Pharyngeal Electrical Stimulation – success story or dead end?

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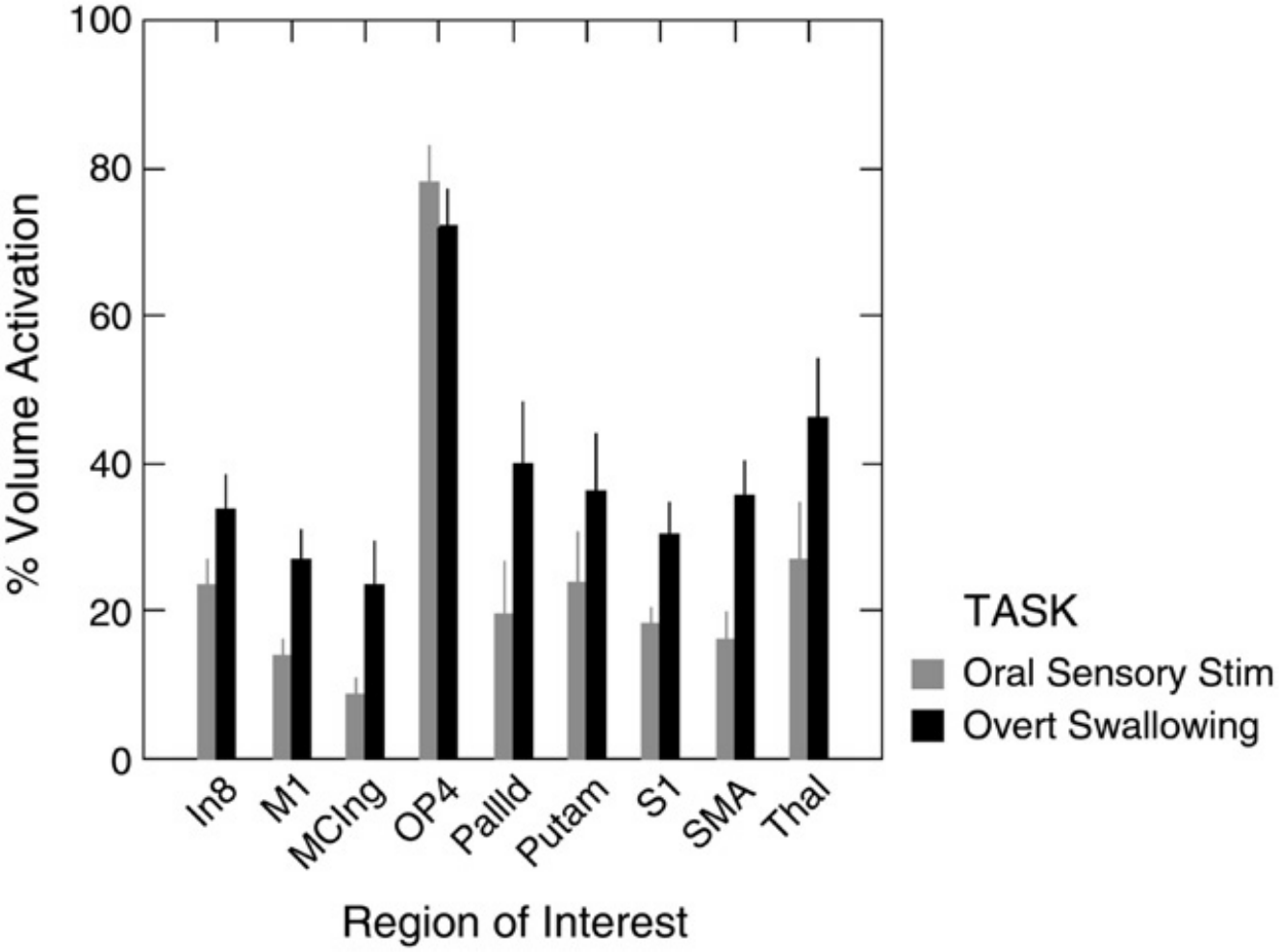
Deutsche Forschungsgemeinschaft DFG

Overview

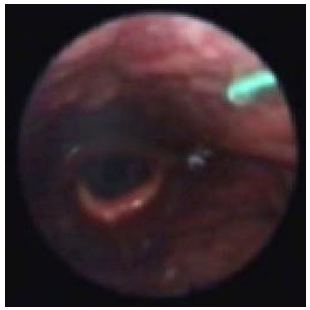
- Introduction
  - Physiology and pathophysiology of sensory feedback
- Pharyngeal electrical stimulation (PES)
  - Peripheral and central targets
- STEPS & Co.
  - How to survive a negative multicenter trial
- PHAST-TRAC
  - Adressing dysphagia in tracheostomized stroke patients

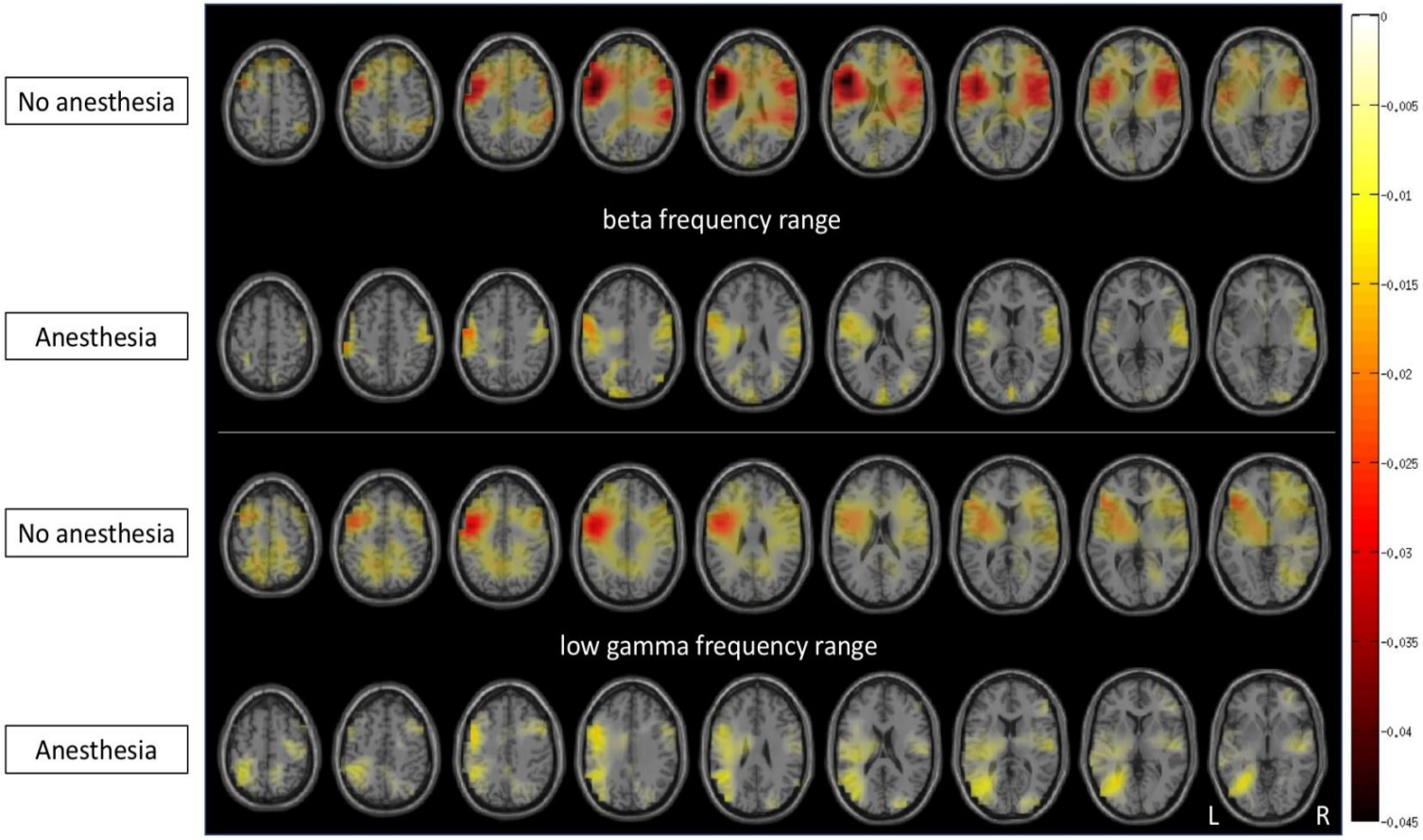
Impact of sensory feedback



Lowell et al., NeuroImage 2008

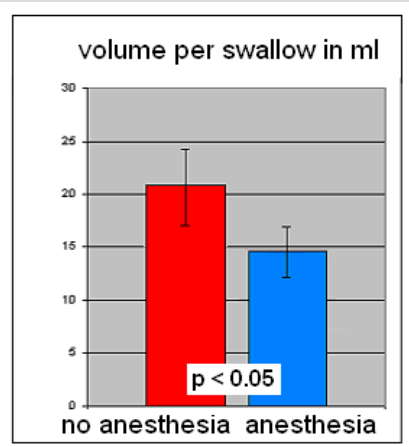
Pathophysiologie
Sensible Afferenzen

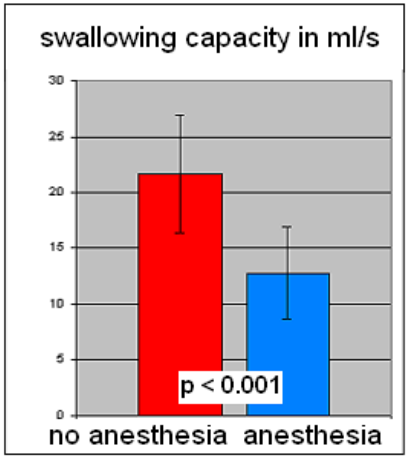




Muhle et al., Neurosignals 2017

Impact of sensory feedback





→Sensory input drives motor output!

Teismann et al., BMC **Neuroscience 2007**

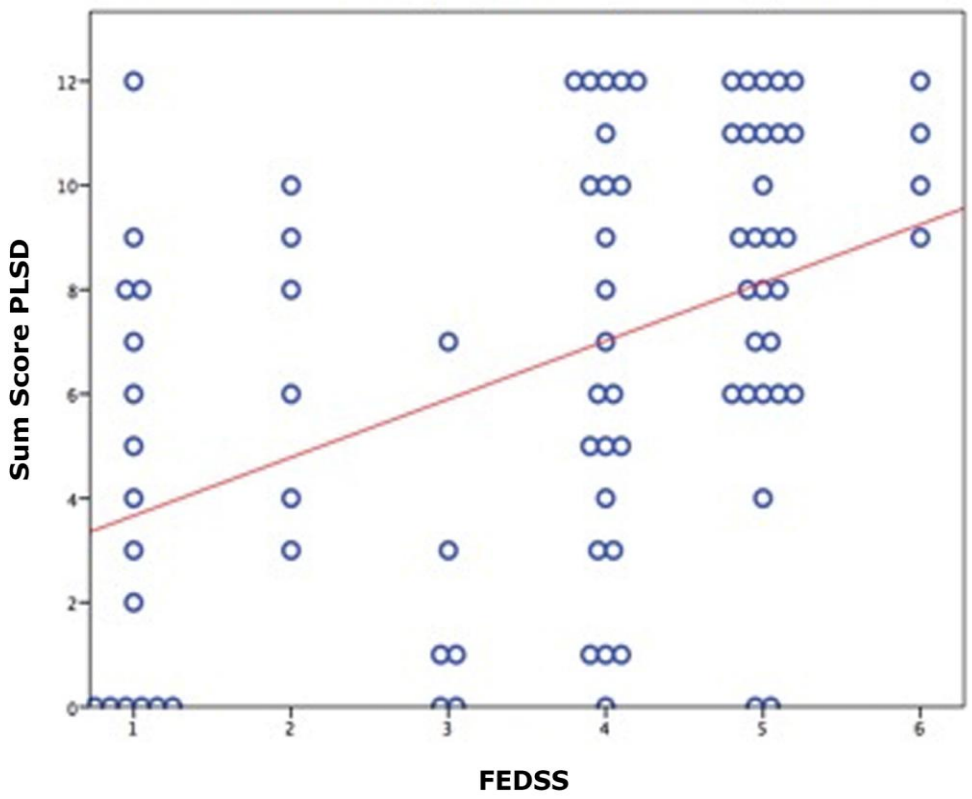
Disturbed sensory feedback

Disturbed sensory feedback

Sensory feedback & Dysphgia severity

- 84 acute stroke patients
  - 41 MCA left
  - 43 MCA reicht
- FEES based rating of
  - Pharyngo-laryngeal sensory defitic
  - Dyshgia severity

Spearman, r=.452, p<.01



Marian et al., submitted

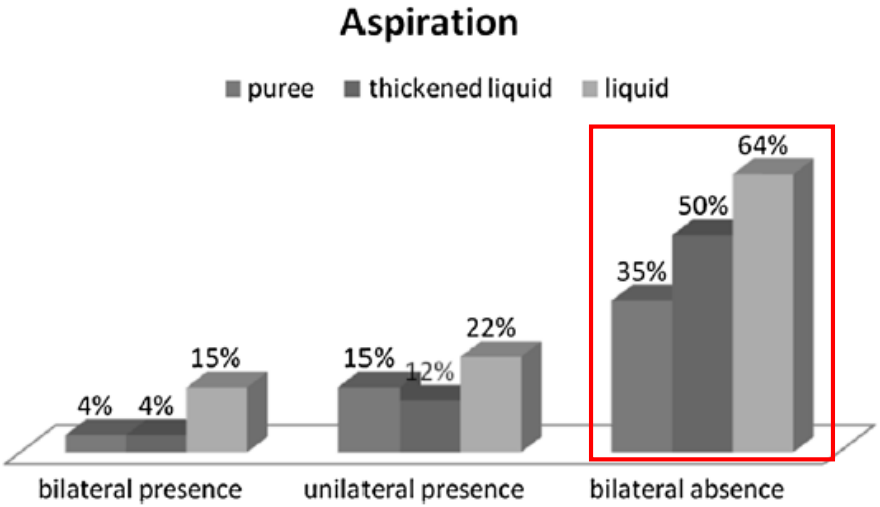
Sensory feedback & Complications

TABLE 6. LARYNGOPHARYNGEAL SENSORY DEFICIT AND OUTCOME

LP Sensory Deficit	*Aspiration*			*PEG*		
	No	*Yes*	*Total*	*No*	*Yes*	*Total*
Moderate	3	2	5	3	2	5
Severe	3	5*	8	4	4	8
Total	6	7	13	7	6	13

*There was one death in this group of aspirating patients.

