Neurally adjusted ventilatory assist

for patients at risk of extended ventilation:

A randomised feasibility trial with local and national surveys

Daniel Hadfield

Intensive Care Society SOA23 CONGRESS

Mechanical ventilation (MV)

Duration associated with ↑ morbidity, mortality & cost

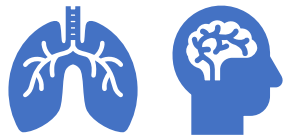
MV weaning

Limitations to current practice / opportunities to improve (dysynchrony; over/under assist; time and expertise; national practice variation)

MV automation
(Neurally Adjusted Ventilatory Assist - NAVA)

Automated weaning tech: meets patient need

NAVA matches support to diaphragm electrical activity



JAMA | Original Investigation | CARING FOR THE CRITICALLY ILL PATIENT

Ventilator Weaning and Discontinuation Practices for Critically Ill Patients

Weaning from mechanical ventilation in intensive care units across 50 countries (WEAN SAFE): a multicentre, prospective, observational cohort study

Cochrane Database of Systematic Reviews | Review - Intervention

Automated versus non-automated weaning for reducing the duration of mechanical ventilation for critically ill adults and children

Louise Rose, Marcus J Schultz, Chris R Cardwell, Philippe Jouvet, Danny F McAuley, Bronagh Blackwood

Authors' declarations of interest

Version published: 10 June 2014 Version history

https://doi.org/10.1002/14651858.CD009235.pub3

Pressure support ventilation in intensive care patients receiving prolonged invasive ventilation

Crit Care Resusc 2021; 23 (4): 394-402

Mechanical Ventilation-induced Diaphragm Atrophy Strongly Impacts Clinical Outcomes

AJRCCM

Ewan C. Goligher [1,2,3,4], Martin Dres [5,6], Eddy Fan [1,2,4,7], Gordon D. Rubenfeld [1,4,7,8], Damon C. Scales [1,4,7,8], Margaret S. Herridge [1,2,4,9], Stefannie Vorona [2], Michael C. Sklar [5,10], Nuttapol Rittayamai [5], Ashley Lanys [5], Alistair Murray [2],

Duration associated with ↑ morbidity, mortality & cost

Limitations to current practice / opportunities to improve (dysynchrony; over/under assist; time and expertise; national practice variation)

NAVA evidence pre 2014 – numerous physiological studies

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Laurence Vignaux
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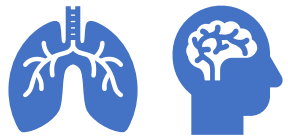
Neurally adjusted ventilatory assist improves patient–ventilator interaction

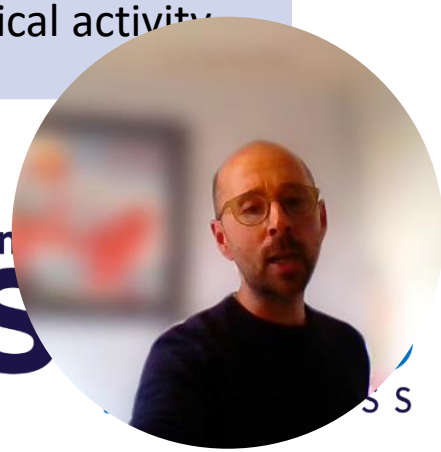
Intensive Care Med (2011) 37:263–271
DOI 10.1007/s00134-010-2052-9

Automated weaning tech: meets patient need

NAVA matches support to diaphragm electrical activity

No large clinical trials of NAVA





2012 NIHR | National Institute for Health Research **BRC STEM Fellowship**

2014 **The Moulton Charity** **Clinical Research Award**

2015 NIHR | National Institute for Health Research **Clinical Doctoral Research Fellowship**

No large clinical trials of NAVA

Methods / results

Extensive peer review
(NIHR applications / UKCCRF / conferences etc.)

Development / adaption to new guidance
(Consort extension to randomized pilot & feasibility trials, 2016)

Overall aim: To investigate important uncertainties and test methods prior to a large effectiveness trial (feasibility)

1. A parallel group, allocation concealed, open label, pilot randomised controlled trial

Sample size: 76 patients (38 in each arm)

P IMV + risk of extended support (COPD, Heart Failure, or ARDS)

I NAVA (monitor / mode)

C Usual care using PSV

O Compliance (% eligible time in ventilation mode)
Exploratory secondary including VFDs, LOS and sedation

- **Feasibility: Mode adherence, protocol compliance, protocol acceptability**
  Median (95%CI) adherence 83.1% (64.0–97.1%); protocol compliance 66.7% (50.3–80.0%)
  Physician refusal (12%) & consent rates (72%)
- **Exploratory outcomes** suggest potential clinical benefit for NAVA
  More VFDs to D28 (p = 0.04); fewer in-hospital deaths (p = 0.032); RASS scores closer to 0 (p=0.02)

2. Single centre, web and paper cross-sectional ICU staff survey

Aim: To investigate experience, attitudes, beliefs, facilitators and barriers to NAVA use and future research

Design: Single centre, web and paper cross-sectional ICU staff survey. 39 mixed open and structured questions. Rigorous development and testing

Of 466 distributed questionnaires, 301 (64.6%) were returned from 236 nurses (78.4%), 53 doctors (17.6%) and 12 physiotherapists (4.0%).

