

La phase aigüe de l'AVC

Nous y avons cru!
Nous l'avons voulu!
nous l'avons prouvé!

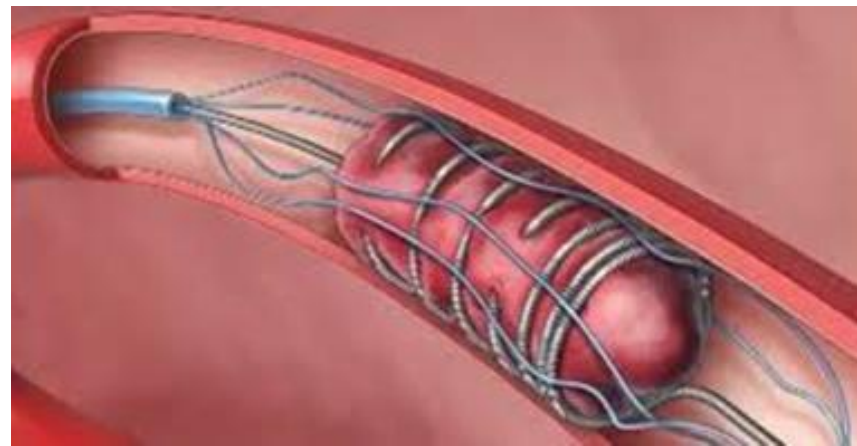
What's next ?

H Desal

SFNR 2016

Notre boulot!

N'est pas que de "déboucher" des artères



Une grande responsabilité !

- Formation / Enseignement (Clinique, physiopath, radiologique)
- Organisation (15 – UNV – selection)
- Soins – permanence de soins
- Recherche:
 - Prestation > Investigation
 - Registre / Cohorte
 - Recherche clinique (DM, Imagerie)
 - Recherche translationnelle (thrombus...)

Neuro-Thrombectomy-France

un registre ...
you're kidding ?

H Desal
for the NTF *investigators*

SFNR 2016

Disclosures

- Travel, housing and registration to the SFNR meeting (Microvention)
- PI of NTF (funding by all industrials)
- PI of Leo II+
- Research collaboration (no fund) with NeurAVI
- Research grant (Stryker, Microvention)

Context 2013 - it's been a century

- National et International skepticism
- IMS 3, Synthesis and Other NEJM
- 2013 > waiting for RCT results and « EBM»
- In France > THRACE (slow inclusion rate)
- NTF > real-world clinical practice outside the THRACE trial
 - May 2013 – September 2014

NTF: Objectives and Judgement criteria

Principal Objective:

Collect the outcomes of patients treated by thrombectomy outside the THRACE trial

Principal Judgement Criteria :

The primary outcome was the **modified Rankin score** at 3 months, by independant neurologist .

Inclusion Criteria:

all the thrombectomy realized with a stent retriever during the period of inclusion

NTF: Design et planning

Design

- *Multicenter nationale (30 centers)*
- *Non controled*
- *Non randomized*
- *Prospective, consecutivity*
- *On DATA*
- *eCRF*

