Gli studi indipendenti:
La ventilazione

Maria Luisa Ventura
Paolo Tagliabue

Network Neonatale Italiano

INN data and respiratory support

- Survey of neonatal respiratory support use in very preterm infants in Italy (2012)

- HFOV or CMV in preterm infants < 28 weeks gestation? An Italian Survey (to be submitted)

Survey of neonatal respiratory support use in very preterm infants in Italy

- Analysis of the data of respiratory support in VLBW enrolled in INN
- Brief survey of the protocols in use in the neonatal units adhering to the INN

Luigi Gagliardi[1], Paolo Tagliabue[2], Roberto Bellù[3], Carlo Corchia[4], Fabio Mosca[5], Rinaldo Zanini[3]; for the Network Neonatale Italiano

The Journal of Maternal-Fetal and Neonatal Medicine, 2012; 25(S3): 1–5

Survey of neonatal respiratory support use in very preterm infants in Italy

- Population
  - NICU
    - 83
  - 8297 newborns
    - 3981 in year 2009
    - 4316 in year 2010
  - Exclusion criteria
    - Death in delivery room (n 73)
  - Mortality
    - 14.2%
  - BPD (supplemental O2 at 36 wks pma)
    - 13.9%

Luigi Gagliardi[1], Paolo Tagliabue[2], Roberto Bellù[3], Carlo Corchia[4], Fabio Mosca[5], Rinaldo Zanini[3]; for the Network Neonatale Italiano

The Journal of Maternal-Fetal and Neonatal Medicine, 2012; 25(S3): 1–5

Survey of neonatal respiratory support use in very preterm infants in Italy

Data on respiratory support

Table I. Percentage of infants receiving any of the listed procedures.

	INN	VON
Delivery room procedures		
Supplemental oxygen	76.29	85.3
Bag-and-mask ventilation	61.39	61.8
Tracheal intubation	41.49	50.8
Surfactant administration	16.80	32.3
After delivery room		
Oxygen	80.80	88.2
Conventional ventilation	53.19	62.7
HFV	15.84	22.1
nCPAP	71.57	68.2
CPAP before ETT	41.99	40.0
Any surfactant	56.18	63.1
HFNC	8.26	49.9
NIMV/NSIMV	17.66	18.7
Any mechanical ventilation	55.56	65.1
Non-invasive ventilation	71.73	–
Any respiratory assistance[a]	84.53	–
NIV only[b]	34.02	–

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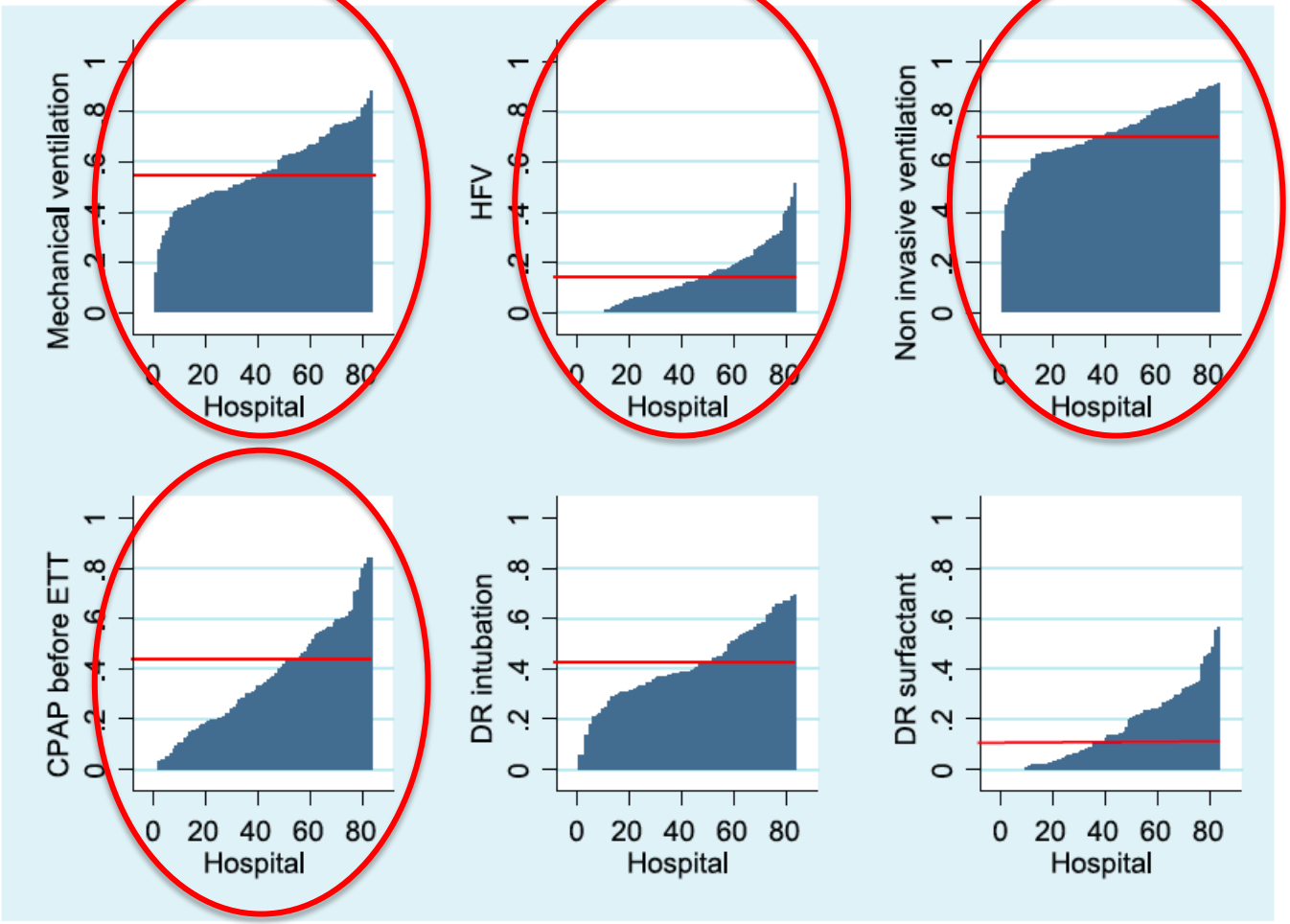
Data on respiratory support