Aviv et al., Ann Otol Rhinol Laryngol 1996



Onofri et al., Dysphagia 2014

Table 1. Prevalence of aspiration by laryngopharyngeal sensory and motor status

Sensation	Motor function	Aspiration (%)	n
Normal	Normal	2	137
Normal	Absent	29	7
Moderate decrease	Normal	0	9
Moderate decrease	Absent	67	3
Severe decrease, absent	Normal	15	33
Severe decrease, absent	Absent	100	15

Setzen et al., Otolaryngol Head Neck Surg 2003

Sensory feedback & Complications

Dysphagia (2018) 33:192–199
https://doi.org/10.1007/s00455-017-9845-8

ORIGINAL ARTICLE

Relationship Between Laryngeal Sensory Deficits, Aspiration, and Pneumonia in Patients with Dysphagia

Asako Kaneoka[1,2] · Jessica M. Pisegna[2] · Haruhi Inokuchi[1] · Rumi Ueha[3] · Takao Goto[3] · Takaharu Nito[3] · Cara E. Stepp[2,4] · Michael P. LaValley[4] · Nobuhiko Haga[1] · Susan E. Langmore[2,5]

Table 4 The laryngeal adductor reflex and pneumonia

Pneumonia	Laryngeal adductor reflex		
	Present (%)	Absent (%)	Total
Absent	36 (90.0)	12 (57.1)	48 (78.7)
Present	4 (10.3)	9 (42.9)	13 (21.3)
Total	40	21	61

Fisher's exact test; $p < 0.01$

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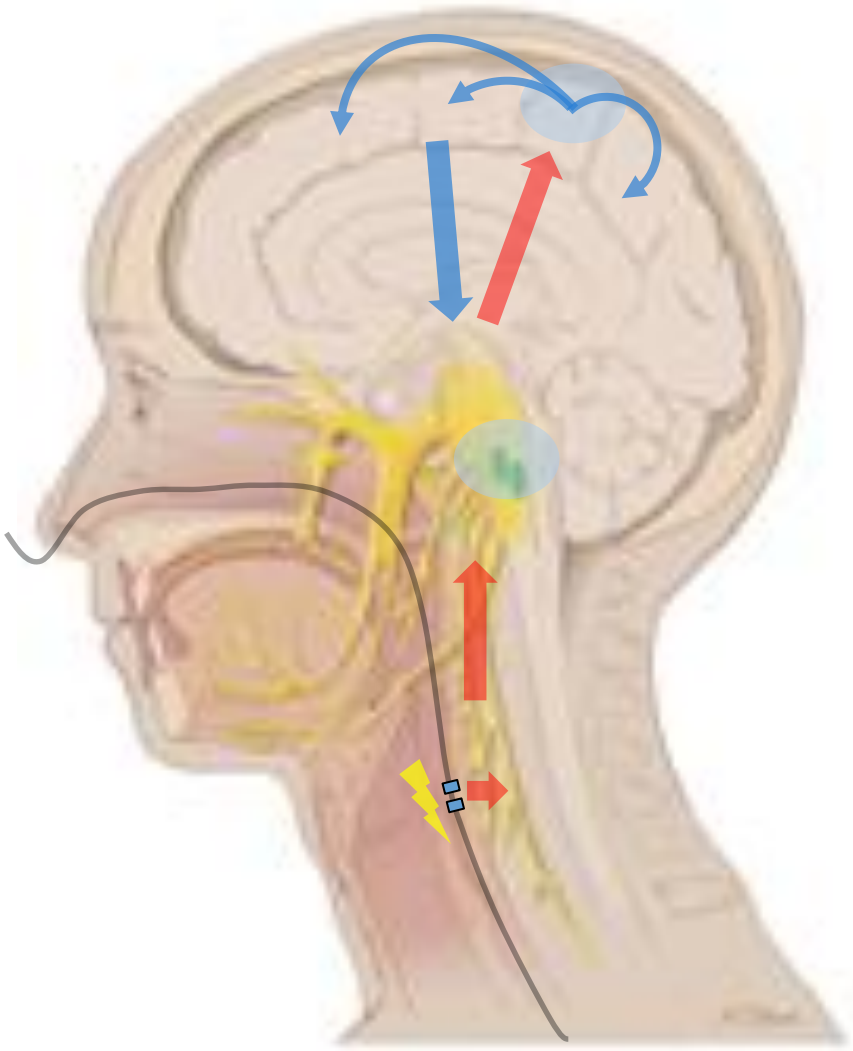
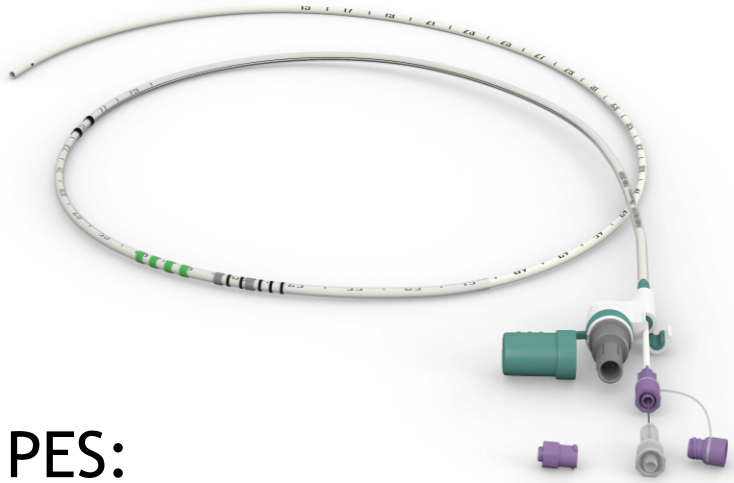
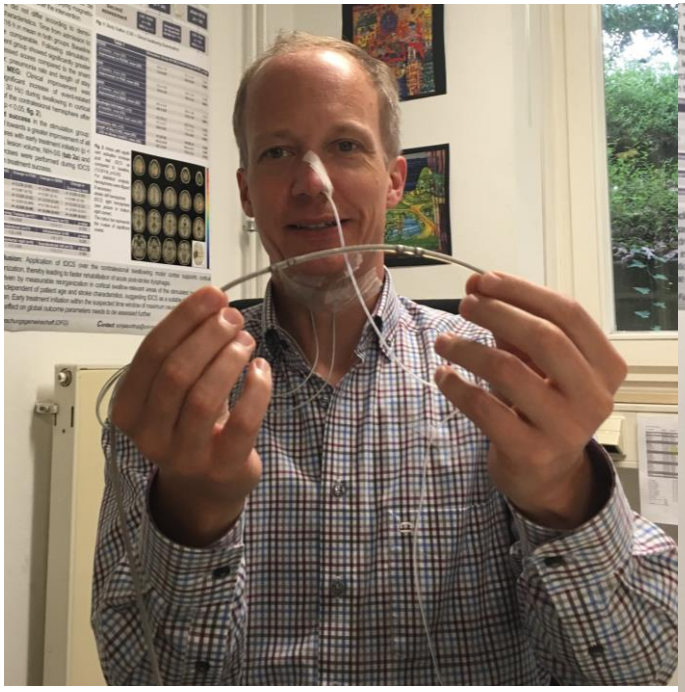
Pharyngeale Elektrostimulation (PES)

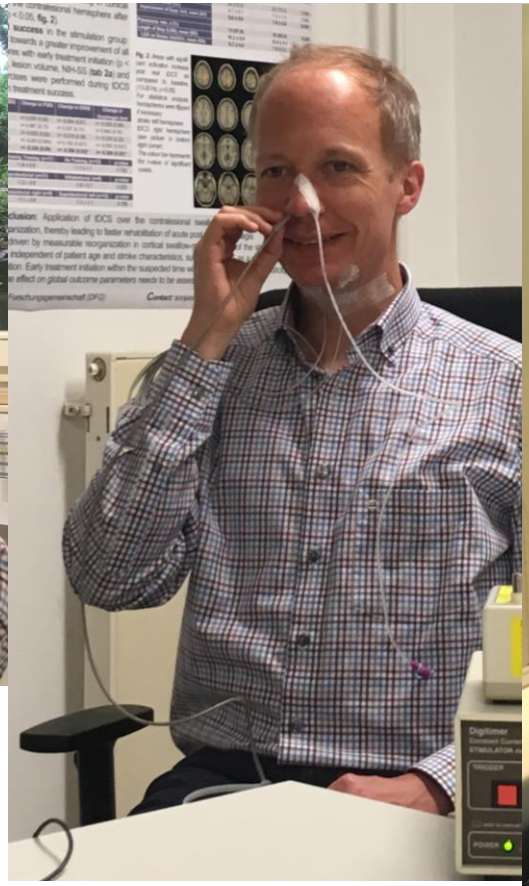




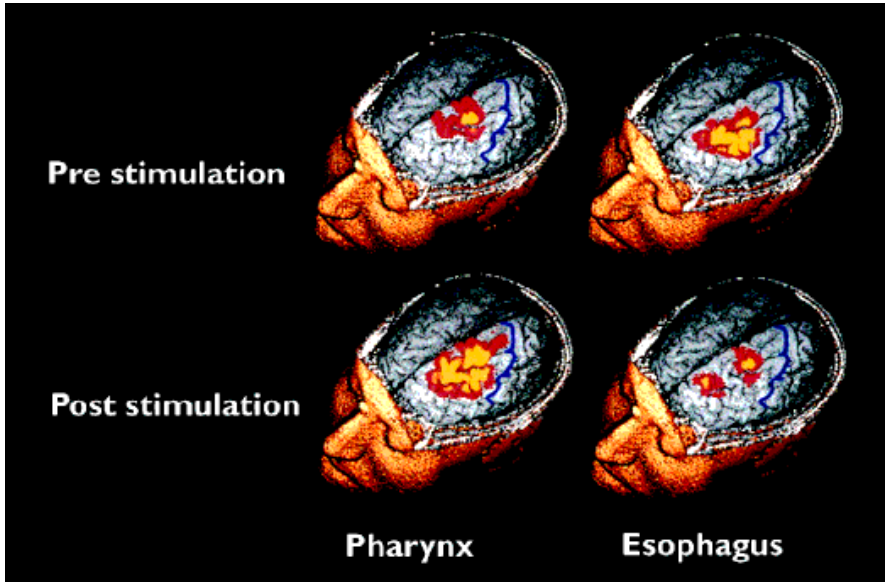
- PES:
  - An 3 aufeinanderfolgenden Tagen
  - für je 10 Minuten

PES
im Labor

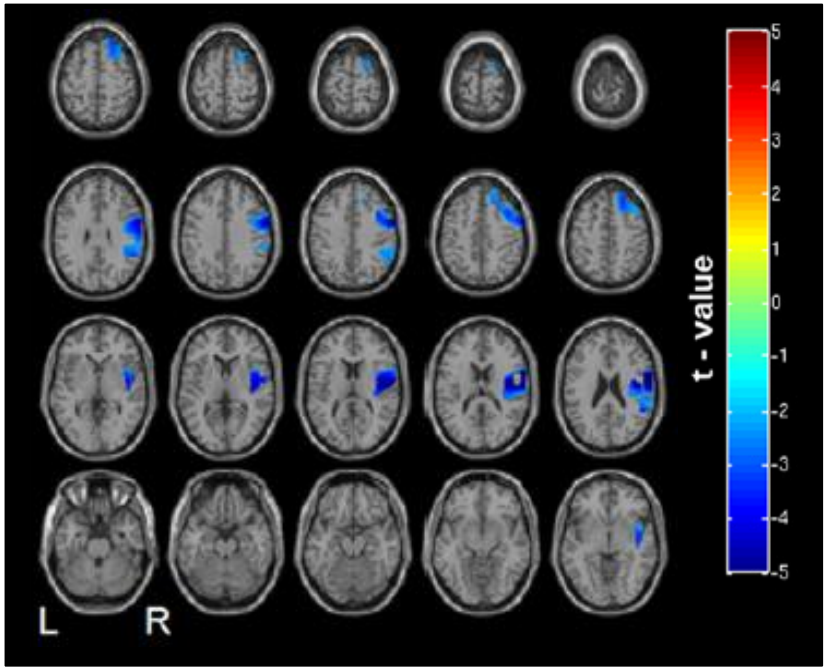




PES
Basic principles (1)