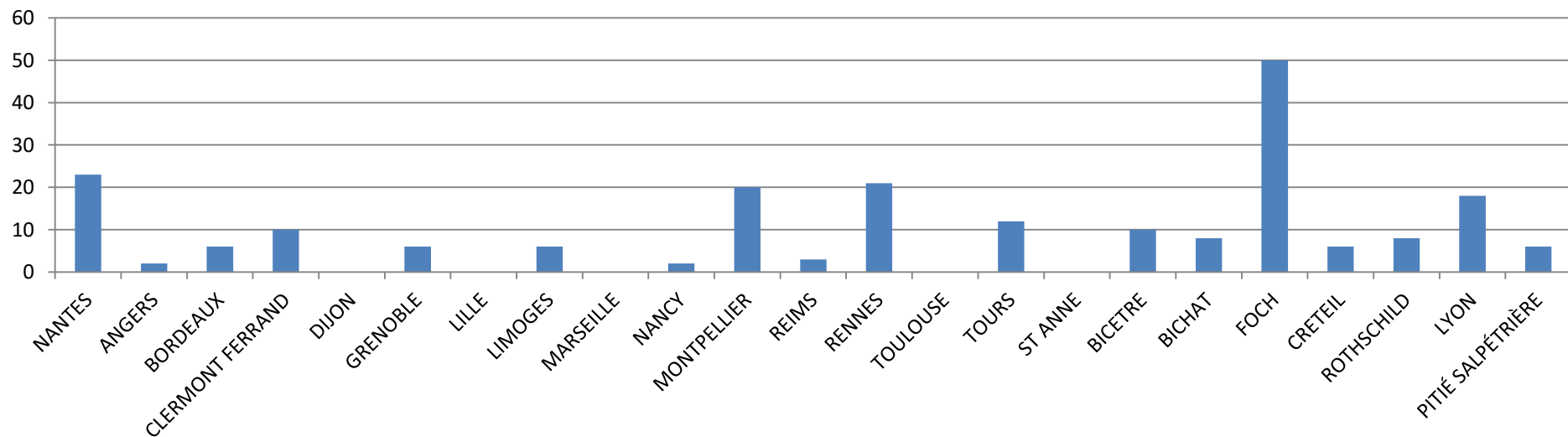
Planning

- Inclusion Period : 12 months
- Inclusion of 200 patients
- Length of follow-up : 3 months
- Total Duration : 15 months

Financing all industrial

18 French Actives centers

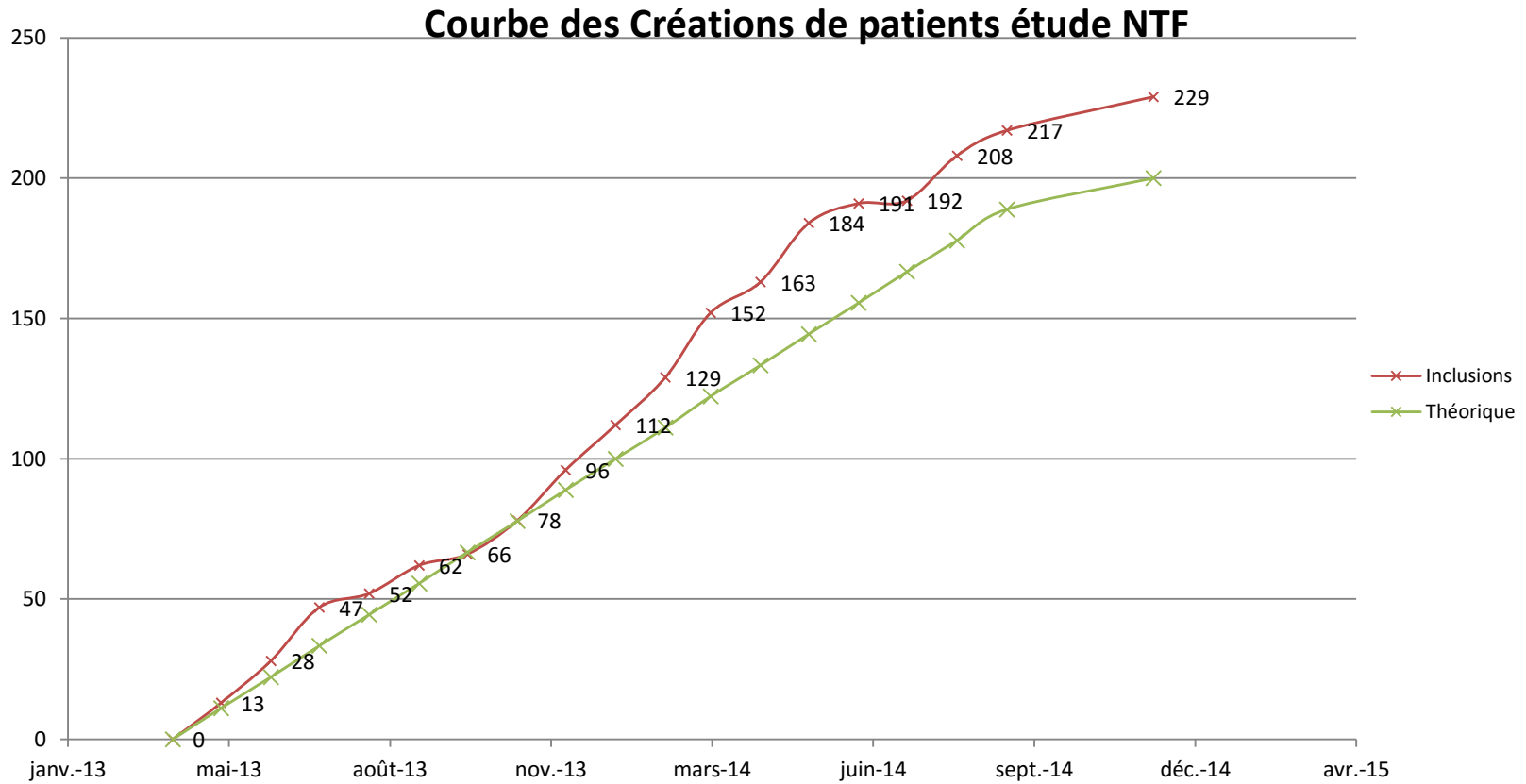
- 232 patients
- 11 exclusions because missing data mRs 3 months
 - 221 patients analyzed