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Survey of neonatal respiratory support use in very preterm infants in Italy

Data on respiratory support

Correlation between mean use of selected procedures between hospitals

	HFV	Any mechanical ventilation
HFV	1.000	
Any mechanical ventilation	-0.0177	1.000
Non invasive technique only	-0.0915	-0.8845

NIV-only is negatively affected (as expected) by conventional ventilation (i.e. hospitals that ventilate more, use less NIV-only)

but not with HFV (hospitals that use more HFV have the same number of infants managed non-invasively)

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Survey of neonatal respiratory support use in very preterm infants in Italy

Survey of the protocols

Protocol for respiratory assistance	Number of NICU	%
no	6	10
verbal	21	37
written	30	52
total responders to questionnaire	57	68
Total INN NICU*	83	

* years 2009-2010

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Survey of neonatal respiratory support use in very preterm infants in Italy

Survey of the protocols

first intention respiratory support	N	%
NInV Technique*	51	100

* NCPAP, NCPAP + surfattante, Non invasive ventilation

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Survey of neonatal respiratory support use in very preterm infants in Italy

Survey of the protocols

first intention respiratory support*	N	%
IPPV/IMV	2	4
SIPPV/SIMV	14	27
(S)IPPV/VG	4	8
VG	21	41
HFOV selective**	5	10
HFOV	5	10
total	51	100

* in mechanically ventilated infants
** based on GA and/or BW

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The Journal of Maternal-Fetal and Neonatal Medicine, 2012; 25(S3): 1–5

HFOV or CMV in preterm infants < 28 weeks gestation? An Italian Survey

- Type of study
  - Non interventional
- Aim
  - Comparison
    - NICU HFOV first intention vs NICU CMV first intention (intention to treat, irrespective of the actual treatment)
  - Short respiratory outcomes
    - Need for mechanical ventilation
    - PNX
    - Postnatal steroids
    - CLD
    - CLD + mortality
  - Other adverse outcomes
    - IVH>2°
    - PVL
    - Surgical PDA
    - Surgical NEC
    - Surgical ROP

Paolo Tagliabue, Maria Luisa Ventura, Carlo Dani, Diego Gazzolo, Stefano Martinelli, Fabio Mosca, Giovanni Vento, Rinaldo Zanini, Luigi Gagliardi for Italian Neonatal Network

HFOV or CMV in preterm infants < 28 weeks gestation? An Italian Survey

- Data Source: INN
- Study period
  - 1 Jan 2005 - 31 Dec 2010
- Inclusion criteria
  - EG 23.0-27.6
- Exclusion criteria
  - Outborn
  - Death before 12 hours of life
  - Major congenital anomalies
- 51 NICU (with protocols from the previous survey)
  - 41 first intention oriented CMV
  - 10 first intention oriented HFOV*

* The neonates born in the hospitals using both techniques were attributed to the CMV group or to the HFOV group according to their gestational age or birth weight

Ventilation strategies
in RDS if ventilated
Number of italian NICU 51

CMV 41

HFOV selective * 5

HFOV 5

* HFOV if
<28 GA 1
<27 GA 1
<27 GA and/or <1000 g BW 1
<25th week 1
<1000g 1

HFOV or CMV in preterm infants < 28 weeks gestation? An Italian Survey

Tab 1. Characteristics of infants

	Conventional Mechanical Ventilation Group	High Frequnecy Oscilaltory ventilation Group	p
Newborns	2496	631	
Gestational age w	25.9±1.3	25.9±1.3	0.139
Birthweight g	791±200	789± 190	0.828
Prenatal steroids	83.8%	83.8%	0.982
Caesarean section	68.1%	60.5%	< 0.001
VON-RA Score*	0.236± 0.199	0.242 ±0.190	0.413
Apgar at 5'	7.1±1.64	7.1±1.66	0.250
Singleton births	73.9%	73.2%	0.721
Male	51.2%	52.1%	0.674
Small for gestational age	10.1%	8.4%	0.209

* VON-RA score: Vermont-Oxford Network Risk-Adjustment score [16].

