# WORKSHEET for Evidence-Based Review of Science for Emergency Cardiac Care

**Worksheet author(s)**

| KHALID AZIZ | Date Submitted for review: 15 February 2009 |

**Clinical question.**

"In neonates receiving positive pressure ventilation (P) does the use of gas volume monitoring (I) versus clinical assessment with or without pressure monitoring (C) improve clinical outcome (O)?"

**Is this question addressing an intervention/therapy, prognosis or diagnosis?** Intervention

**State if this is a proposed new topic or revision of existing worksheet:** New topic

**Conflict of interest specific to this question**

Do any of the authors listed above have conflict of interest disclosures relevant to this worksheet? NO

**Search strategy (including electronic databases searched).**

**PubMed:** 2227 Hits on 31 Jan 2010.

(("Cardiopulmonary Resuscitation"[Majr] OR "Respiration, Artificial"[Majr] AND ((infant, newborn[MeSH])))

AND

(("tidal volume" OR "compliance" OR "pressure" AND (infant, newborn[MeSH]))))

**AHA Endnotes Library (up to 28 Mar 2008):** 319 hits

(("newborn") AND ("compliance" OR “volume” OR “pressure”))

**All EBM Reviews - Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA, and NHSEED:** 63 hits on 31 Jan 2010.

("ventilation” AND "resuscitation”) AND ("compliance" OR "pressure" OR "tidal volume") AND (“newborn” OR “neonatal”)

**EMBASE:** 237 Hits on 31 Jan 2010

("ventilation” AND "resuscitation”) AND ("compliance" OR "pressure" OR "tidal volume") AND (“newborn” OR “neonatal”)

**SCOPUS:** 186 Hits on 28 Jan 2009

[['ventilation” AND "resuscitation”) AND ("compliance" OR "pressure" OR "tidal volume") AND (“newborn” OR “neonatal”)] limited to medical, nursing, health professional and articles only

**State inclusion and exclusion criteria**

**Inclusion criteria:**
- Newborn humans and bench models of neonatal resuscitation that compare volume measurement with clinical/pressure assessment
- Studies that assess tidal volume or flow during lung inflation
- Studies that measure a clinical outcome or credible surrogate

**Exclusion criteria**
- Adult and pediatric studies
- Animal studies
- Studies unrelated to resuscitation practices
- Studies that only measure pressure (and not volume)
- Reviews or editorials

**Number of articles/sources meeting criteria for further review:**

Ten articles met criteria for further review.
# Summary of evidence

## Evidence Supporting Clinical Question

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### Good
- Scavacini (2007, p329) E
- Kattwinkel (2009, p465) E
- Stenson (1995, p257) E
- Schmoelzer (2010, in press) E
- Finer (2009, p865) E
- O'Donnell (2005, pF392) E
- O'Donnell (2005, pF397) E
- Roehr (2010, p202) E

### Level of evidence

- A = Return of spontaneous circulation
- C = Survival to hospital discharge
- E = Other endpoint
- B = Survival of event
- D = Intact neurological survival

### Italics

= Animal studies/Simulations

## Evidence Neutral to Clinical question

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### Good

- Menakaya (2004, pF494) E

### Level of evidence

- A = Return of spontaneous circulation
- C = Survival to hospital discharge
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- B = Survival of event
- D = Intact neurological survival

### Italics

= Animal studies

## Evidence Opposing Clinical Question

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- A = Return of spontaneous circulation
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REVIEWER’S FINAL COMMENTS AND ASSESSMENT OF BENEFIT / RISK:

Ten studies were identified for review. All studies asked whether observation of pressure manometry alone reflected delivered tidal volume, either in infants or in simulations. Some studies asked participants to evaluate chest rise as a surrogate for tidal volume.

Nine out of 10 studies suggest that pressure manometry alone cannot be used as an estimate of delivered tidal volume: only one study was neutral to the question (Menakaya LOE1 2004, F494), probably because it was inadequately powered to look at clinical outcome.

Operators using pressure manometry alone were shown (by assessment of volume or flow) to be poor at assessing flow during face-mask ventilation (Finer LOE5 2009, p865), compliance changes during manual bagging (Kattwinkel LOE5 2009, e465), mask leak (O’Donnell LOE5 2005, F392 & F397), or tidal volume/compliance from observing chest rise (Scavacini LOE4 2007, p329; Stenson LOE4 1995, p257). One simulation showed that a t-piece resuscitator was better at consistently delivering volume and pressure than a self-inflating bag (Roehr LOE5 2010, p202). None of these studies adequately assessed the effect on patient outcomes of measuring tidal volume in addition to pressure.