Remerciements

- Angers, Bordeaux, Clermont-Ferrand,
Grenoble, Limoges, Nancy, Montpellier, Reims,
Rennes, Tours, Kremlin-Bicêtre, Bichat, Foch,
FO Rothschild, Pitié-Salpêtrière, Lyon et
Nantes

Rate of Inclusions



Characteristics of 221 Patients

Mean Age 63,63+/-14,22 yo
(12,3% > 80 yo)

56,6% Male

Median NIHSS	16
<=10	36 (17.06%)
[10-20]	127 (60.19%)
>20	48 (22.75%)

78,8% MRI screening

89,4% anterior circulation

Mean ASPECTs	7,15	Median	7
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Delay onset-Admission

		Total N=221
Délaît AVC - admission	N	169
	Min-Max	[0:00;23:16]
	Moyenne	2:22
	Ecart-type	2:12
	Médiane	106 min
	Q1-Q3	[1:15;2:55]

Time onset - end of the procedure

- <5h 81 (47.37%)
- 5-6h 44 (25.73%)
- >6h 46 (26.90%)
- Median 313 min (241_{escape}-355_{Revascat})

Therapeutic Strategy

	Total N=221
« Bridging »	85 (38.64%)
Failure of IV fibrinolysis/ RESCUE IV	41 (18.64%)
Thrombectomy alone	94 (42.73%)
Données manquantes	1