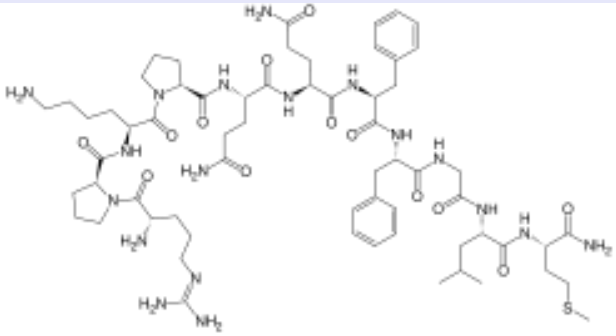
Hamdy et al, Nature Neurosci 1998



Suntrup et al., Neuroimage 2015

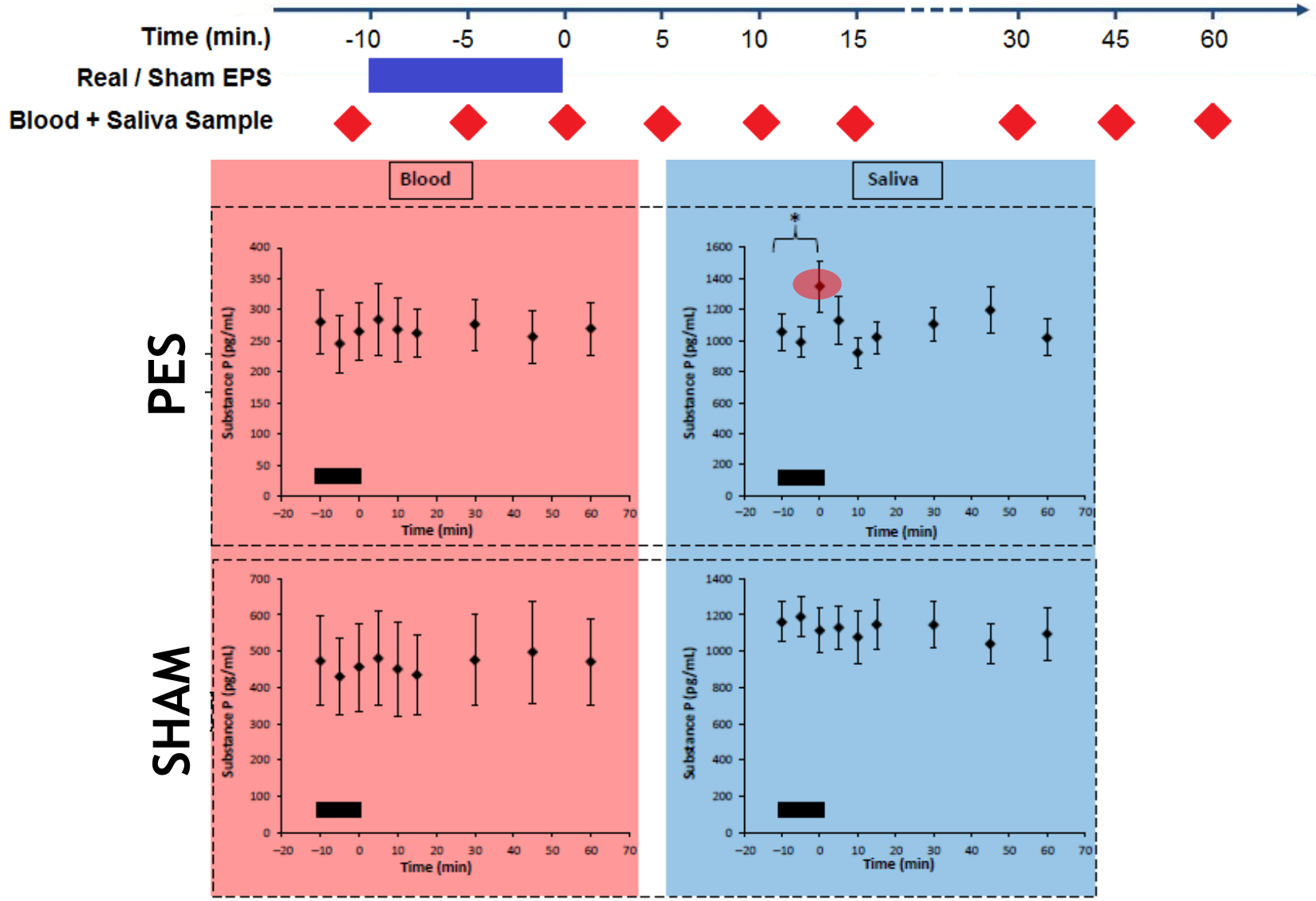
- Facilitation of cortical reorganization!

PES
Basic principles (2)



- Substance P is
  - a neuropeptide (“Neurokinine family”)
  - ubiquitary in the CNS and PNS
  - found within the sensory nerve fibres innervating the pharynx, larynx, and trachea *(Hauser-Kronberger, et al. 1994)*
  - known to enhance cough and swallow reflex in animal model *(Kohrogi, et al., 1988; Jia, et al., 1998)*
- Blocking pharyngeal receptors for substance P impairs the swallowing reflex *(Jin et al., 1994)*
- Dysphagia after stroke may be related to reduced levels of substance P in saliva *(Arai et al., Neurology 2003)*

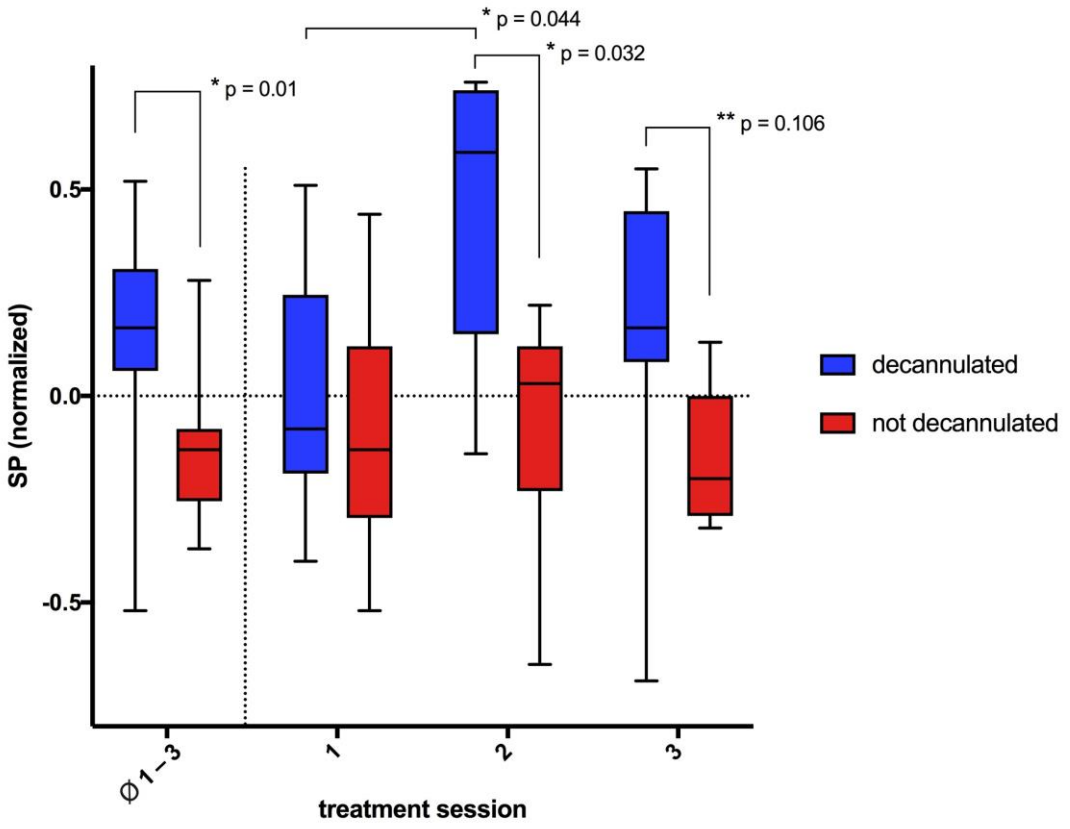
PES
Basic principles (3)



Suntrup-Krueger et al, Neurogastroenterol Motil 2016

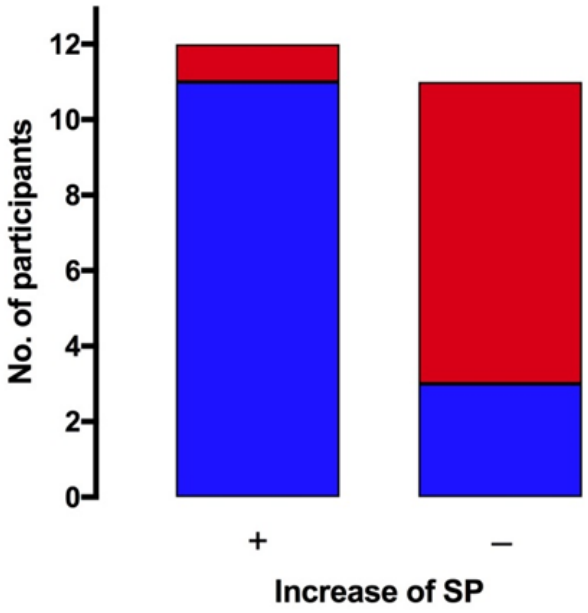
PES
Proof-of-Principle Study

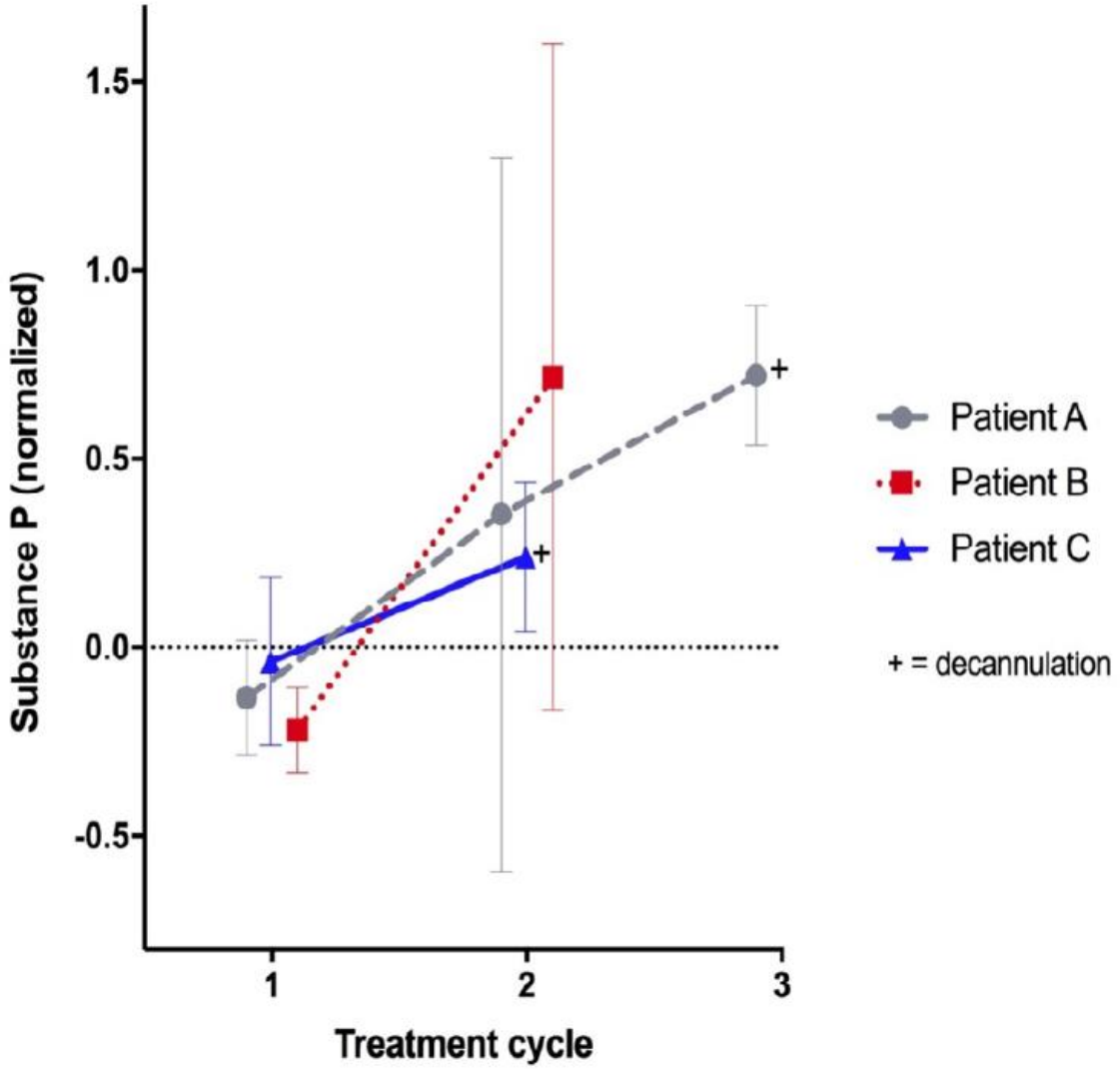
- Methods:
  - 23 severly dysphagic tracheotomized stroke patients
  - PES on 3 consecutive days
  - Saliva SP samples pre and post PES
- Analysis:
  - Comparing groups with and without treatment success



