

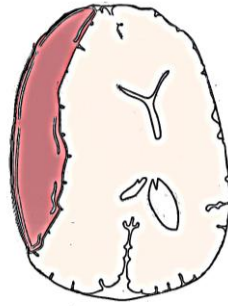


Embolisation de l'artère méningée moyenne comme traitement adjuvant à la chirurgie pour les hématomes sous-duraux chroniques symptomatiques : étude pilote évaluant la résorption volumétrique

Sam Ng, Imad Derraz, Julien Boetto, Cyril Dargazanli, Gaëtan Poulen, Gregory Gascou, Pierre-Henri Lefevre, Nicolas Molinari, Vincent Costalat, Nicolas Lonjon



Rationnel ?



Hématome sous dural chronique

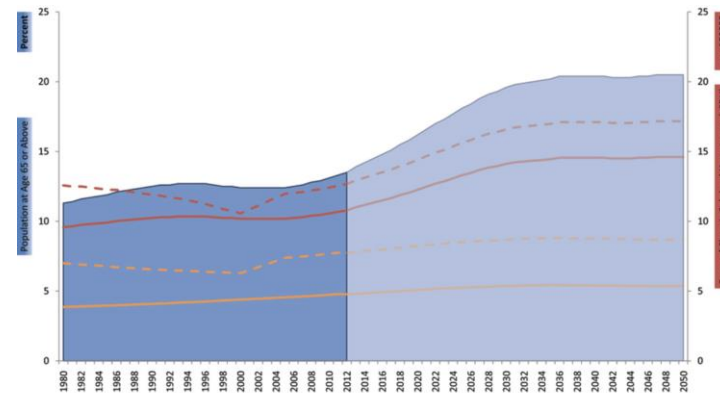
Pathologie frustrante:
Récurrence élevée: 9 à 26%

Physiopathologie
incomplètement comprise

Rôle des statines ?
Rôle corticoïdes ?
Part inflammatoire ?

Augmentation de la population âgée=
Augmentation de la population à risque

Réel enjeu de santé publique



Balser et al, JNS 2015

Rôle de l'artère méningée moyenne ?

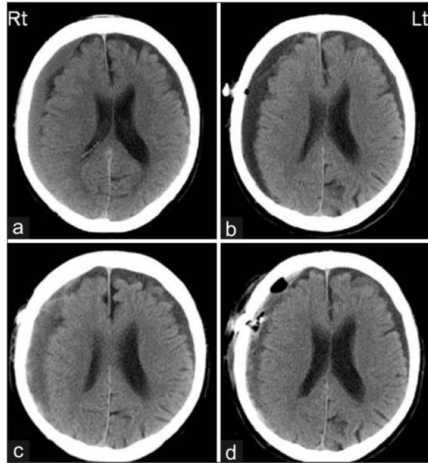


Figure 1: (a) CT scan on admission showing the right CSDH. (b) CT scan after the first irrigation. (c) CT scan 1 month after the second irrigation, showing re-recurrence of right CSDH. (d) CT scan after