Airway occlusion and mask leak may be important factors in determining effective ventilation (Finer LOE5 2009, p865; O’Donnell LOE5 2005, F392 & F397) and may be estimated by volume/flow measurement. Mask leak can be diminished during simulations by providing operators with feedback on tidal volume (Wood LOE5 2008, F230). In one case series from simulated and human resuscitations suggested that measurement of flow, in addition to pressure, during resuscitation would assist assessment of mask seal, airway obstruction, endotracheal tube placement, Inspiratory and expiratory times, and adequacy of ventilatory pressures in delivering inflation volumes (Schmoelzer LOE4 2010, in press). These studies suggest that measurement of either pressure or flow alone may be insufficient for an operator to make these determinations.

None of these studies were designed or powered to measure any clinical outcomes. So the primary research question of this worksheet, whether the addition of tidal volume measurement to pressure manometry aids neonatal resuscitation, has not been answered.
Citation List


Reviewer’s comments Of 18 infants who required bag-mask ventilation during resuscitation, 14 were identified using carbon dioxide colorimetric detection as having periods of no flow despite bagging. This study supports the premise that pressure alone during bag-mask ventilation does not equate to volume delivery. Does not directly answer the question

Level of evidence LOE 5 (observational, case series)
Relevance to question Low – supportive evidence in newborn babies during resuscitation that pressure alone is not adequate to ensure flow
Methodological quality Poor with respect to the question – colorimetric measurement of flow does not equate to tidal volume
Outcome(s) assessed Detection of carbon dioxide using colorimetry during bag-mask ventilation
Magnitude of any observed effect Poor flow detected for limited time periods in 14 out of 18 babies
Direction of support or otherwise for the question asked Supportive, suggesting that measuring pressure alone is inadequate – but does not directly address the question of outcome.


Reviewer’s comments 45 professionals were asked to adjust manual ventilation (using one of 3 devices) as compliance of a computerized lung model was varied in order to deliver optimal volumes. When only allowed to view pressure, only those using a self-inflating bag could adapt to change in compliance. When volume was displayed, all 3 devices could be adjusted to deliver desired volumes. This is a learner performance outcome rather than a clinical outcome.

Level of evidence LOE 5 (computerized lung model)
Relevance to question High – specifically asks whether at pressure or volume targets optimal tidal volume
Methodological quality Good – masked participants, randomized to different sequences of lung compliance scenarios
Outcome(s) assessed Ability to target optimal tidal volumes using 3 different devices (self-inflating, flow-inflating and t-piece) using either pressure manometer or delivered volume feedback in a model with varying compliance
Magnitude of any observed effect Significant at p<0.001
Direction of support or otherwise for the question asked Supportive, although the “clinical outcome” is optimal tidal volume in a lung model


Reviewer’s comments Described as a “short report” and “pilot”, 24 out of 40 eligible babies born <27 weeks gestation were either resuscitated by manual ventilation using a pressure manometer, or by a fixed tidal volume using a ventilator. No clinical differences were shown, not surprising given the small number. However, the volume ventilator appeared to be more consistent in its delivery of ventilatory pressures. This study supports the feasibility of a clinical trial.

Level of evidence LOE 1 – changed to a lower LOE because of high dropout and inadequate power: human infants, randomized prior to delivery to mask resuscitation with self-inflating bag with pressure manometer vs volume ventilator.
Relevance to question High – but the intervention is a fixed tidal volume rather than “gas volume monitoring”
Methodological quality Poor – inadequately powered to demonstrate significant differences in clinical outcome (n=24).
Outcome(s) assessed No primary outcome described. Outcomes recorded included pressure and expiratory volume, CRIB score, a/A ratio over time, time to surfactant delivery, oxygen therapy at 36 weeks
postmenstrual age, worst head ultrasound, ROP, and death.

Magnitude of any observed effect: The only difference shown was the ability of a ventilator to deliver consistent PEEP (at 7.9 vs 5.2 cm water, p=0.001). All other parameters were not significantly different.

Direction of support or otherwise for the question asked: Neutral – not really designed to show a difference.


Reviewer's comments: When 34 participants were asked, with a variety of masks, to ventilate a mannequin at specified pressures, peak pressures were achieved, but with wide variations in expired tidal volumes, presumably due to variable mask leak. Airway pressure and volume delivered are poorly correlated.

Level of evidence: LOE 5 (mannequin with flow sensor in mask)

Relevance to question: Low – did infer whether participants who only viewed pressure were able to deliver volume consistently. Study was actually about comparing masks and devices (t-piece and self-inflating), not directly about pressure vs volume


Outcome(s) assessed: Ability of operators of differing experience to deliver set pressures and optimal tidal volumes using different masks and devices

Magnitude of any observed effect: Significant discrepancies in delivery of volume at a given pressure

Direction of support or otherwise for the question asked: Supportive, although the “clinical outcome” in this case is consistent delivery of tidal volume.