Muhle et al, in preparation

PES
Proof-of-Principle Study





Muhle et al, Neurosignals 2017

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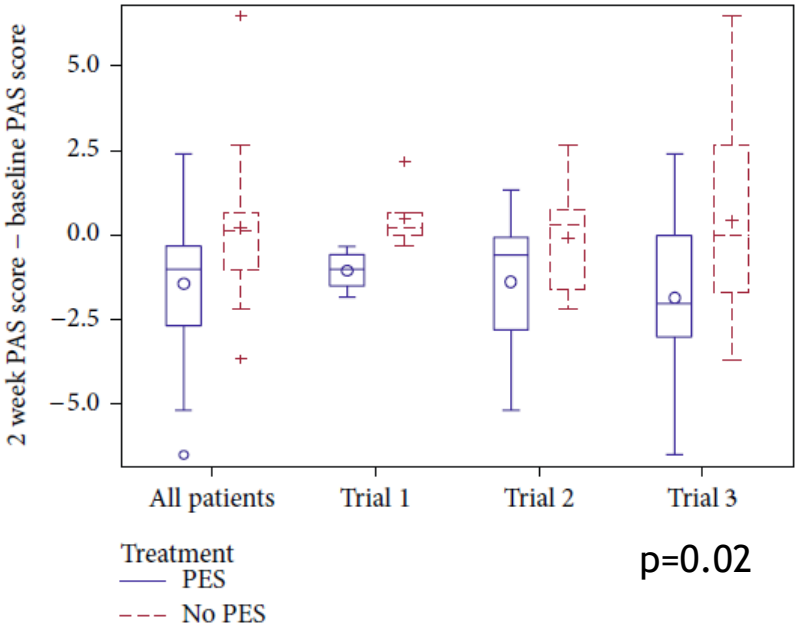
PES
Meta-analysis of first trials

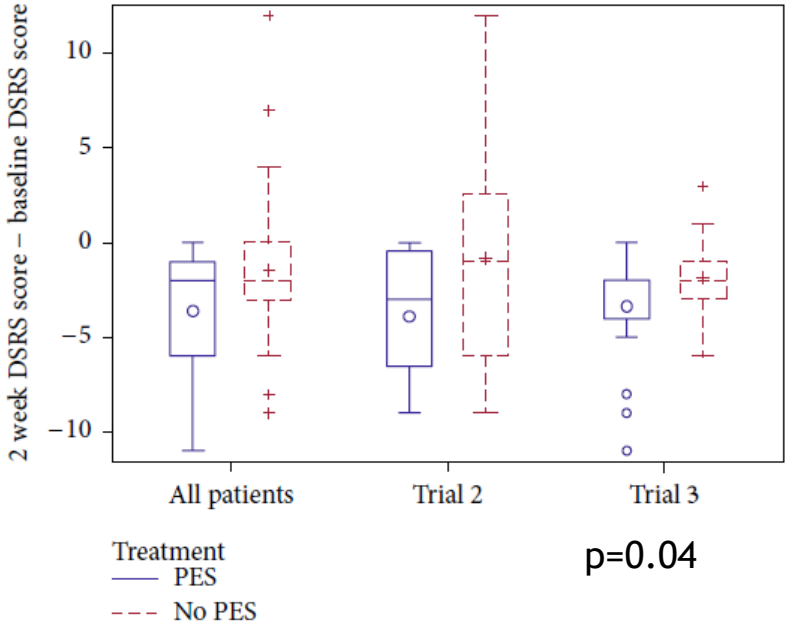
Review Article

Pharyngeal Electrical Stimulation for Treatment of Poststroke Dysphagia: Individual Patient Data Meta-Analysis of Randomised Controlled Trials

Polly Scutt,[1] Han S. Lee,[1] Shaheen Hamdy,[2] and Philip M. Bath[1]



p=0.02



p=0.04

Stroke Res Treat 2015

PES
Large multicenter RCT

Pharyngeal Electrical Stimulation for Treatment of Dysphagia in Subacute Stroke

A Randomized Controlled Trial

Philip M. Bath, DSc, FMedSci; Polly Scutt, MSc; Jo Love, BSc; Pere Clavé, MD, PhD; David Cohen, FRCP; Rainer Dziewas, MD, PhD; Helle K. Iversen, MD, DMSci; Christian Ledl, MA; Suzanne Ragab, FRCP, MPhil; Hassan Soda, MD, PhD; Anushka Warusevitane, MRCP(UK); Virginie Woisard, MD, PhD; Shaheen Hamdy, FRCP, PhD; on behalf of the Swallowing Treatment Using Pharyngeal Electrical Stimulation (STEPS) Trial Investigators

Aims:

- Assess safety and efficacy of pharyngeal electrical stimulation (PES) in subacute post-stroke dysphagia
- Assess feasibility of treatment

Design:

- International multicentre parallel-group single-blind phase III trial of PES versus sham

Bath *et al*. *Stroke* 2016;47:1562

STEPS
Outline

- Primary Endpoint:
  - Penetration Aspiration Score (PAS) on VFS at 2 weeks, adjusted for baseline and covariates

- Secondary endpoints (active vs sham treatment):
  - PAS on VFS at 12 weeks
  - Dysphagia Severity Rating Scale (DSRS)
  - Impairment (NIHSS)
  - Function: modified Rankin Scale, Barthel Index
  - Death, serious adverse events

STEPS
Results

	All (N=126)	PES (N=70)	Sham (N=56)	OR/MD (95% CI), Adjusted	*P* Value	OR/MD (95% CI), Unadjusted	*P* Value
Baseline							
PAS (/8)	4.8 (2.0)	4.8 (2.1)	4.7 (1.9)	…	…	…	…
2 wk primary outcome							
Mean of all boli (/8)	3.6 (2.0)	3.7 (2.0)	3.6 (1.9)	0.14 (–0.37 to 0.64)	0.60	0.06 (–0.62 to 0.74)	0.86
Change from baseline	–1.2 (1.8)	–1.2 (1.8)	–1.2 (1.8)	0.14 (–0.37 to 0.64)	0.60	0.00 (–0.62 to 0.61)	1.00
Any PAS >3 (%)	105 (83.3)	60 (85.7)	45 (80.4)	1.22 (0.29 to 5.15)	0.79	1.47 (0.57 to 3.75)	0.42
12 wk							
Mean of all boli (/8)	3.2 (2.1)	3.3 (2.2)	3.0 (2.1)	0.29 (–0.04 to 0.99)	0.41	0.24 (–0.6 to 1.08)	0.57
Any PAS >3 (%)	69 (72.6)	36 (70.6)	33 (75.0)	0.62 (0.20 to 1.90)	0.41	0.80 (0.32 to 1.99)	0.63
Repeated measures							
Mean (/8)*	…	4.1 (2.3)	3.9 (2.3)	0.51 (–0.23 to 1.25)	0.18	0.19 (–0.67 to 1.04)	0.67

→ **STEPS was a negative trial, primary endpoint was completely missed**

- **Potential reasons:**
  - **Undertreatment of patients**
  - **Wrong patient selection**

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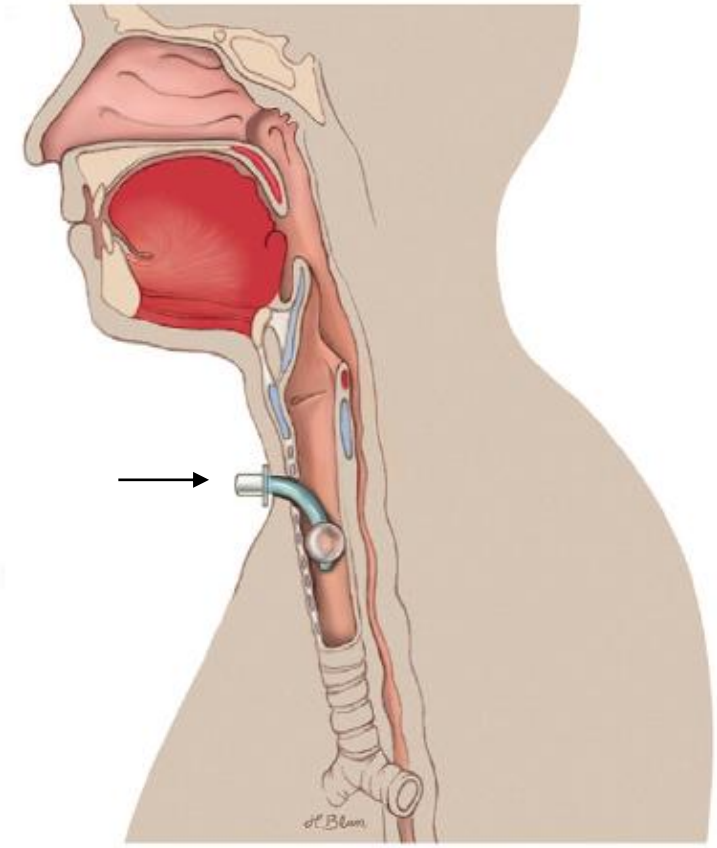
PES
New Multicenter RCT

Benefit of **PHA**ryngeal electrical **ST**imulation for early decannulation in **TRAC**heotomised stroke patients with neurogenic dysphagia: a prospective randomized single-blinded interventional study (PHAST TRAC study)

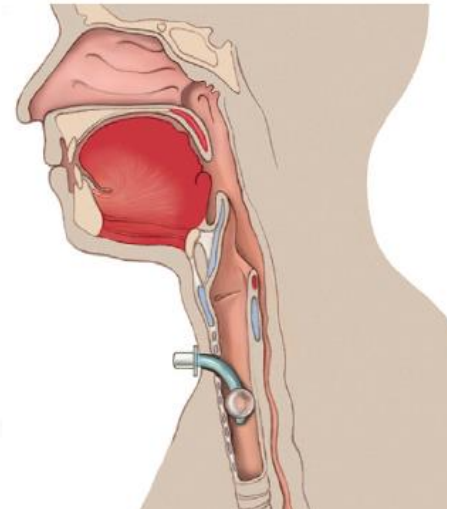
PES
New target population

- 1-2% of all stroke patients and 30% of stroke patients treated on the ICU receive a trachostomy



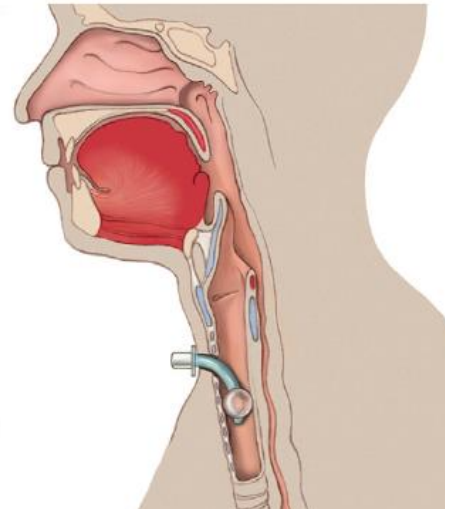
PES
New target population

- Putative advantages of the tracheal cannula:
  - Prevention of laryngeal or tracheal damage
  - Shorter duration of mechanical ventilation
  - Reduction of ICU LOS
  - Reduction of related health care expenditures
- Disadvantages:
  - Delay of rehabilitation
  - Patient discomfort
  - **Higher rate of complications and increased mortality when the patient is discharged from the ICU with a tracheal cannula in place.**
- Decannulation is important to enable
  - verbal communication
  - oral feeding