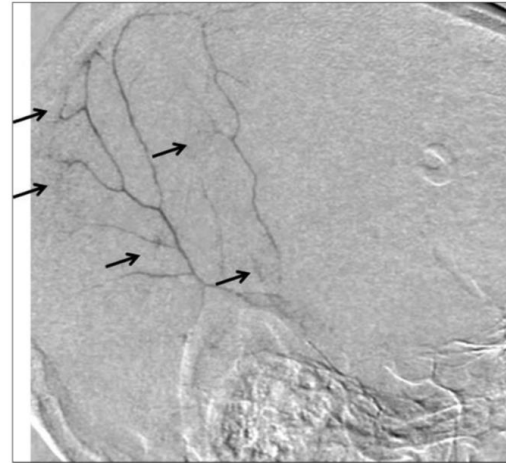
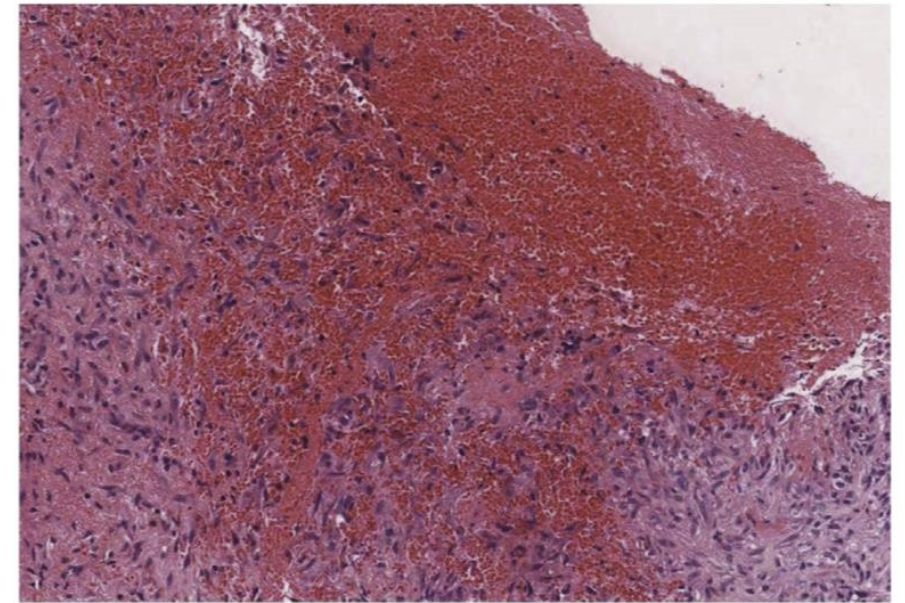


Figure 2: Superselective angiography of the right MMA. Abnormal vascular networks are seen (arrows)

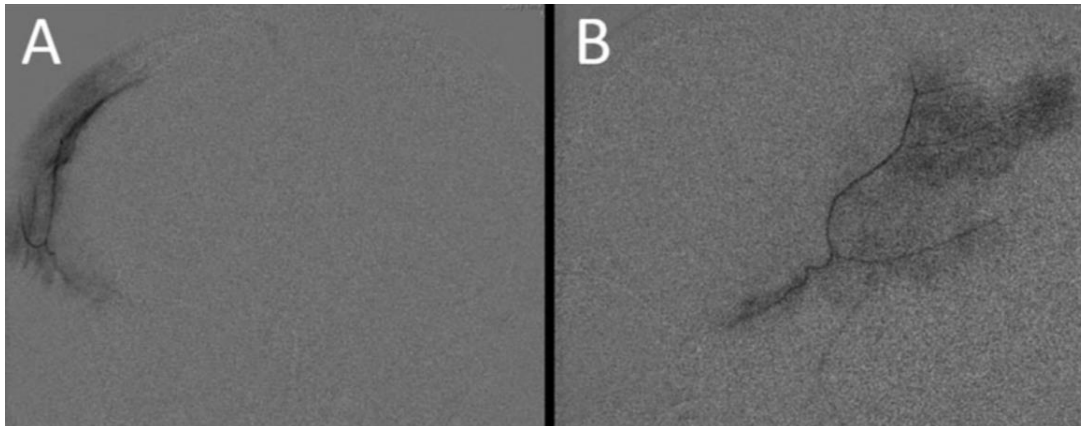


Néovaisseaux immatures de la coque externe des HSDC, développés à partir de la dure mère

Kim et al, World Neurosurgery 2017

Modification de l'artère méningée moyenne

Hashimoto et al, Surgical Neurology International 2013



« Contrast pooling »

Link et al, Interventional Neuroradiology 2018

Apports de la littérature

Radiology

Middle Meningeal Artery Embolization for Chronic Subdural Hematoma¹

Ban et al, Radiology 2018

Groupe embolisation, prospectif
72 patients
27 patients asymptomatiques sans chirurgie
45 patients symptomatiques après chirurgie

versus

Groupe non embolisé, rétrospectif
469 patients (sur 20 ans)
67 traitement médical seul
402 chirurgie

Main outcome: clinico-radiological recurrence
Résidu >10mm grand axe à 6 mois OU
Reprise chirurgicale à 6 mois

1/72 récurrence contre 129/469
Conclue à une supériorité du groupe embolisation...