-Belief that NAVA is safe and clinically effective

- Low confidence; perception of technical difficulty; need for i

- Strong support for future research

Research outputs

2020

Hadfield et al. Critical Care (2020) 24:220
https://doi.org/10.1186/s13054-020-02923-5

Critical Care

RESEARCH Open Access

Neurally adjusted ventilatory assist versus pressure support ventilation: a randomized controlled feasibility trial performed in patients at risk of prolonged mechanical ventilation

Daniel J. Hadfield[1,2*], Louise Rose[3,4], Fiona Reid[5], Victoria Cornelius[6], Nicholas Hart[2,7], Clare Finney[1], Bethany Penhaligon[1], Jasmine Molai[1], Clair Harris[1], Sian Saha[1], Harriet Noble[1], Emma Clarey[1], Leah Thompson[1], John Smith[1], Lucy Johnson[1], Phillip A. Hopkins[1†] and Gerrard F. Rafferty[2†]

2020

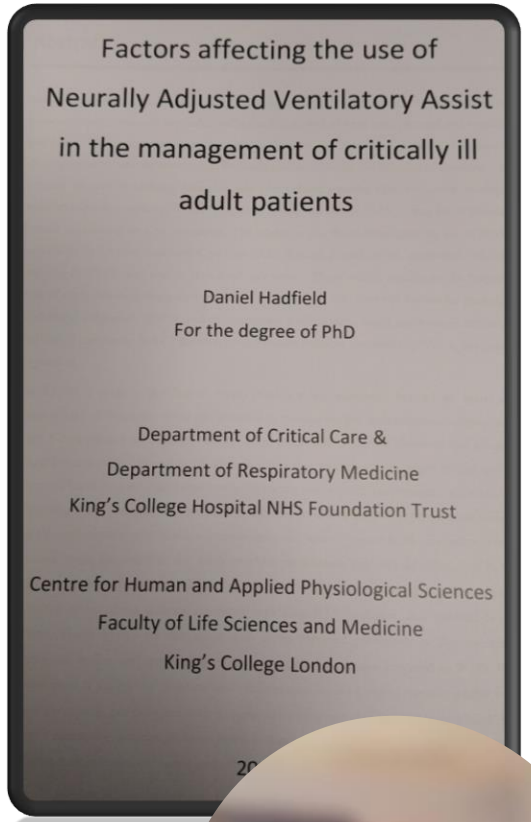
BMJ Open Respiratory Research Critical care

Factors affecting the use of neurally adjusted ventilatory assist in the adult critical care unit: a clinician survey

Daniel Hadfield,[1,2] Louise Rose,[3,4] Fiona Reid,[5] Victoria Cornelius,[6] Nicholas Hart,[7,8] Clare Finney,[1] Bethany Penhaligon,[1] Clare Harris,[1] Sian Saha,[1] Harriet Noble,[1] John Smith,[1] Philip Anthony Hopkins,[1] Gerrard Francis Rafferty[2]

1	ICS 2022	*Oral Pres*	NAVA: A randomised, controlled, clinical and cost effectiveness trial
2	BACCN 2022	*Oral Pres*	Weaning modes of mechanical ventilation
3	UKCCRF 2021	*Oral Pres*	NAVA in the adult critical care unit
4	ESICM 2019	*Poster*	NAVA: A cross-sectional staff survey
5	UKCCRF 2018	*Oral Pres*	NAVA vs PSV in Prolonged Weaning
6	ATS 2018	*Poster*	NAVA vs Pressure Support in Prolonged Mechanical Ventilation: A Randomised Feasibility Study
7	ESICM 2018	*Poster*	The effect of NAVA on sedation score and sedation load
8	ESICM 2018	*Poster*	A pilot study to develop the feasibility of patient-controlled ventilatory weaning using NAVA
9	BACCN 2017	*Oral Pres*	NAVA in prolonged ventilation
10	ISICEM 2017	*Poster*	NAVA vs Pressure Support in prolonged mechanical ventilation: A feasibility study
11	ESICM 2017	*Poster*	The use of neural monitoring to assist decision-making in terminal extubation...
12	ICS 2016	*Poster*	NAVA in Prolonged Mechanical Ventilation: The challenges of conducting a feasibility...
13	UKCCRF 2012	*Oral Pres*	A randomised feasibility study examining NAVA...
14	ISICEM 2011	*Poster*	An observational retrospective review of utilisation and outcomes of diaphragmatic EMG...
15	ESICM 2010	*Poster*	The Introduction of NAVA into a Central London Teaching Hospital...
16	ISICEM 2011	*Poster*	Diaphragmatic EMG monitoring during common interventions in critically ill adult patients
17	BACCN 2010	*Poster*	NAVA: Introduction of a new ventilation mode to a General Critical Care Unit
18	BACCN 2010	*Poster*	NAVA: Establishing the Edi signal as a useful monitoring tool...