* Takes into consideration GA, BW for GA, Mode of delivery, multiple pregnancy, Apgar, race, being inborn, sex

Alfirevic Z, Milan SJ, Livio S

THE COCHRANE COLLABORATION®

Caesarean section versus vaginal delivery for preterm birth in singletons (Review)

2012

Analysis 1.12. Comparison 1 Planned immediate caesarean section versus planned vaginal delivery in singletons (infant outcomes), Outcome 12 Respiratory distress syndrome.

Review: Caesarean section versus vaginal delivery for preterm birth in singletons

Comparison: 1 Planned immediate caesarean section versus planned vaginal delivery in singletons (infant outcomes)

Outcome: 12 Respiratory distress syndrome

Study or subgroup	Planned CS n/N	Planned vaginal delivery n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 Breech					
Viegas 1985	1/12	3/15		16.6 %	0.42 [0.05, 3.51]
Zlatnik 1993	5/18	9/20		53.2 %	0.62 [0.25, 1.50]
Subtotal (95% CI)	**30**	**35**		**69.8 %**	**0.57 [0.25, 1.30]**
Total events: 6 (Planned CS), 12 (Planned vaginal delivery)					
Heterogeneity: Chi?? = 0.11, df = 1 (P = 0.74); I?? =0.0%					
Test for overall effect: Z = 1.33 (P = 0.18)					
2 Cephalic					
Wallace 1984	3/23	4/15		30.2 %	0.49 [0.13, 1.88]
Subtotal (95% CI)	**23**	**15**		**30.2 %**	**0.49 [0.13, 1.88]**
Total events: 3 (Planned CS), 4 (Planned vaginal delivery)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.04 (P = 0.30)					
Total (95% CI)	**53**	**50**		**100.0 %**	**0.55 [0.27, 1.10]**
Total events: 9 (Planned CS), 16 (Planned vaginal delivery)					
Heterogeneity: Chi?? = 0.16, df = 2 (P = 0.92); I?? =0.0%					
Test for overall effect: Z = 1.69 (P = 0.092)					
Test for subgroup differences: Chi?? = 0.04, df = 1 (P = 0.85), I?? =0.0%					

HFOV or CMV in preterm infants < 28 weeks gestation? An Italian Survey

Tab 2. Comparison between Conventional Mechanical Ventilation and High Frequency Oscillatory Ventilation group for selected outcomes

	crude (unadjusted) analysis*			adjusted for VON RA score*		
	OR	95% IC	p	OR	95% IC	p
Mortality	0.84	0.71-1.05	0.137	0.84	0.68-1.05	0.128
CLD**	1.57	1.25-1.98	<0.001	1.63	1.28-2.07	< 0.001
Mortality+CLD**	1,26	1.05-1.50	0.012	1.38	1.13-1.68	0.002
Need of mechanical Ventilation	1.79	1.40-2.28	<0.001	2.26	1.73-2.97	< 0.001
Postnatal Steroids	1.54	1.23-1.93	0.001	1.57	1.25-1.96	<0.001
Need of Surfactant ***	1.08	0.82-1.42	0.575	1.17	0.88-1.55	0.279
Pneumothorax**	0.88	0.62-1.24	0.458	0.88	0.62-1.25	0.477
s-IVH**	0.78	0.62-0.98	0.032	0.77	0.61-0.97	0.033
surgical-PDA**	2.13	1.48-3.09	<0.001	2.15	1.49-3.11	< 0.001
surgical-NEC**	0.87	0.59-1.28	0.476	0.87	0.59-1.29	0.098
surgical-ROP**	0.83	0.62-1.12	0.228	0.83	0.62-1.12	0.226
c-PVL**	1.80	1.20-2.70	0.005	1.81	1.20-2.72	0.004

HFOV or CMV in preterm infants < 28 weeks gestation? An Italian Survey

CLD

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Filip Cools, Lisa M Askie, Martin Offringa, Jeanette M Asselin, Sandra A Calvert, Sherry E Courtney, Carlo Dani, David J Durand, Dale R Gerstmann, David J Henderson-Smart, Neil Marlow, Janet L Peacock, J Jane Pillow, Roger F Soll, Ulrich H Thome, Patrick Truffert, Michael D Schreiber, Patrick Van Reempts, Valentina Vendettuoli, Giovanni Vento, on behalf of the PreVILIG collaboration