Usefulness of interventional embolization of the middle meningeal artery for recurrent chronic subdural hematoma: Five cases and a review

Interventional Neuroradiology
2015, Vol. 21(3) 366-371
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sagepub.co.uk/journalsPermissions.nav
DOI: 10.1177/1591019915583224
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SAGE

Tsubota¹,
Nishio¹

Surgical Neurology International

OPEN ACCESS Editor-in-Chief: James I. Ausman, MD
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Original Article

Usefulness of embolization of the middle meningeal artery for refractory chronic subdural hematomas

Takao Hashimoto, Tomoo Ohashi¹, Daisuke Watanabe, Syunichi Koyama², Hiroaki Namatame, Hitoshi Izawa, Rei Haraoka, Hirofumi Okada, Norio Ichimasu, Jiro Akimoto, Jo Haraoka

Middle Meningeal Artery Embolization for Recurrent Chronic Subdural Hematoma: A Case Series
Thomas W. Link¹, Justin T. Schwarz¹, Stephanie M. Paine¹, Hooman Kamel², Jared Knopman¹

LITERATURE REVIEW

Check for updates

Middle Meningeal Artery Embolization for Chronic Subdural Hematoma: Meta-Analysis and Systematic Review

Aditya Srivatsan¹, Alina Mohanty¹, Fábio A. Nascimento², Muhammad U. Hafeez², Visish M. Srinivasan¹, Ajith Thomas⁴, Stephen R. Chen³, Jeremiah N. Johnson¹, Peter Kan¹

2020

Head and Neck

REVIEW

Middle meningeal artery embolization for the management of chronic subdural hematoma

David Fiorella,^{1,2} Adam S Arthur³ 2020

RESEARCH—HUMAN—CLINICAL STUDIES

Middle Meningeal Artery Embolization for Chronic Subdural Hematoma: A Series of 60 Cases

Thomas W. Link, MD, MS*
Srikanth Boddu, MD, MS*
Stephanie M. Paine, NP*
Hooman Kamel, MD*
Jared Knopman, MD*

BACKGROUND: Chronic subdural hematoma (SDH) is a particularly challenging pathology due to high recurrence rates (2%-37%) and complex medical comorbidities that tend to afflict the patient population. Recently, there have been several case series published describing the use of middle meningeal artery (MMA) embolization as an alternative to surgery for treatment of new or recurrent chronic SDH.
OBJECTIVE: To describe our first 60 cases of MMA embolization for chronic SDH.

2019

COMMENTARY

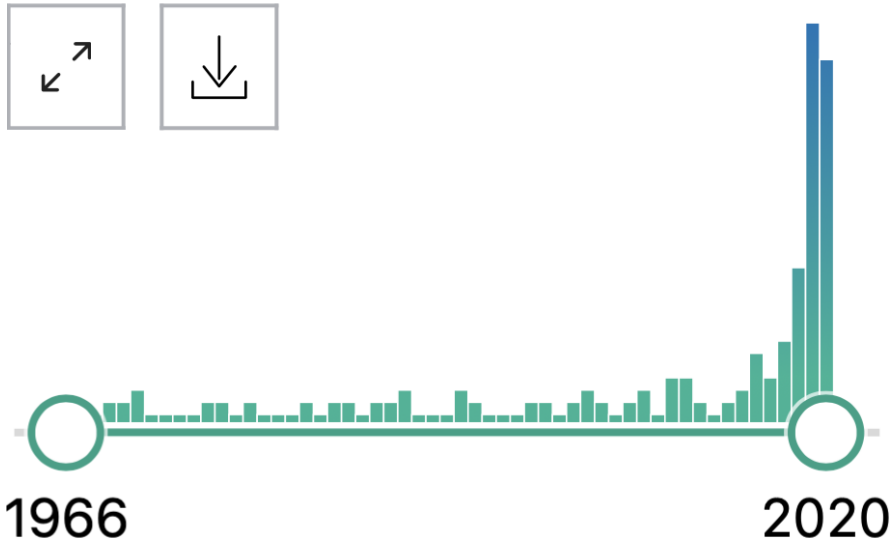
2019

Commentary: Middle Meningeal Artery Embolization for Chronic Subdural Hematoma: A Series of 60 Cases

Clemens M. Schirmer, MD, PhD*
Adnan H. Siddiqui, MD, PhD*

Chronic subdural hematomas (cSDH) were described as early as the mid-1600s and it stands to reason that trephination and release of the evil spirits contained in the skull really referred to the dark oily the patients enrolled in these 3 arms 76%, 100%, and 88% received MMA embolization, respectively. The primary outcome measure described was avoidance of surgery following embolization, however, the follow-up interval

RESULTS BY YEAR



2017: 6 publications
2018: 12 publications
2019: 32 publications
2020: 30 publications (septembre)

Embolization of the Middle Meningeal Artery for the Prevention of Chronic Subdural Hematoma Recurrence in High Risk Patients (EMPROTECT) (EMPROTECT)

ClinicalTrials.gov Identifier: NCT04372147

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. [Read our disclaimer](#) for details.