ICS 2022 Research Prioritisation Shorlist



Impact / Future

Impact on future ICU research capacity…

2012	NIHR | National Institute for Health Research	BRC STEM Fellowship
2014	The Moulton Charity	Clinical Research Award
2015	NIHR | National Institute for Health Research	Clinical Doctoral Research Fellowship
2019	NIHR | National Institute for Health Research	70@70 Nursing & Midwifery Research Leadership
2021	NHS Health Education England	ICA Post-Doctoral Bridging
2022	NIHR | National Institute for Health Research	CRN Greenshoots

Research leadership, collaboration and support for colleagues across all professional groups…

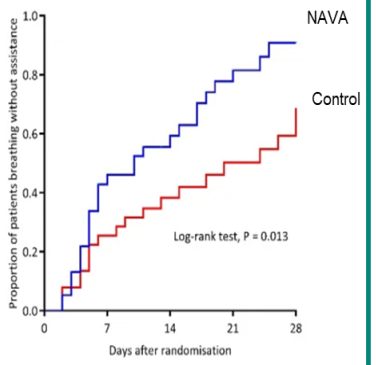
Impact / Future

HADFIELD, CRIT CARE 2020

78 patients 'at risk' of prolonged MV Single site

D28 VFDs median difference 3
95% CI 0–11, p=0.041

Mean MV difference (days)
-8.3, 95% CI -16.6 to -0.1; p = 0.049

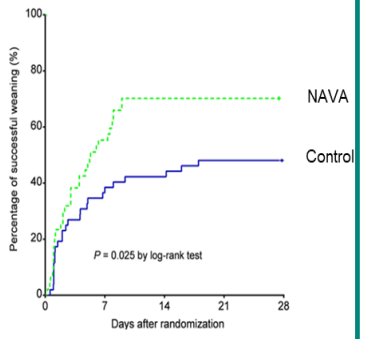


LIU, ANESTHESIOLOGY 2020

99 patients with one failed SBT . Single site

D28 VFDs mean difference 5.3
95% CI 1.2–9.7; p=0.039

Mean MV difference (days)
–5.3, 95% CI –9.2 to –1.4; p= 0.039

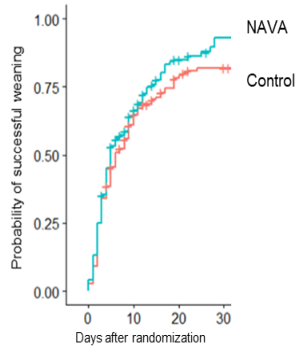


KACMAREK, ICM 2020

306 ARF patients ventilation ≥72h. 15 sites

D28 VFDs median difference 4
95% CI (0–8); p=0.016

Mean MV difference (days)
-4.1, 95% CI -7 to -1.3; p=0.005



Health Technology Assessment

NIHR | National Institute for Health Research

Innovative ventilation technologies for treatment of patients in ICU commissioning brief

NATIONAL SURVEY (2021 unpublished)

Aims: NAVA availability, use and trial support

Sample: ICU clinicians (ICS / UKCCRF)

Results summary:

- 163 responses from 86 NHS hospitals
- Automated technologies available at 63/86 (73.3%) hospitals. NAVA ventilators available in 31% NHS Trusts.
- Amongst hospitals with NAVA, 56.5% indicated experience
- Overall opinions:
  - 62.3% would use NAVA if available (31.5% unsure)
    85.4% agreed current evidence is uncertain
    91.5% wanted more evidence.
- Relating to the proposed trial only 4.6% said
  not recruit.

Impact / Future

Question: What is the clinical and cost-effectiveness of NAVA for patients at risk of extended durations of mechanical ventilation?

Design: A randomized, parallel group, allocation concealed, controlled, open, phase 3 pragmatic clinical and cost effectiveness trial with internal pilot

Population: Adult ICU admissions + IMV + risk of extended support

Sample: 950 (475 per arm) to detect a 2-day difference in mean duration of MV

Sites: 40 adult UK ICUs

…starting soon (hopefully)

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Ged Rafferty, Phil Hopkins, Nick Hart (PhD supervisors); Christine Norton (PhD mentor); KCH ACET Research Team; KCH Critical Care Staff; Fiona Reid and Victoria Cornelius (statistical support during my PhD) and many more…

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