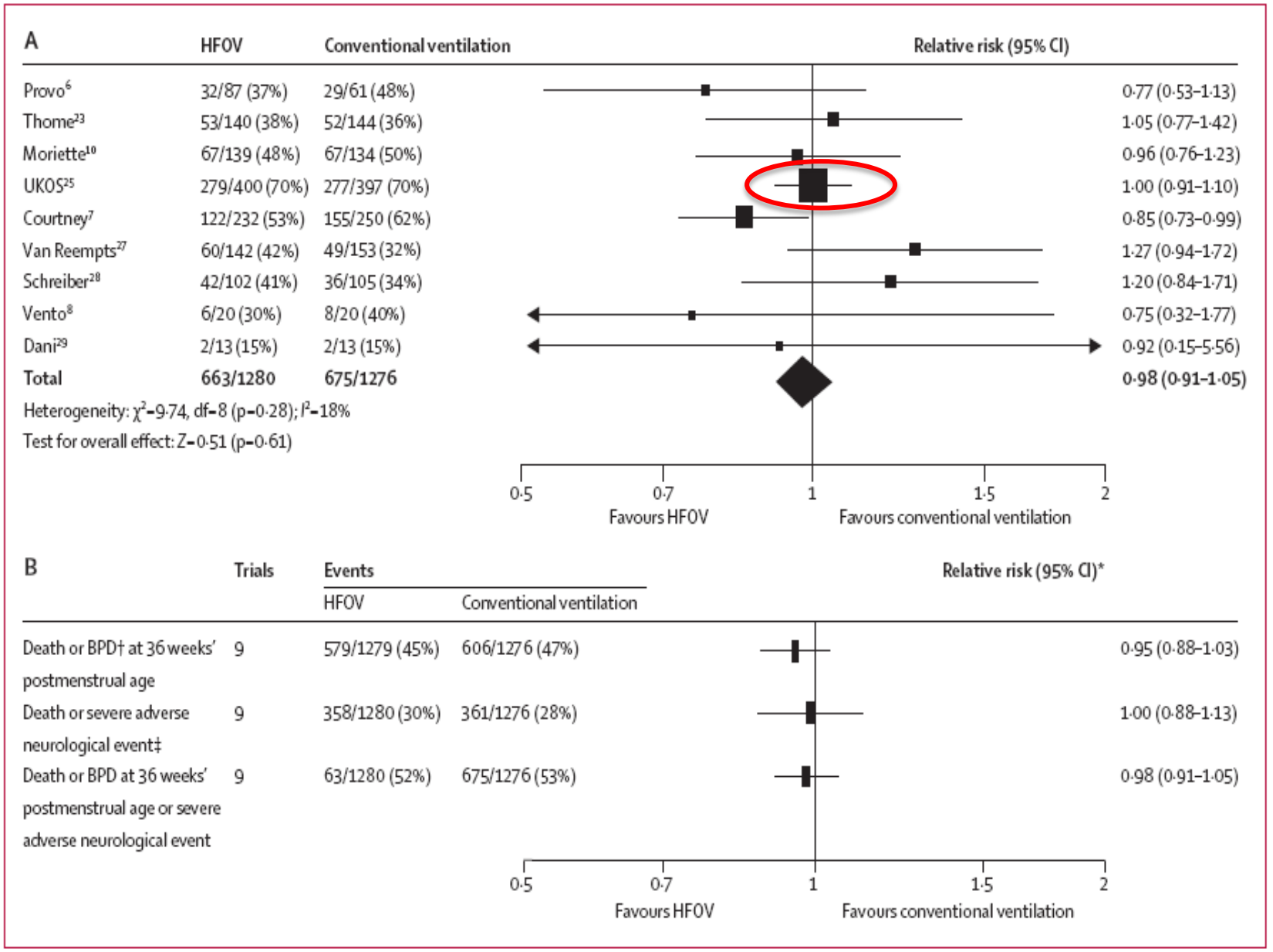
Elective high-frequency oscillatory versus conventional ventilation in preterm infants: a systematic review and meta-analysis of individual patients' data

Lancet 2010; 375: 2082–91

Background: Population and study design heterogeneity has confounded previous meta-analyses, leading to uncertainty about effectiveness and safety of elective high-frequency oscillatory ventilation (HFOV) in preterm infants. We assessed effectiveness of elective HFOV versus conventional ventilation in this group.

Interpretation HFOV seems equally effective to conventional ventilation in preterm infants. Our results do not support selection of preterm infants for HFOV on the basis of gestational age, birthweight for gestation, initial lung disease severity, or exposure to antenatal corticosteroids.