Recruitment Status: Recruiting
First Posted: May 1, 2020
Last Update Posted: September 15, 2020
[See Contacts and Locations](#)

Sponsor:
Assistance Publique - Hôpitaux de Paris

Information provided by (Responsible Party):
Assistance Publique - Hôpitaux de Paris

The SQUID Trial for the Embolization of the Middle Meningeal Artery for Treatment of Chronic Subdural Hematoma (STEM) (STEM)

ClinicalTrials.gov Identifier: NCT04410146

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. [Read our disclaimer](#) for details.

Recruitment Status: Not yet recruiting
First Posted: June 1, 2020
Last Update Posted: August 27, 2020
[See Contacts and Locations](#)

Sponsor:
Balt USA

Collaborators:
Balt Extrusion
Embo-Flüssigkeiten A.G.
AXIOM Real Time Metrics

5 essais randomisés doivent débuter en 2020 ! (USA, USA, China, France, France)

Etude pilote – expérience Montpelliéraine

- Recentrer l'analyse sur les population d'HSDC symptomatiques
- Rôle de l'embolisation comme traitement adjuvant à la chirurgie
- Evaluation de l'effet sur le volume et non la reprise, car probablement plus sensible

Avril 2018- Octobre 2018

Inclusion prospective des patients **entre avril 2018 et octobre 2018** = étude PILOTE