PES
New target population

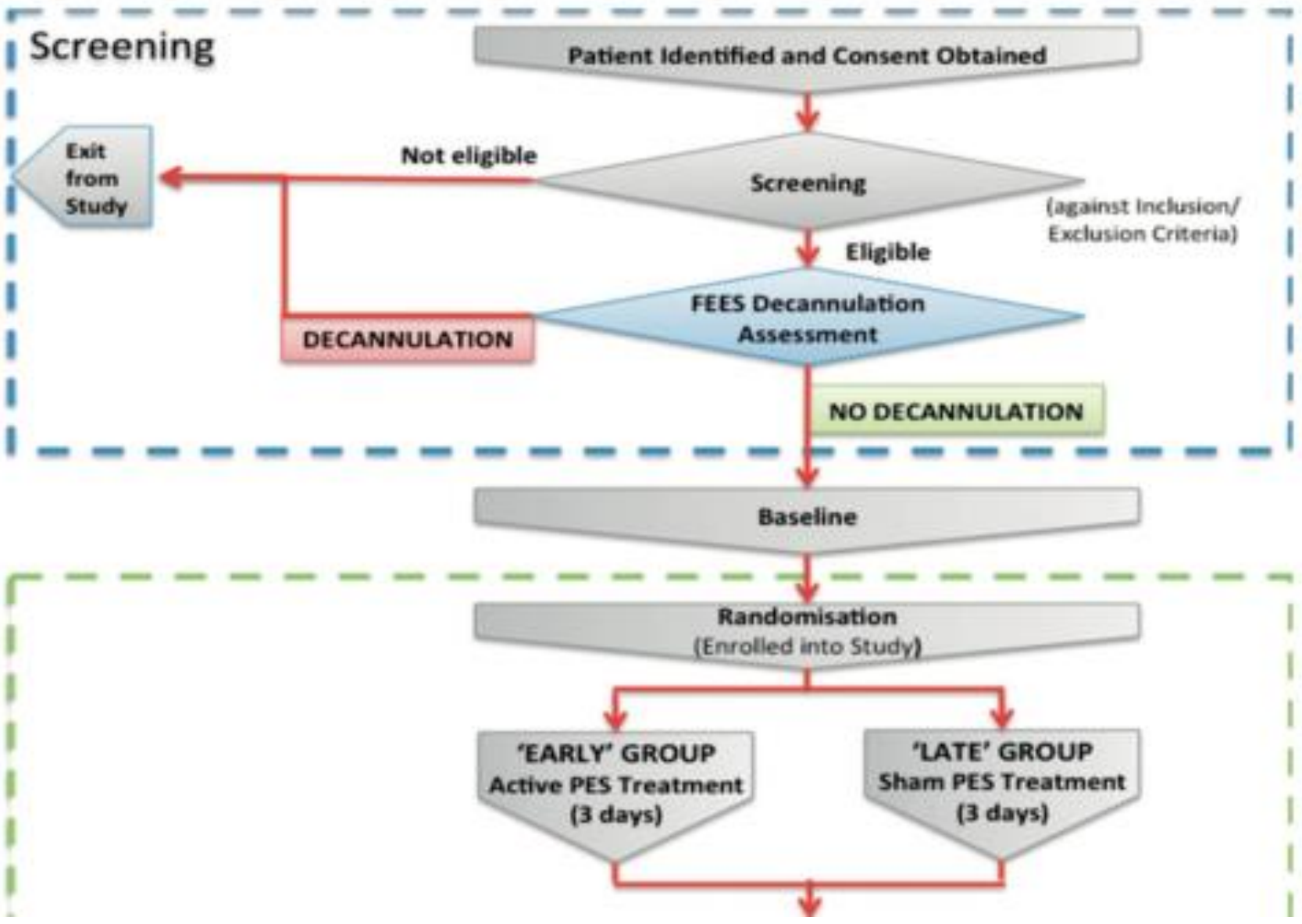
- Rate of decannulation in prospective studies:
  - Schneider et al, Neurocrit Care 2017:
    - 0% (n=53) at discharge
    - 26% (14/53) after 3 months
    - 36% after 12 months
  - Catalino et al., J Intensiv Care 2018:
    - 19% (9/48) at discharge
- Main obstacle to decannulation:
  - Severe dysphagia (30-70% of patients)
  - ➢ Related pathophysiology is complex
  - ➢ No established treatment options



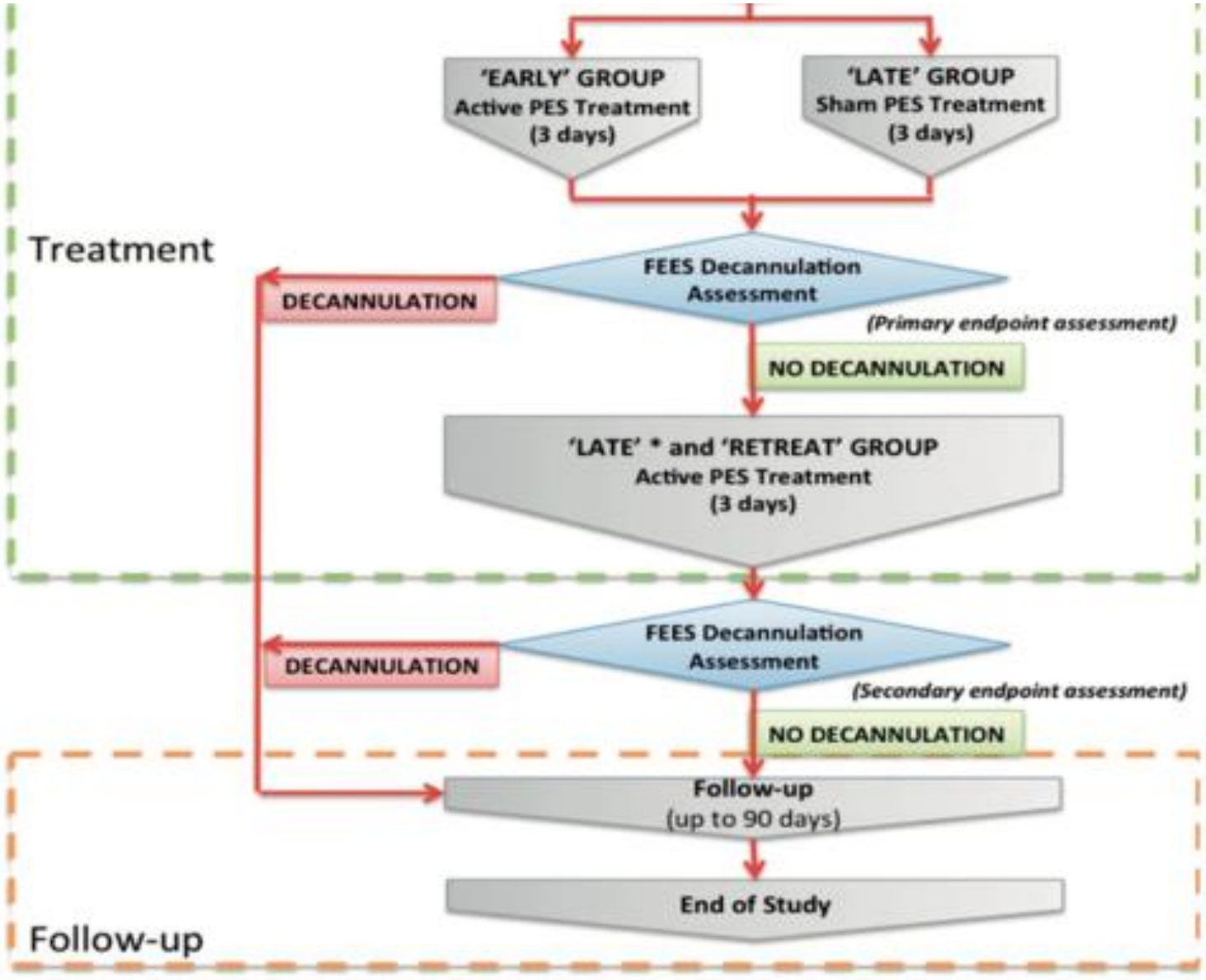
PHAST-TRAC
Methods

- Aim
  - Safety & efficacy of PES in accelerating readiness for decannulation
- Patients
  - Supratentorial stroke (IS or ICH)
  - Prior artificial ventilation and tracheotomy;
  - Safely weaned from mechanical ventilation
  - persistent neurogenic dysphagia with unsafe airway 24-72h prior to randomization
  - No sedation for ≥3 days
  - Germany, Italy, Austria
- Intervention
  - Early PES (Phagenyx)
  - Recurrent PES in persisting dysphagia

PHAST-TRAC
Design (1)



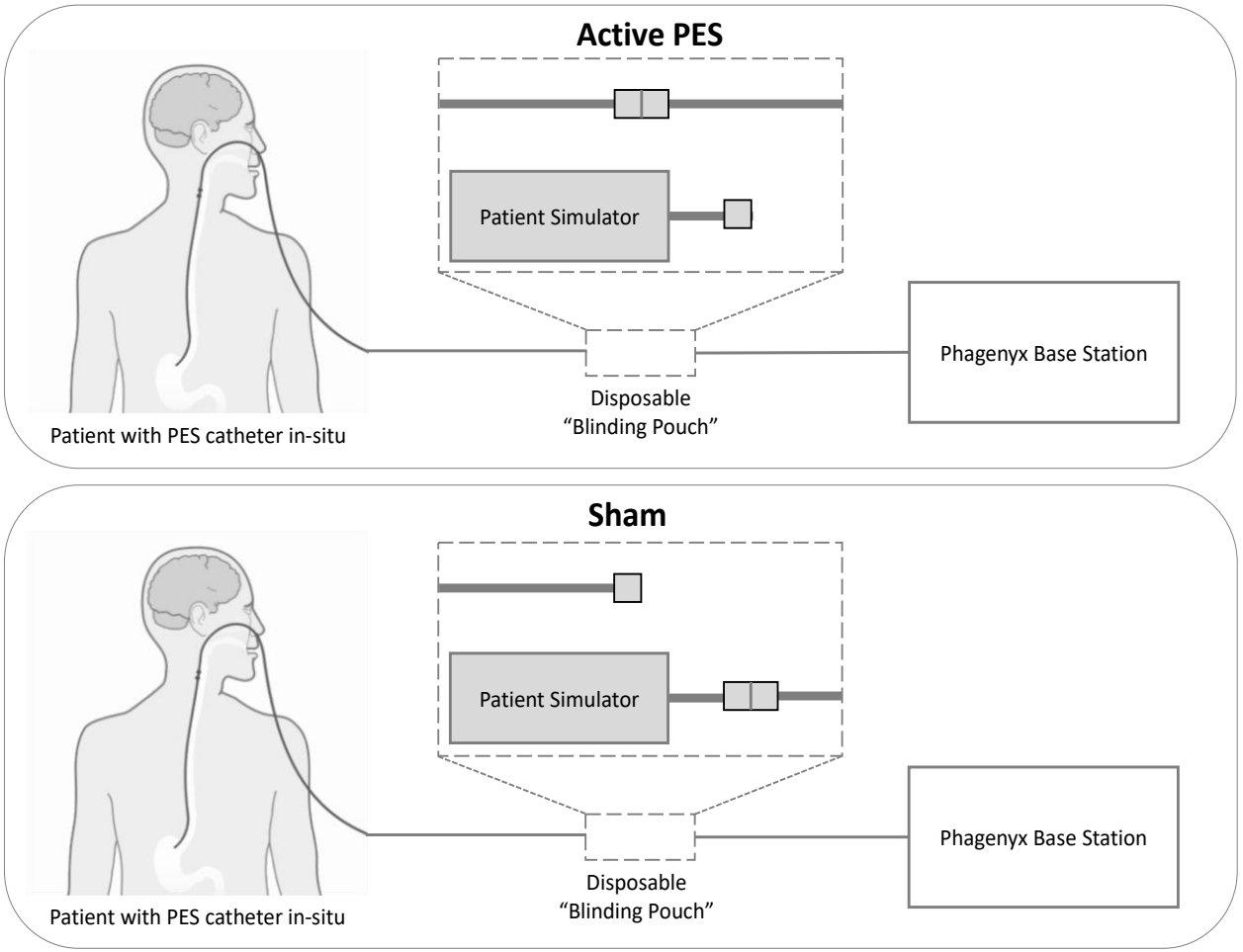
PHAST-TRAC
Design (2)



PHAST-TRAC
Endpoints

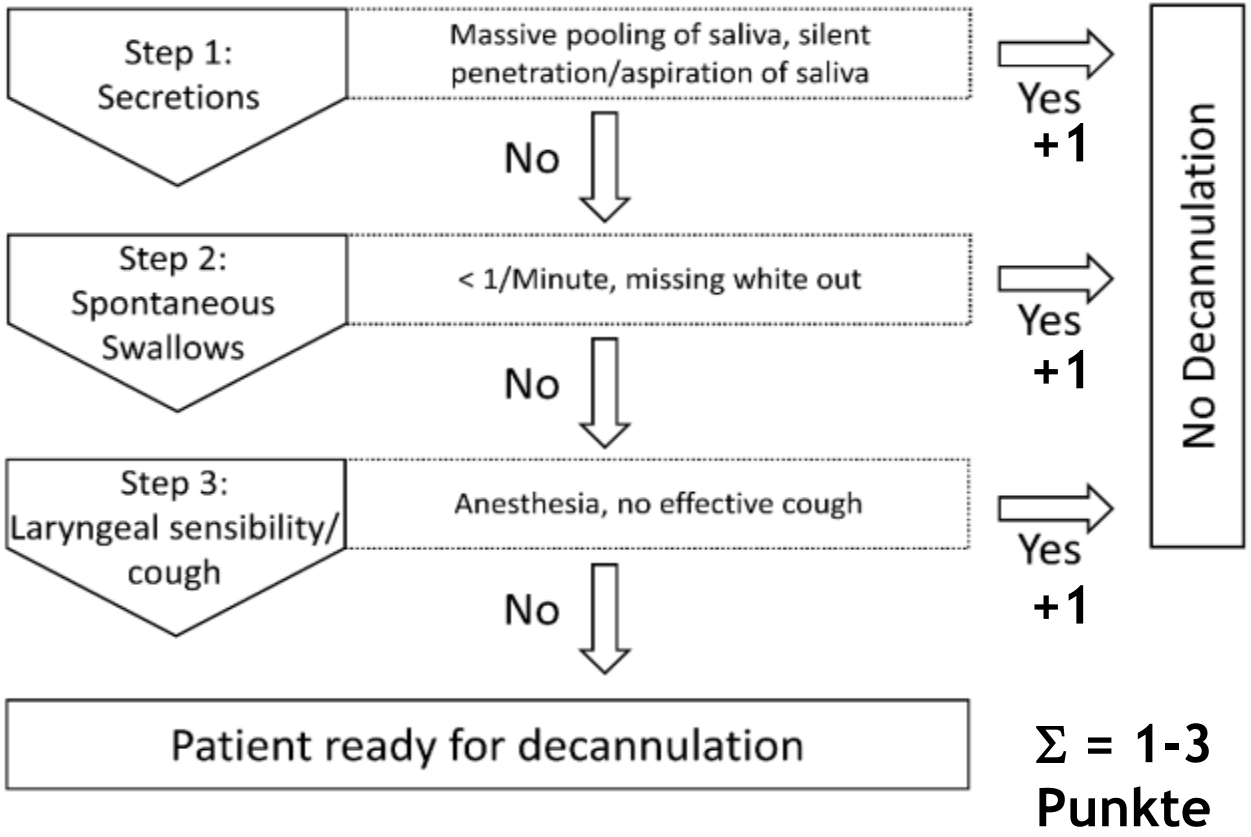
- Primary endpoint
  - Readiness for decannulation according to FEES
- Secondary endpoints
  - Re-cannulation within 48 hours
  - Effect of re-treatment
  - LOS, dysphagia severity
- Design
  - International, prospective, randomised, single-blind parallel group trial
  - sequential design
  - N=70-140
- Sponsor
  - Phagenesis Ltd (UK)