Figure 2: Effect of HFOV compared with conventional ventilation on death or bronchopulmonary dysplasia at 36 weeks postmenstrual age or severe adverse neurological events (A), and primary outcomes (B) on the basis of individual patients' data from randomised controlled trials



HIGH-FREQUENCY OSCILLATORY VENTILATION FOR THE PREVENTION OF CHRONIC LUNG DISEASE OF PREMATURITY

ALICE H. JOHNSON, M.B., CH.B., JANET L. PEACOCK, PH.D., ANNE GREENOUGH, M.D., NEIL MARLOW, D.M., ELIZABETH S. LIMB, M.SC., LOUISE MARSTON, M.SC., AND SANDRA A. CALVERT, M.B., B.CHIR., FOR THE UNITED KINGDOM OSCILLATION STUDY GROUP*

N Engl J Med 2002;347:633-42

Study Population and Entry Criteria

A total of 25 centers participated in the study — 22 in the United Kingdom and 1 each in Australia, Ireland, and Singapore. To ensure that each center had adequate experience with high-frequency oscillatory ventilation, we required participating centers to have used this type of ventilatory support in a minimum of 20 infants before the study began. The quality of collected data was monitored and the statistical analyses were performed at the coordinating center (St. George's Hospital, London). Both the South Thames Multicentre Research Ethics Committee and the local research-ethics committee at each participating center approved the protocol.

PEDIATRICS
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Does the Experience With the Use of Nasal Continuous Positive Airway Pressure Improve Over Time in Extremely Low Birth Weight Infants?

2004;114;697

Hany Aly, Joshua D. Milner, Kantilal Patel and Ayman A.E. El-Mohandes

Sept 1997 → Oct 2002

TABLE 3. Trends for Neonatal Outcomes in Surviving Infants ($N = 115$)

	Group 0 ($n = 33$)	Tertile 1 ($n = 26$)	Tertile 2 ($n = 29$)	Tertile 3 ($n = 27$)	*P* Value
BPD, %	33.3	46.2	25.9	11.1	.026
Ventilator days	7.1	8.7	5.7	3.9	.002
Weight gain, g/d	20.16	19.59	20.15	22.99	.0001
Sepsis	78.8	72.0	56.7	48.2	.007
IVH III/IV, %	12.1	8.0	6.9	3.7	.22
NEC, %	9.1	12.0	3.3	15.4	.72
ROP III/IV, %	12.1	0.0	6.9	3.9	.3
Length of stay, d	72.1	79.3	71.7	71.2	.33

Conclusions. The frequency of use of ENCPAP in ELBW infants and its success improved in our unit over time. The major positive association in this population was a reduction in BPD rates and an increase in average weight gain.

Survey of neonatal respiratory support strategies

Atul Sharma, Anne Greenough (anne.greenough@kcl.ac.uk)

King's College London, MRC-Asthma Centre, Division of Asthma, Allergy and Lung Biology, London, UK

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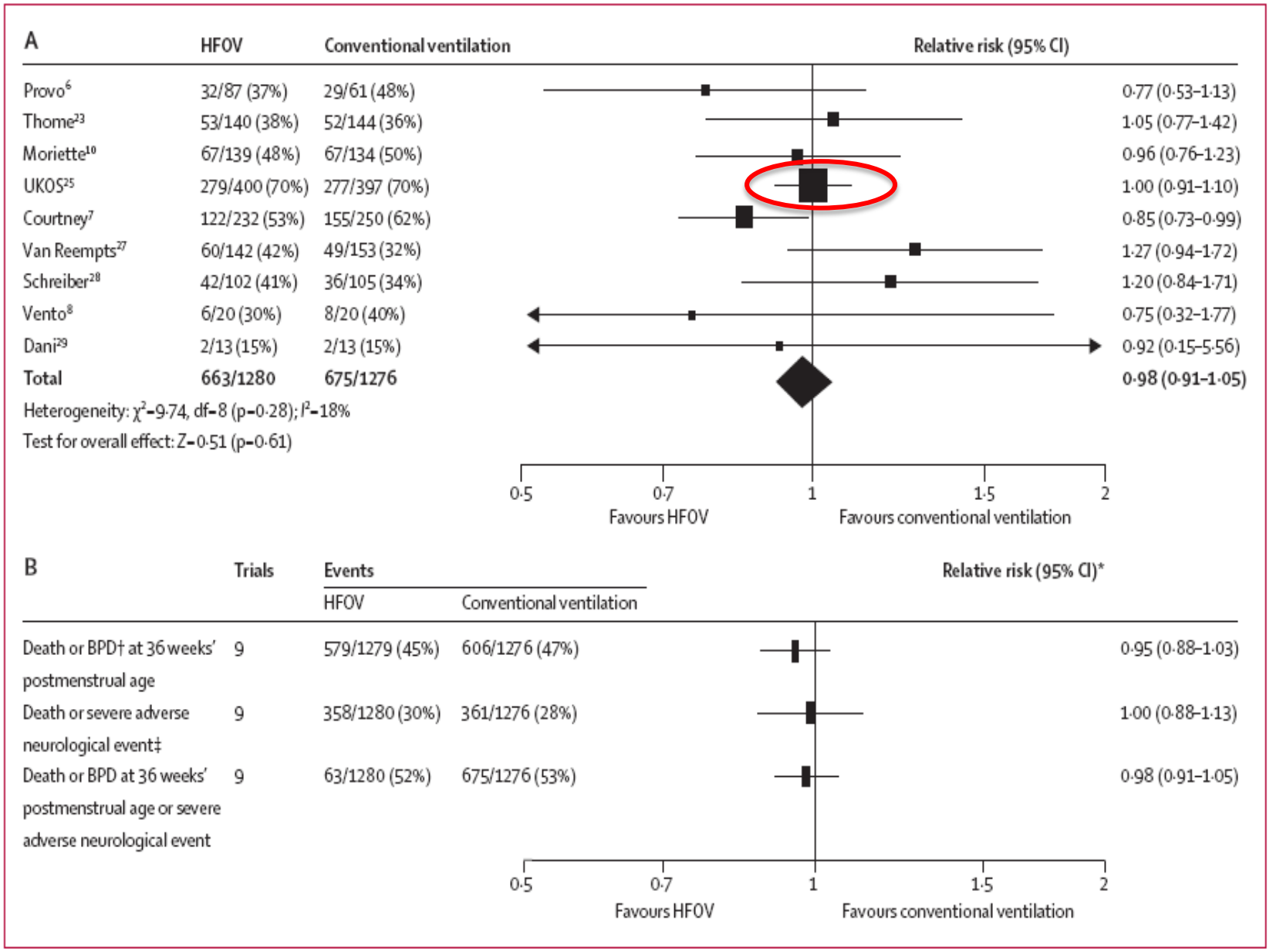
2007