Traitement chirurgical conventionnel premier

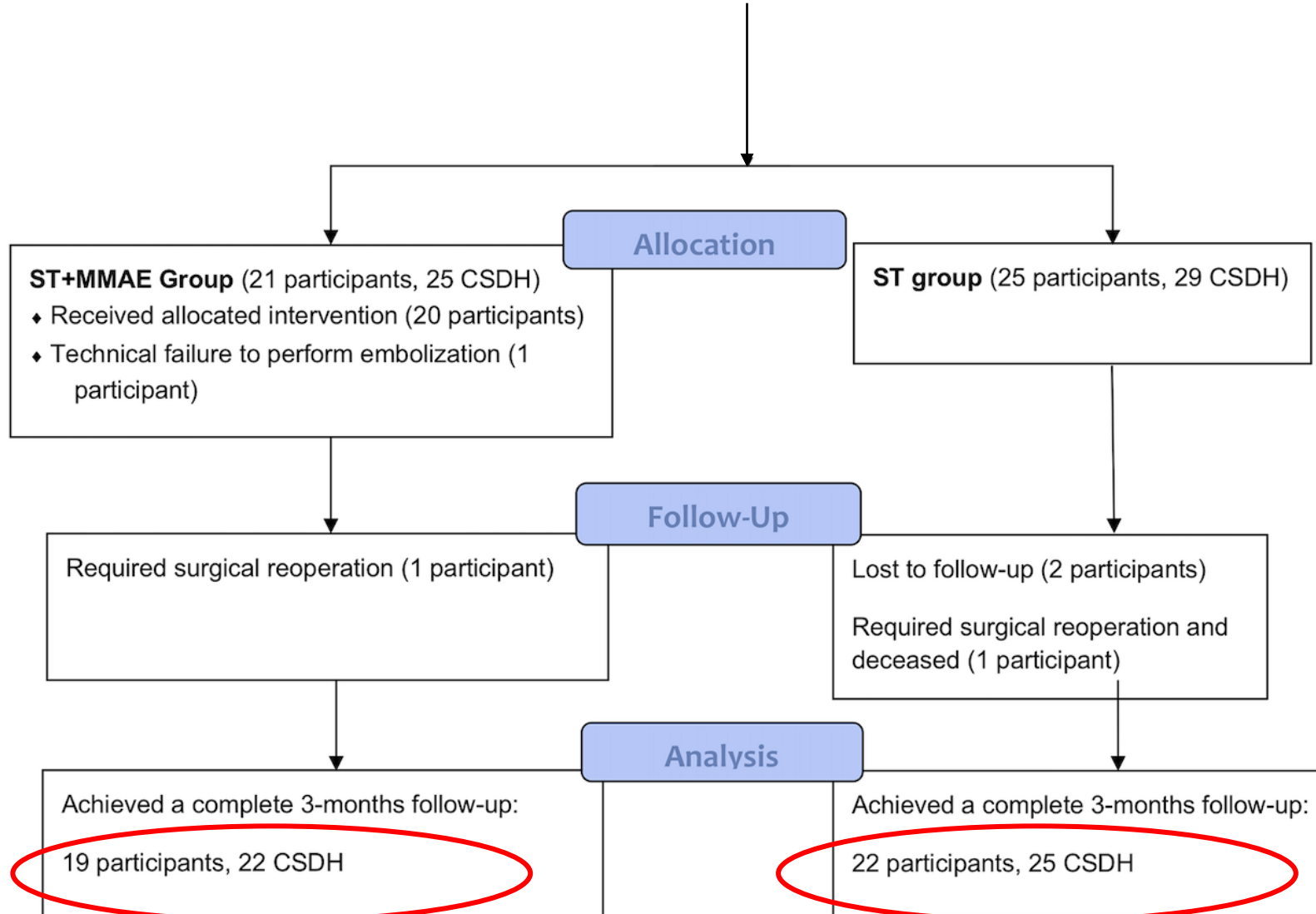


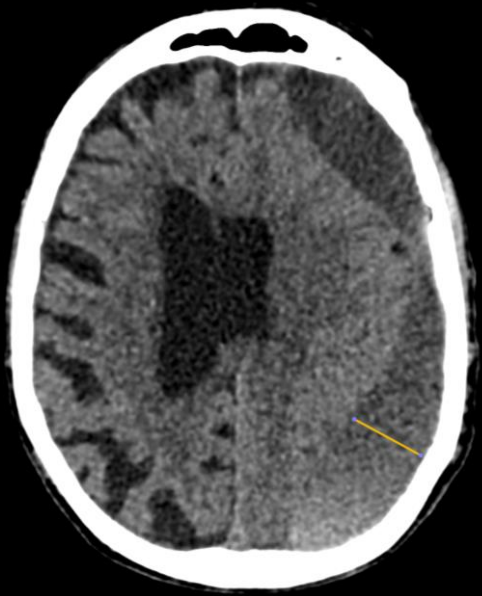
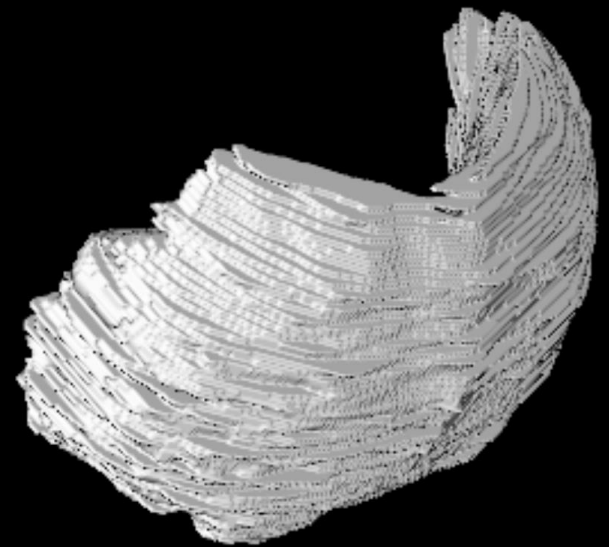
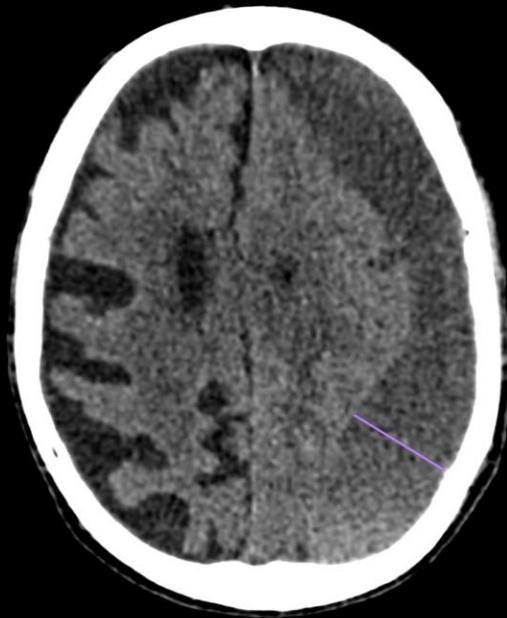
Table 1 Baseline characteristics of ST+MMAE group and ST group