PHAST-TRAC
Blinding



Decannulation algorithm

- FEES-based procedure, previously established
- Endpoint assessment at study sites
- Re-evaluation of FEES-videos by FEES review board



Adapted from: Dziewas *et al*. *Int J Stroke* 2017; 12: 430-7

PES
Decannulation assessment

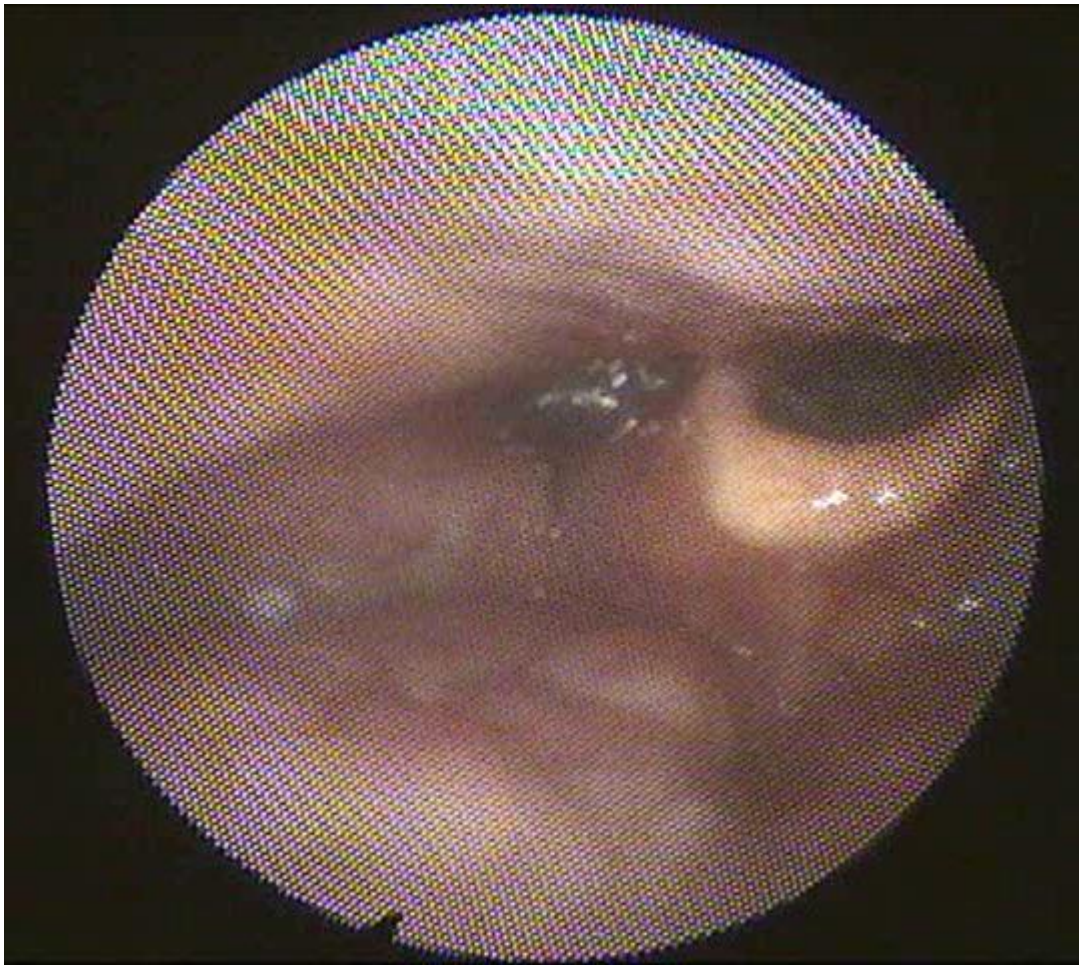
- Prospective observational study
- FEES 4,75 d after weaning
- Clinical swallow evaluation blinded to FEES
- Main findings in FEES:
  - Saliva pooling with aspiration (42)
  - No spontaneous swallow (29)
  - Severe pharyngeal hypesthesia (20)
- Decannulation after FEES:
  - 54 patients
  - Necessity of recannulation: 1 patient
- **Decannulation deemed possible by CSE: 29 patients**

TABLE 1. Description of the Study Population

Patient Characteristics	
Total, *n*	100
Sex: male/female, *n*	55/45
Age (yr)	56.4 ± 14.9
Diagnoses	
Cerebral infarction, *n*	51
Intracerebral hemorrhage, *n*	14
Guillain-Barre syndrome, *n*	11
Meningoencephalitis, *n*	6
Subarachnoid hemorrhage, *n*	3
Other, *n*	15
Duration of mechanical ventilation (d)	20.2 ± 13.1

Warnecke et al., Crt Care 2013

PHAST-TRAC
Dekanülierungsprotokoll



PHAST-TRAC
Dekanülierungsprotokoll

Anaesth Crit Care Pain Med 37 (2018) 281–294

ELSEVIER

SFAR
Société Française d'Anesthésie et de Réanimation

Guidelines

Tracheotomy in the intensive care unit: Guidelines from a French expert panel☆

Jean-Louis Trouillet [a], Olivier Collange [b,c], Fouad Belafia [d], François Blot [e], Gilles Capellier [f,g], Eric Cesareo [h,i], Jean-Michel Constantin [j,k], Alexandre Demoule [l,m], Jean-Luc Diehl [n,o], Pierre-Grégoire Guinot [p,q], Franck Jegoux [r], Erwan L'Her [s,t], Charles-Edouard Luyt [a,u], Yazine Mahjoub [v], Julien Mayaux [l,m], Hervé Quintard [w,x], François Ravat [y], Sébastien Vergez [z], Julien Amour [aa], Max Quillot [c,ab,*], For the French Intensive Care Society, Max Quillot For the French Society of Anaesthesia and Intensive Care, Olivier Collange

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[b] Hôpitaux universitaires de Strasbourg, Nouvel Hôpital Civil, pôle d'anesthésie-réanimation chirurgicale, SAMU, SMURNHC, 1, place de l'Hôpital, 67000 Strasbourg, France
[c] EA 3072, FMTS université de Strasbourg, Strasbourg, France
[d] Inserm, U1046, intensive care unit and department of anesthesiology, research unit, university of Montpellier, Saint-Éloi hospital, Montpellier school of medicine, Montpellier, France
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[h] SAMU de Lyon and department of emergency medicine, Hospices Civils de Lyon, Edouard-Herriot hospital, Lyon, France
[i] Lyon Sud, school of medicine, university Lyon 1, Oullins, France
[j] Department of preoperative medicine university hospital of Clermont-Ferrand, Clermont-Ferrand, France
[k] EA-7281, R2D2, Auvergne University Clermont-Ferrand, France
[l] Inserm, UMRS1158 neurophysiologie respiratoire expérimentale et clinique
[m] AP–HP, groupe hospitalier Pitié-Salpêtrière Charles-Foix, service de pneumologie et réanimation médicale du département, R3S, Sorbonne Université Paris, France
[n] Medical ICU, Georges-Pompidou hospital, AP–HP, Paris, France
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fics FRENCH INTENSIVE CARE SOCIETY

SFAR

R5.3–A pharynfolaryngeal examination should probably be performed at or following decannulation.

GRADE 2+, STRONG Agreement

Prerequisite:

Weaning from mechanical ventilation 24/24 hours in cases of previous neurological disease.

Conditions of examination:

- Cuff deflated.
- Prior aspiration of secretions.
- Seated position >70°.
- No anesthesia so as not to generate swallowing difficulties.
- Nasal endoscopy to the cuff.

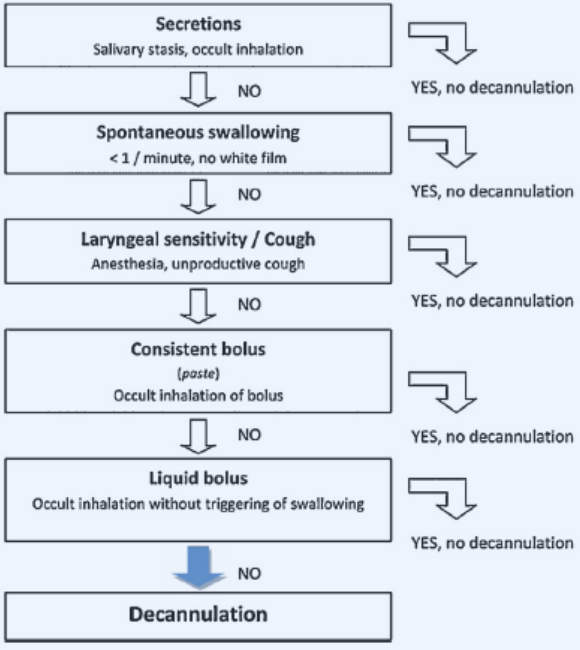


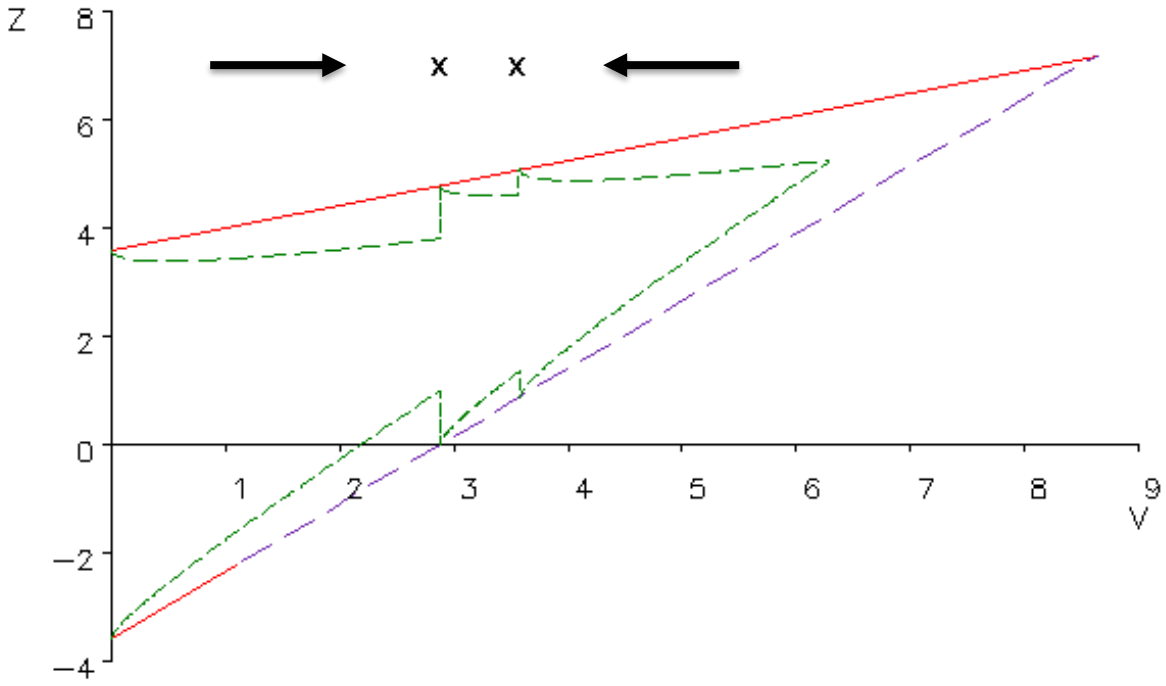
Fig. 4. Proposed endoscopic protocol associated with guideline 5.1 (Expert opinion): (According to Warnecke et al. *Crit Care Med* 2013 [106]).