Table 1 Ventilation modes in acute respiratory distress or during weaning*

	Acute respiratory distress	Weaning
IPPV	73%	N/A
HFO	2%	N/A
IMV	N/A	13%
A/C	4%	15%
SIMV	13%	73%
VG	5%	6%
CPAP	2%	N/A

*Data are demonstrated as the percentage of responders choosing a certain mode.

Figure 2: Effect of HFOV compared with conventional ventilation on death or bronchopulmonary dysplasia at 36 weeks postmenstrual age or severe adverse neurological events (A), and primary outcomes (B) on the basis of individual patients' data from randomised controlled trials



First Intention High-Frequency Oscillation With Early Lung Volume Optimization Improves Pulmonary Outcome in Very Low Birth Weight Infants With Respiratory Distress Syndrome

Peter C. Rimensberger, Maurice Beghetti, Silviane Hanquinet and Michel Berner

PEDIATRICS 2000;105;1202-1208
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

TABLE 2. Survival and CLD Morbidity

Survivors to 36 wk PCA	HFO (n = 27)	CMV (n = 34)	
CLD, oxygen >36 wk PCA, # (%)	0 (0)	12 (35)	.0006†

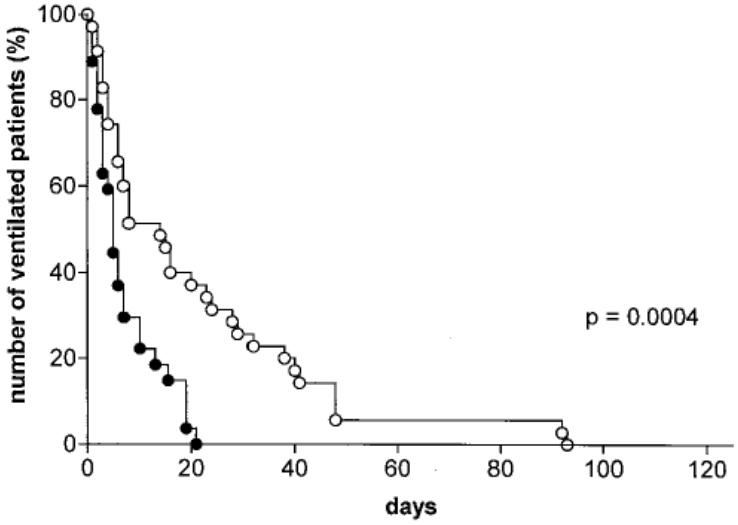


Fig 1. Kaplan-Meier curves showing the percentage of patients (survivors only) ventilated over time: HFO group (closed circles) and CMV group (open circles). Mantel-Cox log-rank test.