Characteristic	ST+MMAE group n=19 (46%)	ST group n=22 (54%)
Demographics		
Age (years) (mean±SD)	77.4±10.9	74.7±13.9
Men/women	10/9	13/9
Trauma history, n (%)	12 (63)	15 (68)
Chronic alcoholism, n (%)	3 (16)	3 (14)
Antiplatelet or anticoagulant drugs, n (%)	7 (37)	9 (41)
Clinical exam at admission		
Glasgow Coma Score (mean±SD)	13.7±2.2	14.3±1.2
Cephalalgia, n (%)	9 (47)	10 (45)
Motor deficit, n (%)	5 (26)	10 (45)
Ataxia, n (%)	10 (53)	12 (55)
Seizure, n (%)	0 (0)	1 (5)
CSDH characteristics		
Left side, n (%)	8 (42)	9 (41)
Right side, n (%)	8 (42)	10 (45)
Bilateral, n (%)	3 (16)	3 (14)
Treated CSDH, n (%)	22	25
Surgical procedure		
Twist drill craniostomy with drainage, n (%)	20 (91)	24 (96)
Craniotomy with drainage, n (%)	2 (9)	1 (4)
Local anesthesia, n (%)	17 (89)	21 (95)
General anesthesia, n (%)	2 (11)	1 (4)

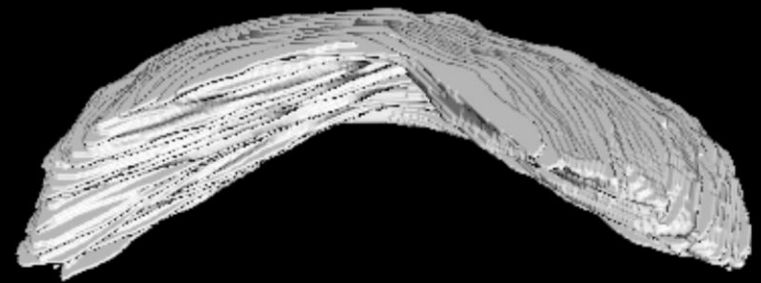
Table 2 Radiological data comparison between ST+MMAE group and ST group

Radiological data	ST+MMAE group	ST group	P value
Nakaguchi classification (specimen and percentage)			
Type I (homogenous)	7 (32)	13 (50)	0.56
Type I (laminar)	7 (32)	4 (15)	
Type II (separated)	4 (18)	5 (19)	
Type III (trabeculated)	4 (18)	4 (15)	
Baseline: immediate postsurgical (mean±SD)			
CSDH volume (mL)	65.2±27.1	51.2±27.4	0.14
CSDH width (mm)	14.7±5.4	13.6±4.7	0.37
End of follow-up: 3 month follow-up (mean±SD)			
CSDH volume (mL)	12.6±18.5	16.2±18.4	0.24
CSDH width (mm)	6.4±5.7	6.8±5.3	0.58

19 versus 22 patients
Comparables, âge moyen 76 ans



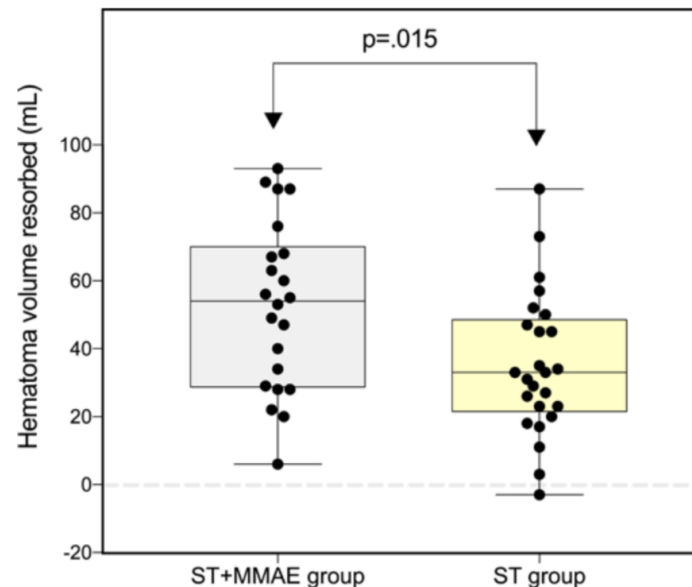
Main outcome: variation volumétrique de la collection sous durale entre post-opératoire immédiat et 3 mois



Main outcome: VOLUME RESORBE entre contrôle postopératoire et contrôle à 3 mois

Intérêt: critère objectif, basé sur une mesure reproductible, critère plus sensible pour essayer de montrer une différence sur un faible nombre de patients.