General Anesthesia in 63,76% versus Conscious Sedation 31,64%

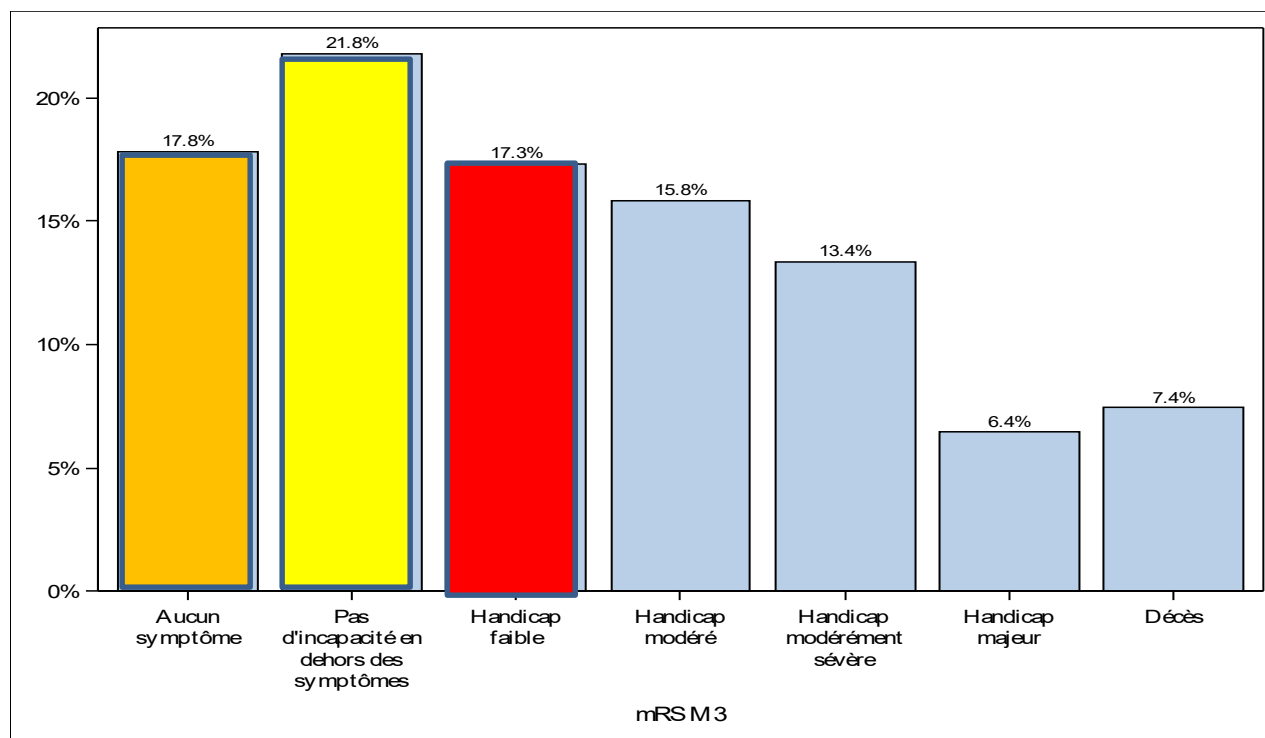
TICI final

	Total N=221
0	27 (12.56%)
1	4 (1.86%)
2A	23 (10.70%)
2B	60 (30.41%)
3	101 (47.47%)
Données manquantes	6

77.88%

Principal Objective

- mRs ≤ 2 at 3 months: 56.9%
- Mortality : 7,5%
- 21 missing data (13 mRs <2 à J+7)



Univariate Analysis

pronostic Factor at M3 (mRS>2)

Variable	N	OR	IC 95 %	p-value
ASPECT score	151	1.12	[0.89 ; 1.42]	0.3244
ASPECT score (classes) : >=7	151	1.60	[0.78 ; 3.27]	0.2020
Age	201	0.98	[0.96 ; 1.00]	0.0240
Age (classes) : >=80ans	201	0.54	[0.23 ; 1.27]	0.1578
Comorbidité - Exclu : tb hémato / néoplasie : OUI	202	0.64	[0.30 ; 1.37]	0.2508
Comorbidité : OUI	202	0.61	[0.28 ; 1.34]	0.2198
Délai entre AVC et admission (classes) : >3h	154	0.66	[0.31 ; 1.39]	0.2735
Délai entre admission et fin de procédure (classes) : b_5-6h	155	1.17	[0.53 ; 2.56]	0.9244
Délai entre admission et fin de procédure (classes) : c_>6h	.	1.04	[0.48 ; 2.24]	.
IRM - Admission : Non	200	0.54	[0.28 ; 1.04]	0.0660
Localisation occlusion : Postérieure	198	0.60	[0.24 ; 1.51]	0.2750
NIHSS Admission (classes) : >20	193	0.16	[0.05 ; 0.48]	0.0045
NIHSS Admission (classes) :]10-20]	.	0.22	[0.08 ; 0.62]	.
Stratégie thérapeutique (2 classes) : Thrombectomie	201	1.08	[0.61 ; 1.91]	0.7860
Stratégie thérapeutique (3 classes) : Rescue	201	0.63	[0.29 ; 1.38]	0.4980
Stratégie thérapeutique (3 classes) : Thrombectomie	.	0.93	[0.50 ; 1.74]	.
TICI final (2 classes) : Failure	198	0.33	[0.16 ; 0.65]	0.0016
				.
Type d'Anesthésie (classes) : Générale	199	0.68	[0.38 ; 1.22]	0.1935

Multivariate Analysis

pronostic Factor at M3 (mRS>2)

Variable	N	OR	IC	p-value
Age	188	0.98	[0.96 ; 1.01]	0.1992
Comorbidité : OUI	.	0.75	[0.29 ; 1.95]	0.5518
IRM - Admission : Non	.	0.56	[0.26 ; 1.24]	0.1526
NIHSS Admission (classes) : >20	.	0.19	[0.06 ; 0.64]	0.0230
NIHSS Admission (classes) :]10-20]	.	0.27	[0.09 ; 0.78]	.
TICI final (2 classes) : Echec	.	0.38	[0.18 ; 0.83]	0.0152
TOAST (3 classes) : Autres	.	2.63	[1.09 ; 6.34]	0.0696
TOAST (3 classes) : Cardiopathie Emboligène	.	2.10	[0.93 ; 4.73]	.
Type d'Anesthésie (classes) : Générale	.	0.54	[0.27 ; 1.06]	0.0717

Summary results RCT and NTF

	Mr CLEAN	Extend-IA	ESCAPE	Swift-Prime	Revascat	THRACE	NTF
Number	233	35	165	98	103	200	221
Onset-reperfusion (min)	332	248	241	252	355		313
Reperfusion (TICI 2b-3)	59%	86%	72%	88%	66%		77%
mRs<=2	33%	71%	53%	60%	44%	54%	56,9%
Mortality	21%	9%	10%	9%	18%	12,5%	8%
GA	38%	36%	9%	37%	7%		64%
% IV fib	89%	100%	76%	100%	73%	100%	57,20%

Discussion

- Our registry findings are consistent with those of RCT published in 2015
- Early termination (analysis) of the RCT reduced the power of subgroup analysis because of the relatively small sample size
- Clinical research must go on !
 - To improve patients selection
 - To decrease the delay
 - To increase recanalization rate
 - To improve clinical outcomes

Still unanswered questions ?