PHAST-TRAC
Baseline Data

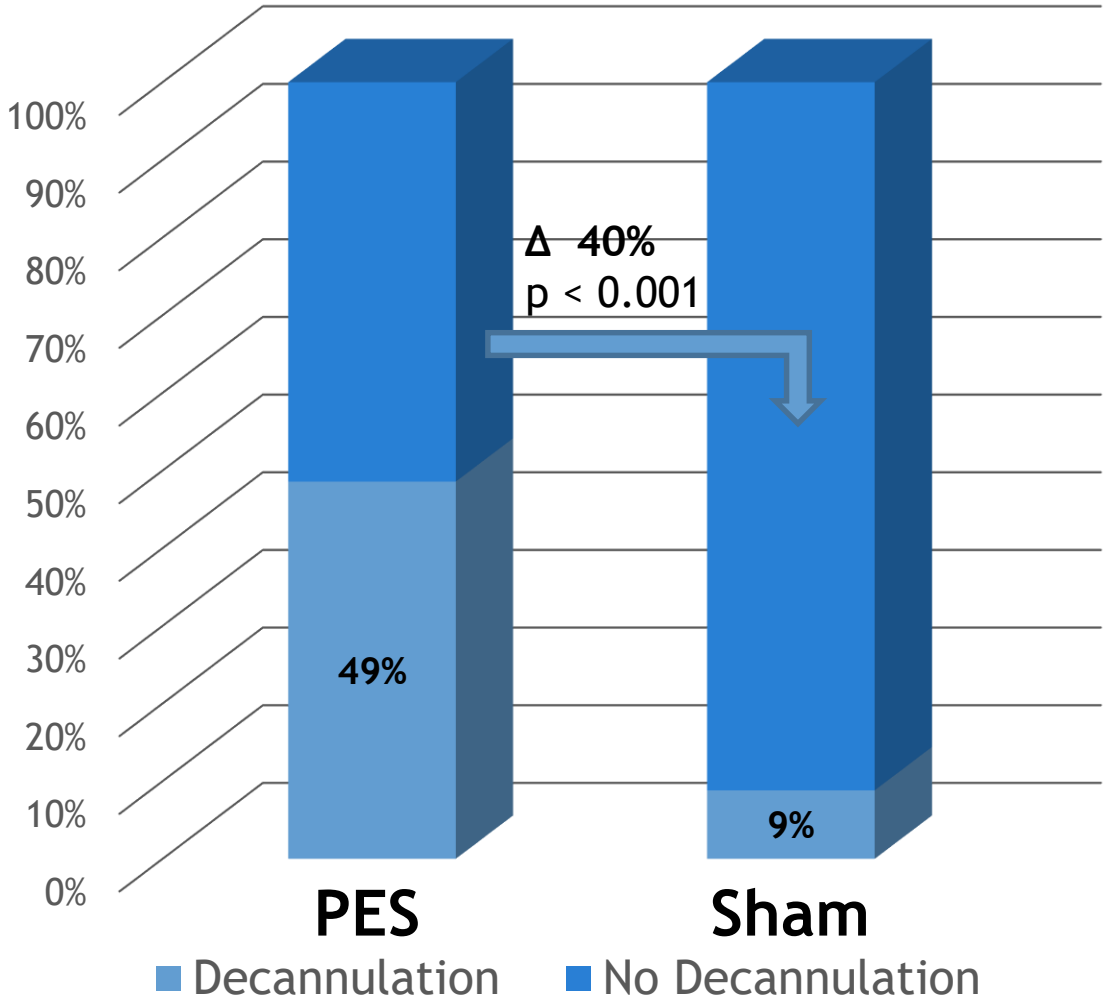
	All	PES	Sham
Patients	69	35	34
Age, years)	**64.2 (11.9)**	**61.7 (13.0)**	**66.8 (10.3)**
Sex, female, %	25 (36.2)	11 (31.4)	14 (41.2)
Premor. mRS>0, %	3 (4.6)	1 (3.0)	2 (6.2)
mRS>4, %	67 (98.5)	34 (100)	33 (97.1)
Previous stroke/TIA	10 (14.5)	7 (20)	3 (8.8)
Smoking, %	8 (11.6)	5 (14.3)	3 (8.8)
OTR, days	**28.0 [22] (11-120)**	**28.0 [29] (11-120)**	**28.0 [22] (11-95)**
Ventilation, days	**15.0 [13] (3-131)**	**15.0 [15] (5, 131)**	**13.5 [13] (3, 60)**
PEG tube, %	9 (20.5)	5 (22.7)	4 (18.2)
NIHSS, /24	**17.5 (4.6)**	**17.6 (5.0)**	**17.5 (4.3)**
Ischaemic stroke	**49 (71.0)**	**27 (77.1)**	**22 (64.7)**

PHAST-TRAC
Sequential Analysis

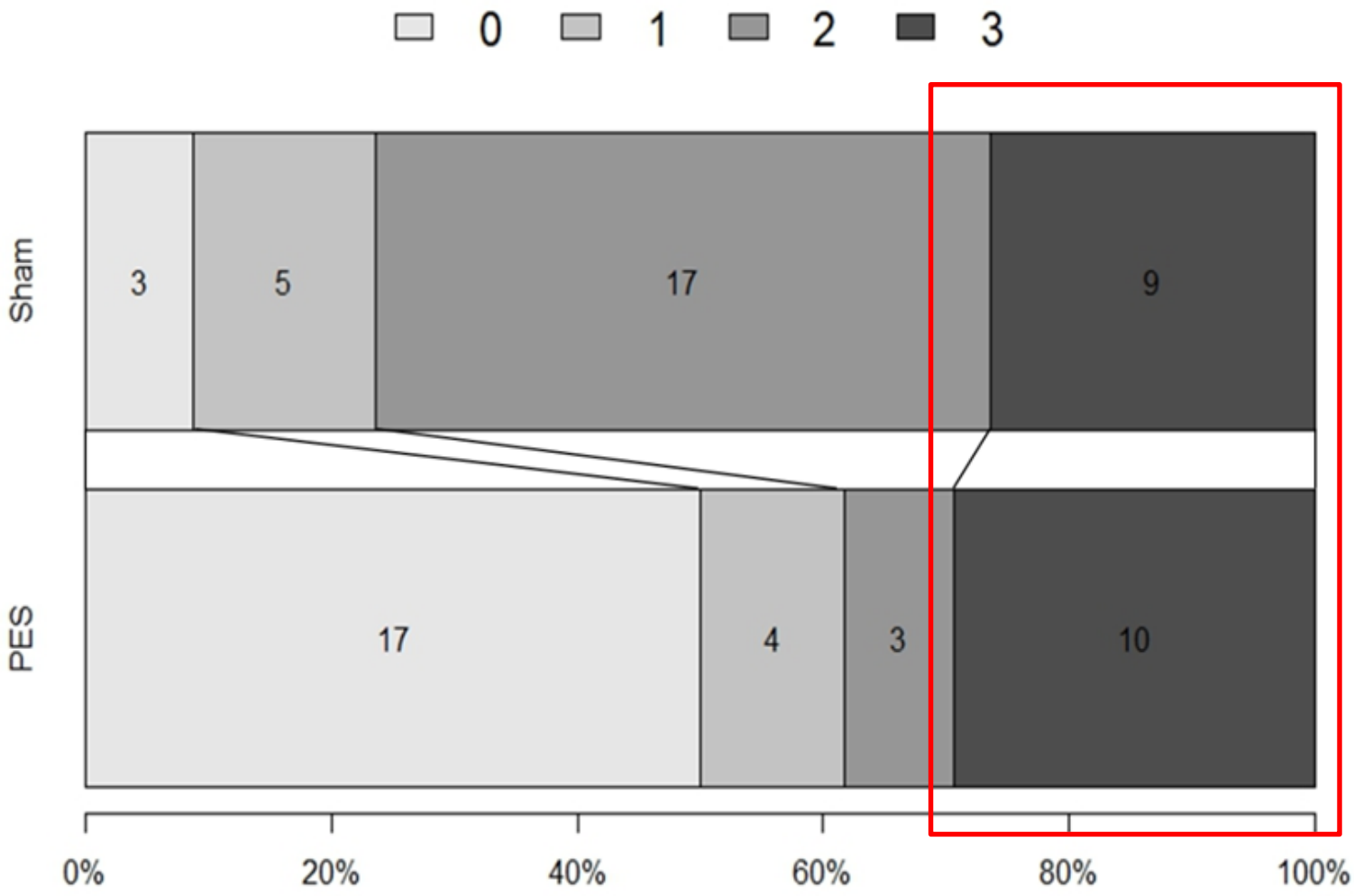
- Two analyses performed: futility at N=50, efficacy at N=70
- Trial continued at N=50, not futile
- Trial stopped at N=70, for efficacy
- 1 patient excluded since catheter not be inserted, so N=69



PHAST-TRAC
Primary Endpoint

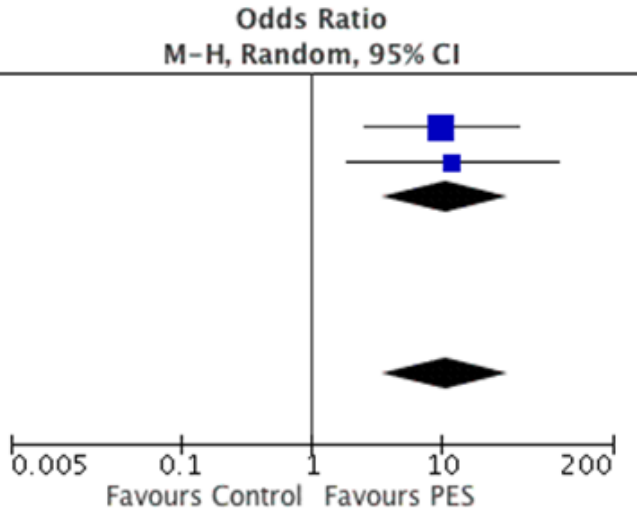


PHAST-TRAC
Primary Endpoint



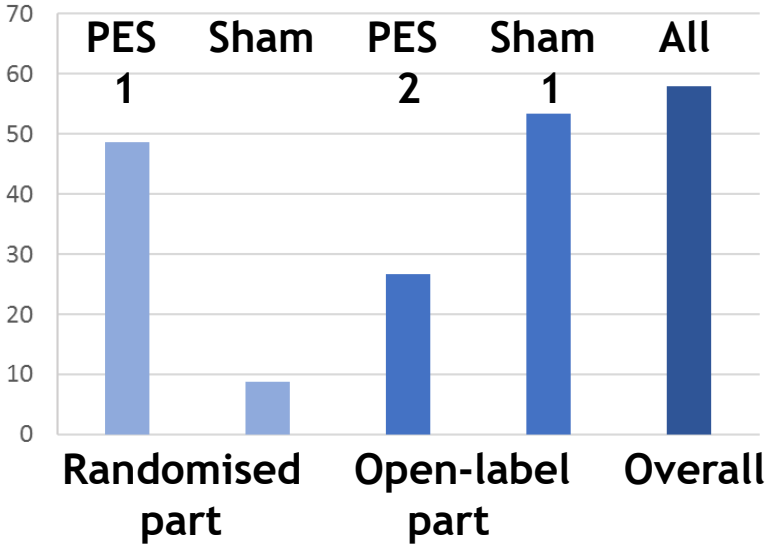
PHAST-TRAC
Meta-Analysis

Study or Subgroup	PES Events	PES Total	Control Events	Control Total	Weight	Odds Ratio M-H, Random, 95% CI
1.1.1 Decannulation						
Dziewas 2017	17	35	3	34	65.0%	9.76 [2.51, 37.94]
Suntrup 2015	15	20	2	10	35.0%	12.00 [1.89, 76.38]
Subtotal (95% CI)		**55**		**44**	**100.0%**	**10.49 [3.51, 31.35]**
Total events	32		5			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.03$, df = 1 (P = 0.86); $I^2 = 0\%$						
Test for overall effect: Z = 4.21 (P < 0.0001)						
Total (95% CI)		**55**		**44**	**100.0%**	**10.49 [3.51, 31.35]**
Total events	32		5			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.03$, df = 1 (P = 0.86); $I^2 = 0\%$						
Test for overall effect: Z = 4.21 (P < 0.0001)						
Test for subgroup differences: Not applicable						