	ST+MMAE group	ST group	Mean difference	95% CI	P value
Primary outcome					
CSDH volume resorption at 3 months from postsurgical (mean±SD)	52.6±24.9	35.1±21.0	17.5	3.87 to 31.16	0.015
Other outcomes					
Surgical reoperation	1/21	1/25			
Death	0/21	1/25			



ORIGINAL RESEARCH

Middle meningeal artery embolization as an adjuvant treatment to surgery for symptomatic chronic subdural hematoma: a pilot study assessing hematoma volume resorption

Sam Ng,¹ Imad Derraz,² Julien Boetto,¹ Cyril Dargazanli,² Gaëtan Poulen,¹ Gregory Gasco ,² Pierre-Henri Lefevre ,² Nicolas Molinari,³ Nicolas Lonjon,¹ Vincent Costalat²

La volumétrie n'est pas un critère d'évaluation clinique ! Pas de conclusion hâtive...

Quelle population doit être ciblée ?

-récurrences post-chirurgicales ?

-traitement adjuvant à la chirurgie ?

-traitement primaire pour diminuer le recours à la chirurgie ?

Innocuité de la procédure ? (population âgée...)

-->Collatérales ophtalmiques de l'AMM

-->Collatérales pétreuses de l'AMM

PROTOCOL SYNOPSIS

Endovascular Treatment for Chronic Subdural Hematoma: Study Protocol for a Randomized Controlled Trial

Title and Code	The <u>Onyx™ Trial For The Embolization Of The Middle Meningeal Artery For Chronic Subdural Hematoma (OTEMACS)</u>
Study Objectives	
Primary Objective	To evaluate the hypothesis that middle meningeal artery (MMA) embolization plus standard (surgical/medical) management leads to significant reduction in recurrence rate within 90 days as compared to standard management alone in patients with chronic subdural hematoma (CSDH).
Secondary Objective(s)	<p>To provide evidence that MMA embolization with Onyx™ is associated with a significant reduction in hematoma volume (HV) compared to the control group at 90 days.</p> <p>To provide evidence that MMA embolization with Onyx™ is associated with a significant reduction in recurrence of CSDH requiring revision surgery or surgical rescue compared to the control group within 90 days.</p> <p>To provide evidence that MMA embolization with Onyx™ leads to superior functional and clinical outcomes compared to the control group at 90 days.</p> <p>To evaluate the safety and efficacy of MMA embolization combined with standard management vs. standard management alone in CSDH patients.</p>
Study Endpoints	
Efficacy Parameter	<p>CSDH recurrence rate within 90 days.</p> <p>The recurrence of CSDH is defined as a subsequent radiographic relapse of hematomas (remaining or reaccumulated hematoma with thickness > 10 mm) in the ipsilateral subdural space with or without any clinical presentation within 90 days after the randomization.</p>
Primary Efficacy Endpoint	Recurrence rate within 90 days in the Experimental group vs. the Control group.
Secondary Efficacy Endpoints	<ol style="list-style-type: none"> 1. Rate of recurrence of CSDH requiring revision surgery (in surgical group) or surgical rescue (in non-surgical group) within 90 days. 2. Change in hematoma volume (HV) at 90 days in the Experimental group vs. the Control group. 3. Shift on the modified Rankin Scale (mRS) score at 90 days in the Experimental group vs. the Control group. 4. Proportion of patients with good functional outcome at 90 days, defined as mRS 0-2. 5. Proportion of patients with favorable functional outcome at 90 days, defined as mRS 0-3.

Essai randomisé multicentrique

The Onyx Trial For the Embolisation of The Middle Meningeal Artery For Chronic Subdural Hematomas (OTEMACS)





Merci de votre attention