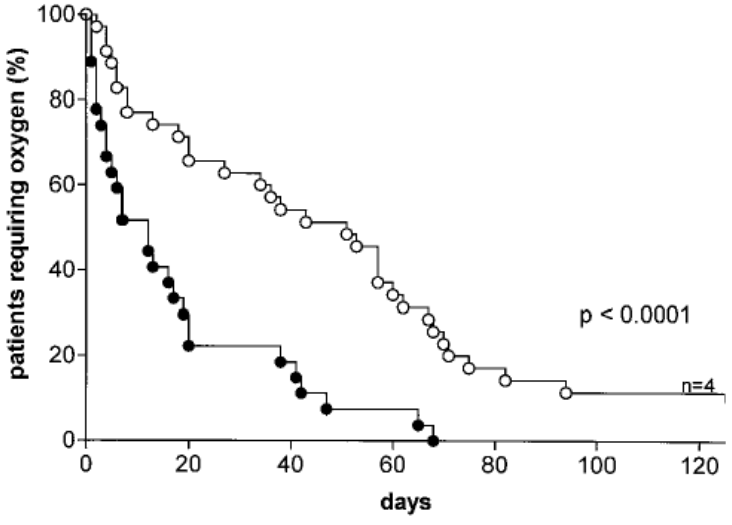


Fig 3. Kaplan-Meier curves showing the percentage of patients (survivors only) requiring oxygen over time: HFO-group (closed circles) and CMV-group (open circles). Mantel-Cox log-rank test.

HFOV or CMV in preterm infants < 28 weeks gestation? An Italian Survey

Need of mechanical ventilation

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BMJ 2013;347:f5980 doi: 10.1136/bmj.f5980 (Published 17 October 2013)

Non-invasive versus invasive respiratory support in preterm infants at birth: systematic review and meta-analysis

Georg M Schmölzer *consultant*[1 2 3], Manoj Kumar *consultant*[1 2], Gerhard Pichler *consultant*[1 2 3], Khalid Aziz *professor*[1 2], Megan O'Reilly *postdoctoral fellow*[1 2], Po-Yin Cheung *professor*[1 2]

Morley (2008)[7]	SUPPORT (2010)[8]	Sandri (2010)[10]	Dunn (2011)[9]
610	1316	208	648*

Variables	No of studies (references)	Nasal CPAP group	Intubation group	Relative risk (95% CI)	Risk difference (95% CI)	Number needed to treat
Death at 36 weeks corrected gestation	4[7-10]	145/1296	180/1486	0.88 (0.68 to 1.14)	−0.02 (−0.04 to 0.01)	
BPD at 36 weeks corrected gestation	4[7-10]	383/1182	461/1354	0.91 (0.82 to 1.01)	−0.03 (−0.07 to 0.01)	
Death or BPD, or both	4[7-10]	532/1296	641/1486	0.91 (0.84 to 0.99)	−0.04 (−0.07 to −0.00)	25
Received any mechanical ventilation	4[7-10]	839/1296	1441/1486	0.56 (0.32 to 0.97)	−0.34 (−0.68 to −0.01)	
Surfactant treatment	4[7-10]	643/1296	1402/1486	0.40 (0.23 to 0.70)	−0.51 (−0.79 to −0.23)	
Pneumothorax	4[7-10]	86/1296	78/1486	1.26 (0.51 to 3.09)	0.01 (−0.04 to 0.05)	
Postnatal corticosteroid treatment	3[7 8 10]	97/1041	137/1024	0.73 (0.49 to 1.10)	−0.04 (−0.07 to 0.00)	

HFOV or CMV in preterm infants < 28 weeks gestation? An Italian Survey

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COM'E' LA VIA?
E' DURA? E' UNTA?
DOVE E' LA SOSTA? LA VEDI?
E' CHIODATA LUNGA?
LE PRESE SONO BUONE?
BASTANO I RINVII?
E' LI' IL PASSO CHIAVE?
CE LA FACCIO IO?
E' GIUSTA LA VALUTAZIONE?
...MANCA TANTO?
CAIO

HFOV or CMV in preterm infants < 28 weeks gestation? An Italian Survey

Neurological outcomes

Tab 2. Comparison between Conventional Mechanical Ventilation and High Frequency Oscillatory Ventilation group for selected outcomes

	crude (unadjusted) analysis*			adjusted for VON RA score*		
	OR	95% IC	p	OR	95% IC	p
Mortality	0.84	0.71-1.05	0.137	0.84	0.68-1.05	0.128
CLD**	1.57	1.25-1.98	<0.001	1.63	1.28-2.07	< 0.001
Mortality+CLD**	1,26	1.05-1.50	0.012	1.38	1.13-1.68	0.002
Need of mechanical Ventilation	1.79	1.40-2.28	<0.001	2.26	1.73-2.97	< 0.001
Postnatal Steroids	1.54	1.23-1.93	0.001	1.57	1.25-1.96	<0.001
Need of Surfactant ***	1.08	0.82-1.42	0.575	1.17	0.88-1.55	0.279
Pneumothorax**	0.88	0.62-1.24	0.458	0.88	0.62-1.25	0.477
s-IVH**	0.78	0.62-0.98	0.032	0.77	0.61-0.97	0.033
surgical-PDA**	2.13	1.48-3.09	<0.001	2.15	1.49-3.11	< 0.001
surgical-NEC**	0.87	0.59-1.28	0.476	0.87	0.59-1.29	0.098
surgical-ROP**	0.83	0.62-1.12	0.228	0.83	0.62-1.12	0.226
c-PVL**	1.80	1.20-2.70	0.005	1.81	1.20-2.72	0.004