- Age > 80 yo
- Wake up stroke
- MR (79%) or CT screening ?
- Collateral influence ?
- Anesthesiology ? (64% de GA dans NTF)
- Is IV thrombolysis still mandatory ?

Les centres Français !

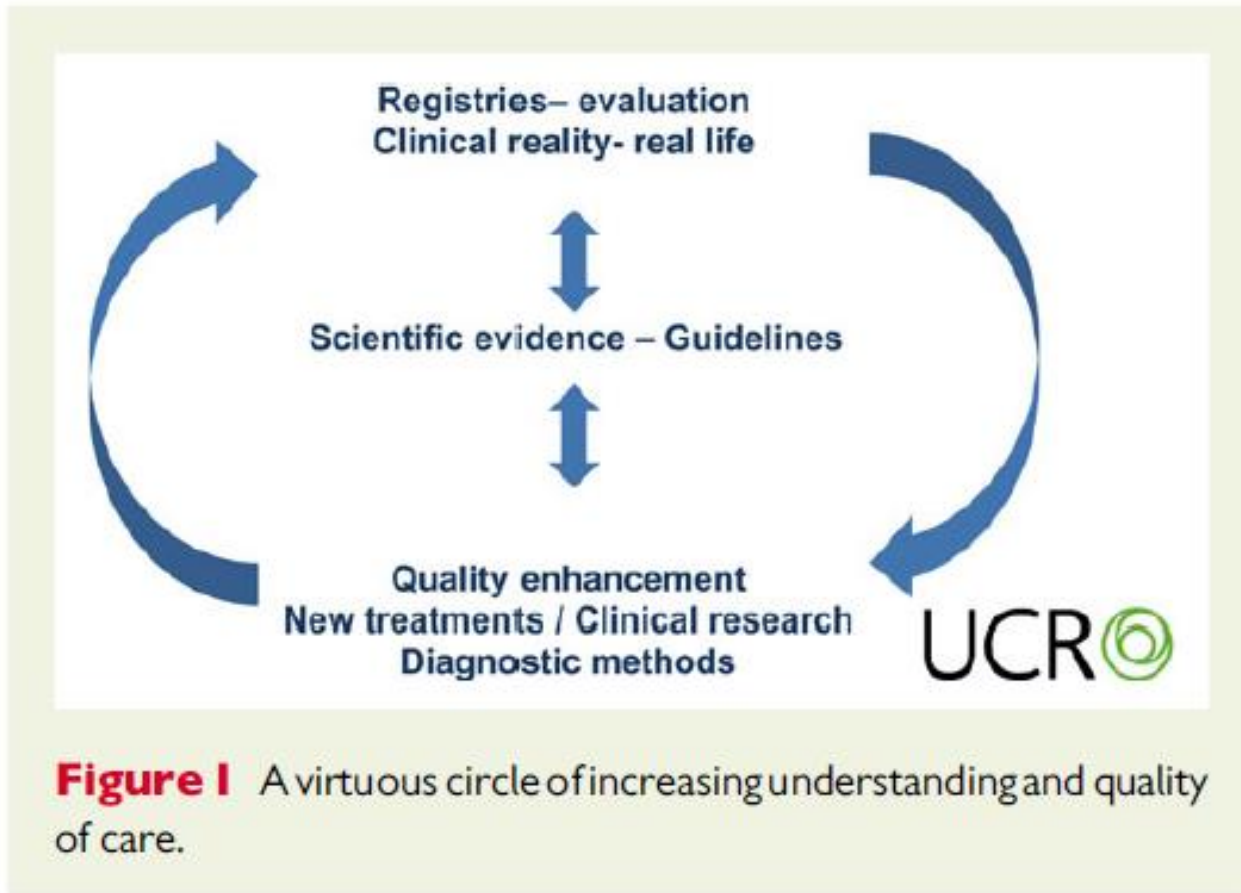
- Il faut continuer et accentuer l'effort +++
- S'organiser localement avec vos DRCl
- Chaque service sait faire de la prestation....
- Il faut faire de l'investigation....
- Ensemble +++

- Clarity, ATENA, THRACE, NTF, French WEB registry etc...

