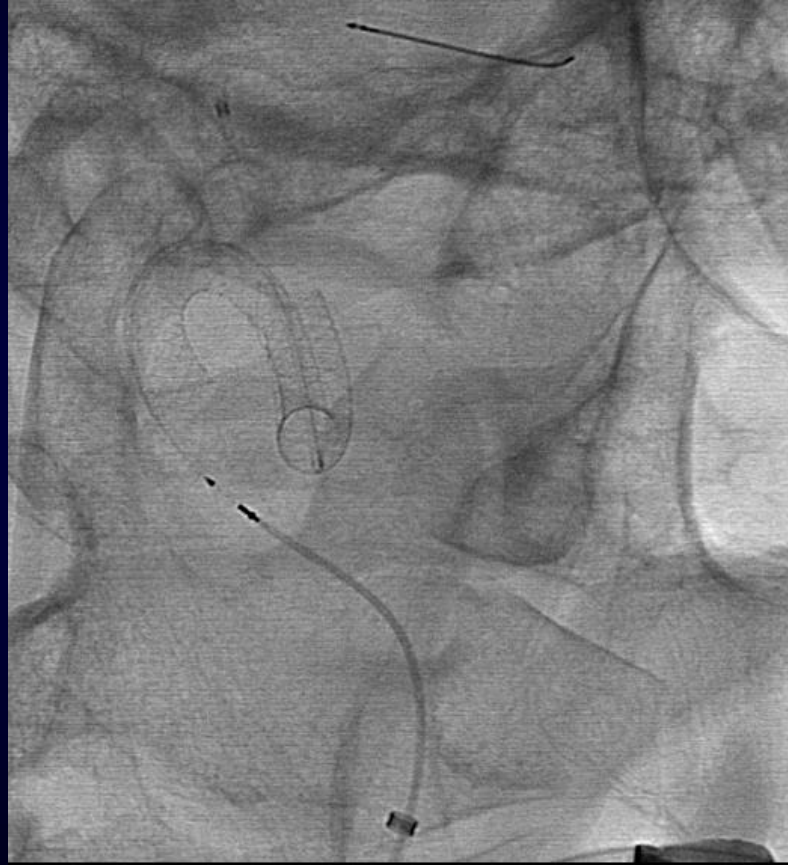
8 weeks FU



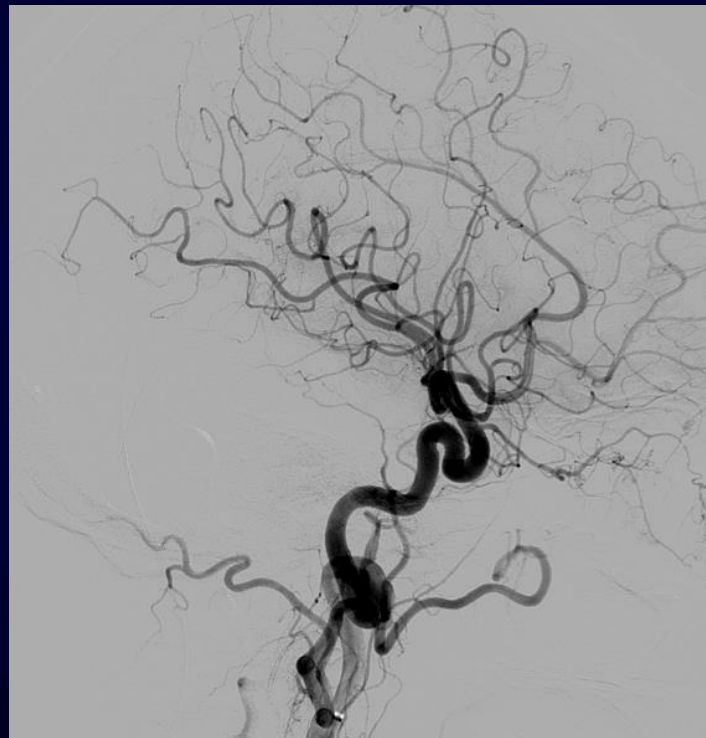
Case 7



Case 7



Case 7



Final angiogram

Results

- Technical success of implantation in 10 pts,
- Complications ? related to implantation , 1 patient with occlusion of the stent on 1 week follow up, with wire dislocation of the FD, minor deficit.
- Bleeding occurred in one patient with paraophthalmic aneurysm and resulted minor deficit

Results

- FD patency at average follow up of 8 weeks in 6 patients showed stent occlusion in 1 patient and patents FD in 5. occlusion was not associated with significant clinical deficit.

Shield with coiling

In 3 patients.

Any aneurysm larger than 6 mm was considered for coiling plus flow diversion

The issue of vasospasm

If vasospasm occurred post FD deployment, what is the risk of thrombosis (symptomatic).

conclusion

- Pipeline flex flow diverter with shield technology pose an improved hemocompatibility with reduction in thrombogenicity.
- In this small group 8 FD cases were patent on discharge and in one case thromboembolic occlusion
 - risk of bleeding appears to be present as we had one case of bleeding.
- at short term follow up 5 out of 6 FD were patent .
- I think better understanding of the thrombin time for the different categories of patients will yield to more proper protocols in the future.

King Hussein Medical Center

1492 Beds