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Prospective Randomized Multicenter Comparison of High-Frequency Oscillatory Ventilation and Conventional Ventilation in Preterm Infants of Less Than 30 Weeks With Respiratory Distress Syndrome

Guy Moriette, MD*; Josefa Paris-Llado, PhD**; Hervé Walti, MD*; Benoît Escande, MD‡; Jean-François Magny, MD§; Gilles Cambonie, MD‖; Gérard Thiriez, MD¶; Sylvain Cantagrel, MD#; Thierry Lacaze-Masmonteil, MD, PhD**; Laurent Storme, MD‡‡; Thierry Blanc, MD§§; Jean-Michel Liet, MD‖‖; Christine André, MD¶¶; Benoît Salanave, PhD##; and Gérard Bréart, MD, PhD##

2001;107:363–372

TABLE 6. Endpoints According to Postmenstrual Age Stratification

	<28 Weeks' Postmenstrual Age		≥28 Weeks' Postmenstrual Age		OR (95% CI)	*P* Value*
	Conventional (n = 72)	High-Frequency (n = 81)	Conventional (n = 62)	High-Frequency (n = 58)		
Primary endpoints	n(%)	n(%)	n(%)	n(%)		
Requirement of ≥2 surfactant instillations	51 (71)	27 (33)	32 (52)	15 (26)	.25 (.15–.42)	.001
In survivors	(n = 53)	(n = 60)	(n = 57)	(n = 51)		
Absence of supplemental oxygen requirement at 28 d	20 (38)	27 (45)	40 (70)	33 (65)	1.05 (.60–1.81)	.87
Secondary endpoints						
Supplemental oxygen requirement at 36 wk†	20 (38)	17 (30)	10 (18)	7 (14)	.69 (.37–1.31)	.26
Incidence of grade 3–4 intraventricular hemorrhage	15 (21)	26 (32)	4/61 (7)	8 (14)	1.91 (1.02–3.59)	.044

* Adjusted on postmenstrual age.
† Survivors at 36 weeks: n = 52, 57, 55, and 51.

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Neuromotor Outcome at 2 Years of Very Preterm Infants Who Were Treated With High-Frequency Oscillatory Ventilation or Conventional Ventilation for Neonatal Respiratory Distress Syndrome

Patrick Truffert, Josefa Paris-Llado, Benoît Escande, Jean-François Magny, Gilles Cambonie, Elie Saliba, Gérard Thiriez, Véronique Zupan-Simunek, Thierry Blanc, Jean-Christophe Rozé, Gérard Bréart and Guy Moriette

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TABLE 2 Neonatal Mortality Adjusted for Presence of Major Cranial Ultrasound Abnormalities, by Treatment Group (Initial Trial)

Parameter	HFOV Group ($N = 139$), n (%)			Conventional Group ($N = 134$), n (%)			Adjusted OR (95% CI)
	Total ($n = 139$)	Died ($n = 32$)	Survivors ($n = 107$)	Total ($n = 134$)	Died ($n = 29$)	Survivors ($n = 105$)	
Occurrence of IVH grades 3–4	34 (100)	20 (59)	14 (41)	19 (100)	15 (79)	4 (21)	0.76 (0.37–1.52)[a]
Occurrence of cystic PVL	14 (100)	6 (43)	8 (57)	18 (100)	6 (33)	12 (67)	1.17 (0.65–2.08)[b]

[a] Mortality adjusted for IVH grade.
[b] Mortality adjusted for cystic PVL.

TABLE 3 Neuromotor Outcome at Corrected Age of 2 Years

CP	HFOV Group ($N = 97$), n (%)	Conventional Group ($N = 95$), n (%)
Yes	4 (4)	16 (17)[a]
No	93 (96)	79 (83)[a]

[a] $P < .01$.

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- Limiti dello studio
  - È uno studio di valutazione degli effetti di un orientamento, di una strategia, non di una tecnica
  - Non confronta i pazienti effettivamente ventilati
  - Alloca al gruppo della convenzionale diverse tipologie di ventilazione convenzionale
  - I criteri per il ricorso alla ventilazione meccanica non sono disponibili

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- Conclusioni
  - La scelta dell'oscillatoria all'interno di una strategia di assistenza respiratoria e in contesti ad alta confidenza con la metodica può entrare nel determinismo di esiti a breve termine
  - Eventuali studi ulteriori (randomizzati o di coorte) dovrebbero considerare e quantificare la "skillness" degli operatori per pesare eventuali differenza di performace