Un registre peut en cacher un autre!

- RC en cours actuellement (39 sur strokecenter.org/trial) :
 - Dawn trial (wake-up and >8h) (Trevo)
 - ASTER (aspi vs mécanique)
 - COMET ou GASS (AG vs AL)
 - KETA
 - Re-Act (ReVive)
 - ReDIRECT (Solitaire)
 - Compass trial (Direct Aspi First pass)
 - EASI, SITS Open, EAST, PISTE, DEFUSE 3....

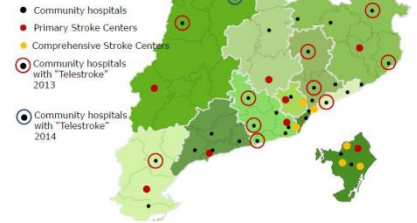
L'intérêt des registres



Observational studies such as that of Kwon *et al.* increase our understanding of current praxis, triggers questions, and stimulates the performance of new randomized trials in a true virtuous circle of knowledge (Figure 1).

SONIIA (Catalunya)

Network of acute public hospitals involved in the acute system of stroke care of Catalonia



- REGISTRE-government-mandated prospectif
- Monitoring continu de la qualitat de tous les traitements de reperfusion cérébrale à la phase aigüe de l'AVC, dans le système publique depuis 1er janvier 2011
- De nov 2012 > dec 2014 > 540 TM
- REVASCAT > 103 patients (0,04%)

[Stroke](#). 2015 Dec;46(12):3437-42.

Mechanical Thrombectomy

in and Outside

the REVASCAT Trial: Insights From a Concurrent Population-Based Stroke Registry.

- **RESULTS:**
- From November 2012 to December 2014, out of 17596 ischemic stroke patients in Catalonia (population 7.5 million), 2576 patients received reperfusion therapies (17/100000 inhabitants-year), mainly intravenous thrombolysis only (2036). From the remaining 540 treated with EVT, 103 patients (out of 206 randomized) were treated within REVASCAT and 437 outside the trial. Of these, 399 did not fulfill some of the study criteria, and 38 were trial candidates (8 treated at REVASCAT centers and 30 at 2 non-REVASCAT centers). The majority of procedural, safety, and functional outcomes were similar in patients treated with EVT within and outside REVASCAT.
- **CONCLUSIONS:**
- REVASCAT enrolled nearly all eligible patients representing 1/3 of all patients treated with EVT. Patients treated with EVT within and outside REVASCAT had similar outcomes, reinforcing the therapeutic value of EVT.

Recommandations

- Mise en place d'un registre national exhaustif de l'activité de soins des AVC (Fibrinolyse IV et / ou Thrombectomie mécanique)
- Optimisation de la filière
 - Appel centre 15, régulation
 - Orientation, transfert vers l'UNV
 - Imagerie
 - Traitement de la phase aiguë

It's our Job !

- ARS Ile de France > registre
- Chaque centre collige ses propres données
- Et maintenant ?
- À la demande de la DGOS, des ARS, du ministère, IPAQ 2015 AVC (indicateurs HAS)
- SFNR et SFNV
- Perspectives d'organisation territoriale

Conclusion

- Always some things to learn from the real life medical practice
- Exhaustivity of french activities in IV fibrinolysis and Mechanical Thrombectomy
- To be continue !

- SFNR +/- SFNV +/- SFMU
- Determines reimbursement ?

Je vous remercie !





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apprendre

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recherche

diplôme

innover

participer

adhérer
à la
Société française
de neuroradiologie



**Total
N=221**

Delay between admission and recanalization

N

168

Min-Max

[0:48;18:00]

Mean

3:17

Ecart-type

1:58

MEDIAN

2:50

Q1-Q3

[2:07;3:59]

Délai entre admission et ponction artérielle

N

175

Min-Max

[0:06;17:30]

Moyenne

2:05

Ecart-type

1:53

Médiane

1:36

Q1-Q3

[1:10;2:30]

Influence de la stratégie thérapeutique sur le TICI final

	Bridging N=85	Rescue N=41	Thrombectomie N=94	Total N=220	p-value
TICI final (2 classes)					0.0610
Echec	16 (19.05%)	5 (12.20%)	27 (29.35%)	48 (22.12%)	
Succès	68 (80.95%)	36 (87.80%)	65 (70.65%)	169 (77.88%)	

mRs 7 days / 3 months