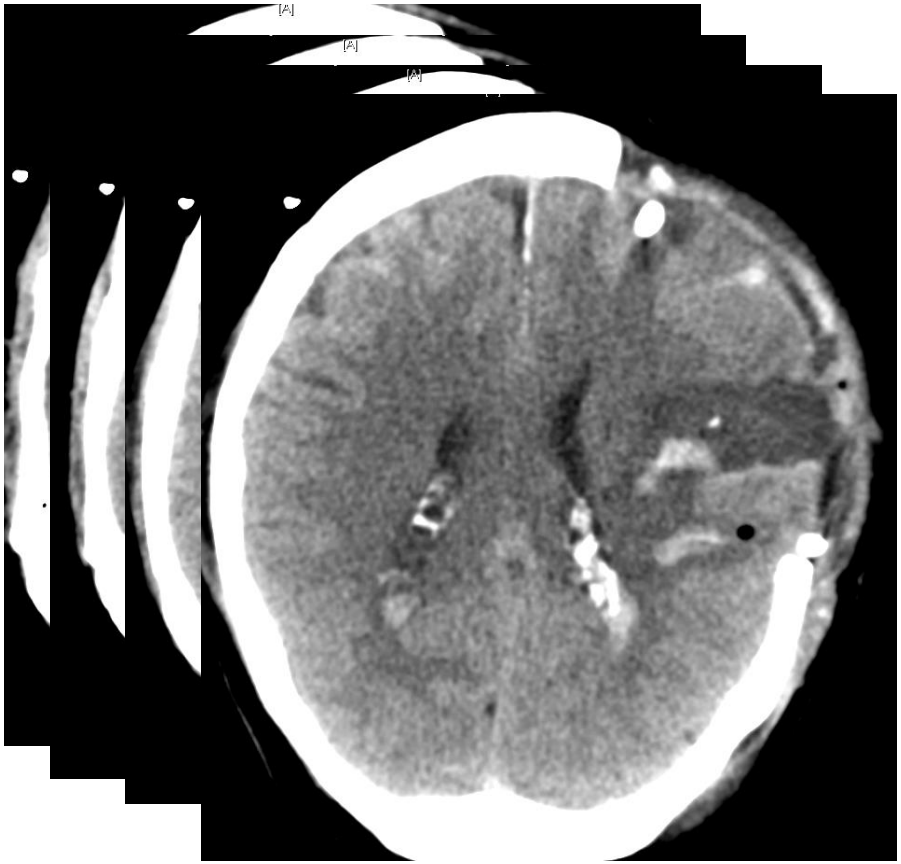


PHAST-TRAC
Randomized & Open-label Parts

	All	PES	Sham
Participants, open-label part	**45**	**15**	**30**
Ready for decannulation (%)	20 (44.4)	4 (26.7)	16 (53.3)
Participants, randomised & open-label parts	**69**	**35**	**34**
Ready for decannulation (%)	40 (58.0)	21 (60.0)	19 (55.9)
Participants	**69**	**35**	**34**
SAEs	18 (26.1)	10 (28.6)	8 (23.5)
Device-related SAEs	0 (0)	0 (0)	0 (0)



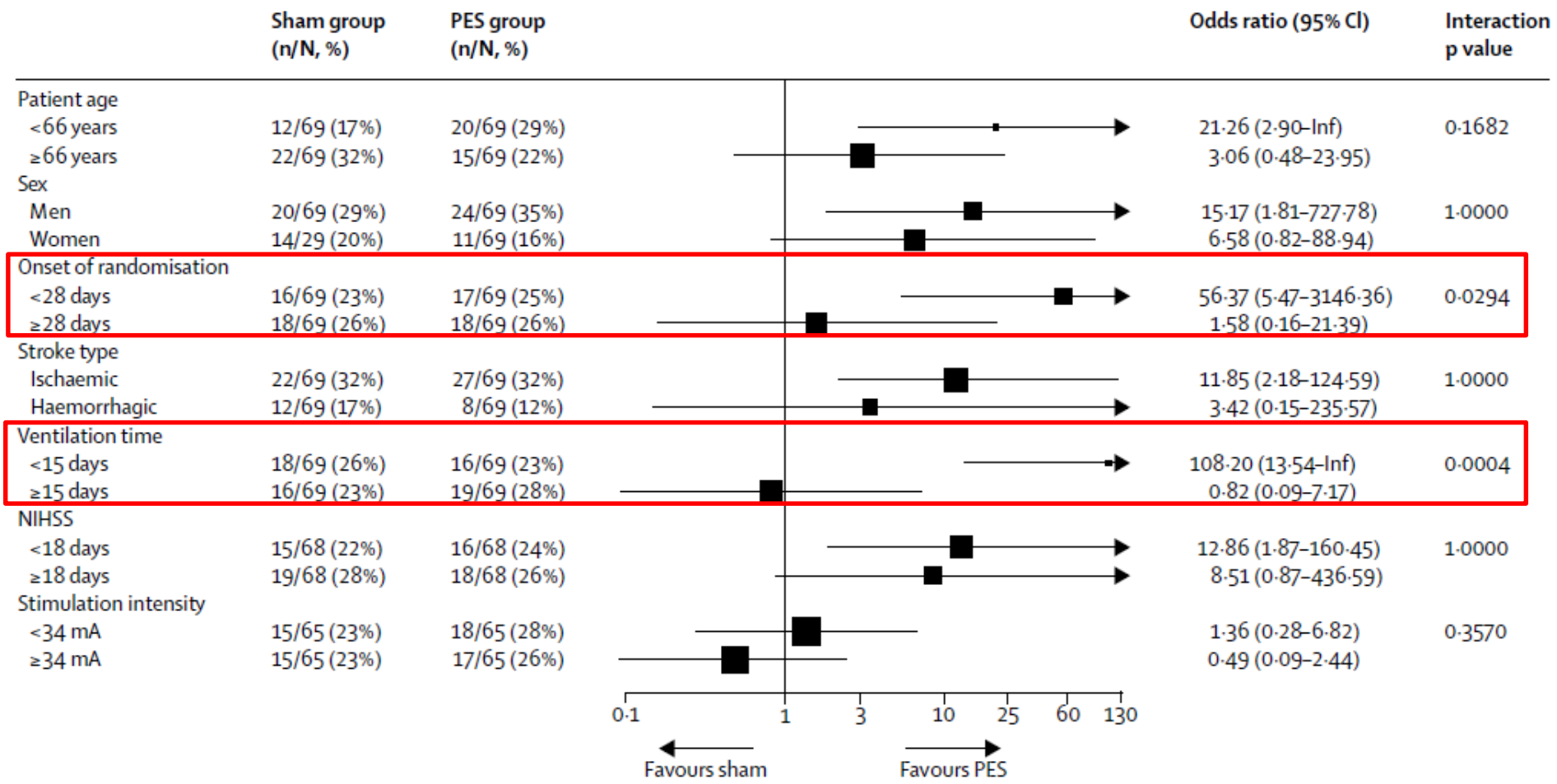
PHAST-TRAC
Clinical Case



- 72 yrs patient
- Left-sided MCA
- Secondary ICH
- Decompressive surgery

- Tracheostomy day 12 post stroke
- Weaning finished day 27 post stroke
- Start of PES at day 30 post stroke

PHAST-TRAC Subgroups

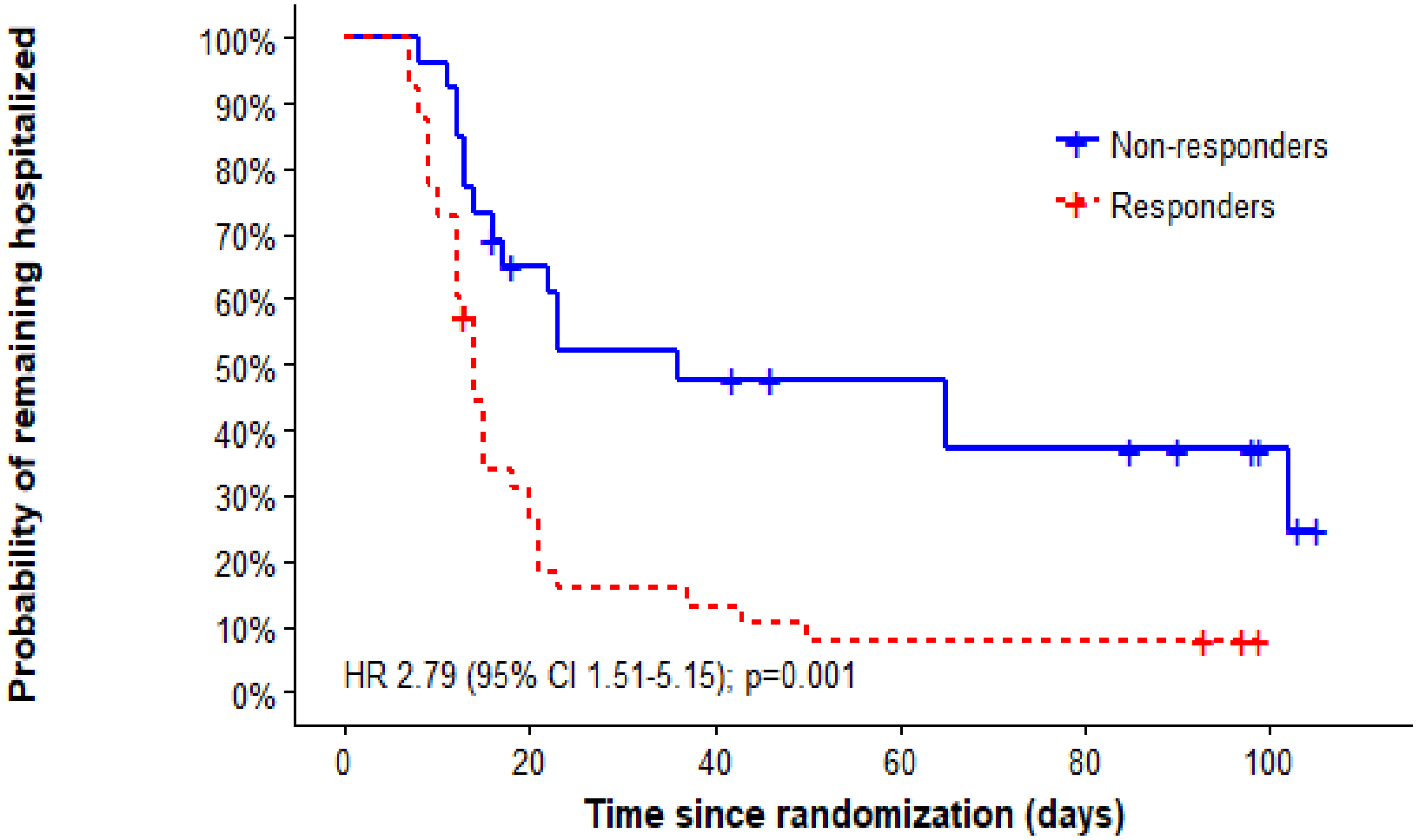


PHAST-TRAC
Serious Adverse Events

SAE	PES	SHAM	Prior randomization
Prior randomization			5 events/ 4 patients
0 - 1 month after randomization	3 events/3 patients	5 events/5 patients	
1-3 months after randomization	9 events/8 patients	3 events/3 patients	
TOTAL study	12 events/10 patients	8 events/8 patients	5 events/ 4 patients

- p=0.79
- No Device-related SAE

PHAST-TRAC
Lengths of stay



PHAST-TRAC
Stimulation Intensities

	Day 1	Day 2	Day 3	Mean
Patients	35	35	34*	104*
Threshold (mA)	16.7 (9.8)	15.4 (9.9)	13.6 (8.1)	15.2 (9.3)
Tolerance (mA)	40.3 (8.8)	40.0 (8.6)	38.9 (10.2)	39.7 (9.2)
Stimulation (mA)	34.5 (8.3)	33.6 (8.1)	32.7 (8.7)	33.6 (8.3)

mA	PES responders	PES non-responders	Diff (95% CI)	P
Patients	17	18		
Threshold (mA)	12.1 (6.6)	18.5 (8.7)	-6.3 (-11.7, -1.0)	0.0212
Tolerance (mA)	37.0 (8.7)	42.3 (7.3)	-5.3 (-10.9, 0.2)	0.0600
Stimulation (mA)	31.2 (7.5)	36.0 (6.8)	-4.8 (-9.8, 0.2)	0.0581

PHAST-TRAC
Conclusion

Limitations

- Small: sequential analysis led to early stopping
- Single-blind: treater was unblinded
- Design meant no long-term follow-up

Strengths

- Multicenter, sham-controlled, well-defined participants
- Robust findings, blinded outcome
- External consistency (with pilot trial)
- Most patients offered PES irrespective of randomisation

PES
More to come…

Condition	Stage	Site	Design	Size	Status	Name	Type
Stroke	Subacute	SU	RCT x3	73	Published	Hamdy *et al*	Academic
	Subacute	SU	RCT	162	Published	STEPS	Commercial
	Subacute	*SU*	*RCT*	*≤225*	*started*	*PhEED*	*Commercial*
	Subacute	**ICU**	**RCT**	**30**	**Published**	**Suntrup *et al***	**Academic**
	Subacute	ICU	Obs	23	Published	Muhle *et al*	Academic
	Subacute	**ICU**	**RCT**	**≤126**	**Completed**	**PHAST-TRAC**	**Commercial**
	Chronic		RCT	18	Published	Michou *et al*	Academic
MS	Chronic		RCT	20	Published	Resitvo *et al*	Academic
	Subacute	*Hosp*	*Register*	*~300*	*Completed*	*† PHADER*	*Commercial*
	Subacute	*ICU*	*RCT*		*About to start*		*Commercial*

† Mixed neurogenic dysphagia: Stroke – ventilation; Stroke – no ventilation; Traumatic brain injury or spinal cord injury; Other – ventilation; Other – no ventilation

Hosp: hospital; ITU: Intensive Care Unit; RCT: randomised controlled trial; SU: Stroke Unit; Obs: Observational study

Summary

- A tracheostomy is frequently required in stroke patients treated on the ICU.
- Impaired sensory feedback critically contributes to dysphagia in these patients.
- PES facilitates cortical plasticity and release of Substance P from peripheral laryngeal nerves.
- PES is considered in addition to other TK-management strategies.
- PES effectively treats dysphagia in tracheotomized stroke patients.
- A second cycle of PES should be given in patients not responding to the first one.

Thank you!

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