Reviewer's comments: This study has very important ramifications: it questions the widely held belief that clinicians can use pressure manometry to deliver desired pressures. This study shows that both delivered pressure and delivered volume are unaffected by the operator viewing the manometer or the manometer being masked.

Level of evidence: LOE 5 (mannequin with flow sensor in mask)

Relevance to question: Low – does not determine any clinical outcome

Methodological quality: Poor – there is no comparison group using gas volume monitoring as the comparator

Outcome(s) assessed: Ability to deliver tidal volume when using a pressure manometer

Magnitude of any observed effect: No effect observed when ventilating with or without a pressure manometer

Direction of support or otherwise for the question asked: Supportive – pressure monitoring did not influence delivered tidal volume. One could argue that this supports the value of direct measurement of tidal volume.


Reviewer's comments: A simulated exercise during which 120 medical professionals were asked to target 20 cm H2O on a manikin using a self-inflating bag or a t-piece resuscitator. This study outlines the unpredictability of both pressure and volume using a self-inflating bag compared to a t-piece resuscitator, suggesting that the former results in considerable variability in both pressure and volume. The setting is artificial as the doll is intubated and the participants are asked to attach the device to an endotracheal tube.

Level of evidence: LOE 5 (mannequin with flow sensor in endotracheal tube)

Relevance to question: Low – does not determine any clinical outcome

Methodological quality: Poor – there is no comparison group using gas volume monitoring as the comparator

Outcome(s) assessed: Ability to deliver pressure and tidal volume using a pressure manometer

Magnitude of any observed effect: Marked variability in both pressure and tidal volume is seen with the self-inflating bag, and markedly less with the t-piece resuscitator

Direction of support or otherwise: Supportive – this study only supports the inference that the mode of delivery of pressure or
for the question asked volume might be important to outcome. One could argue that this supports the value of direct measurement of tidal volume.


Reviewer’s comments This study asks whether observation of chest rise can be used to estimate adequate tidal volume in ventilated newborn infants. The correlation was poor in 111 assessments, but it was noted that more experienced physicians were more able to evaluate tidal volume. If clinicians are poor at estimating tidal volume, this supports the hypothesis that volume ventilation needs further study.

Level of evidence LOE 4 (Observation study in human infants with no controls)

Relevance to question Low – a comparative study of clinical assessment to volume measurement, but not during resuscitation

Methodological quality Good

Outcome(s) assessed Correlation of clinical assessment with measured volume by observers of differing experience – not a “clinical” outcome with respect to the baby

Magnitude of any observed effect Variable

Direction of support or otherwise Supportive – supports the need to measure tidal volume in ventilated infants when compared to clinical assessment.


Reviewer’s comments This is a descriptive study, a collection of case reports, with incomplete details of individual cases and their outcomes. It looks at the utility of respiratory function monitoring in a variety of steps of respiratory support during resuscitation including assessment of mask leak, airway obstruction, adequate ventilatory pressures, rate, inspiratory time, expiratory time, lung inflation and endotracheal tube placement. It does not evaluate the clinical benefit of these observations.

Level of evidence LOE 4 (Observation of flow in human and simulated resuscitations with no controls)

Relevance to question High – but only useful for hypothesis generation

Methodological quality Poor – the descriptions of the cases are very limited

Outcome(s) assessed None except measurement of flow in different situations

Magnitude of any observed effect Not observed

Direction of support or otherwise Supportive – data are suggestive of a benefit in observing ventilatory flow or volume, but with no specified clinical or educational outcome one must classify this paper as poor.


Reviewer’s comments This study asks whether clinicians of varying experience are able to assess compliance by clinical observation. There was poor correlation between clinical observation and actual compliance. This supports the hypothesis that direct measurement of tidal volume, and therefore compliance might be preferable.

Level of evidence LOE 4 – Observational study of junior doctors’ ability to estimate lung compliance by observing chest rise.

Relevance to question Low – investigates the ability of observers to assess compliance (and indirectly volume), but not during resuscitation

Methodological quality Fair – not sure of patient or observer selection.

Outcome(s) assessed Comparison of estimated compliance with true compliance – not a true “clinical” outcome

Magnitude of any observed effect Poor correlation of observers with measured compliance

Direction of support or otherwise Supportive – observation alone does to allow reliable estimation of compliance through inferring tidal volume

Reviewer’s comments
This study showed that 50 clinical staff could improve their ability to minimize facemask leak in a simulation if they were able to visualize expired tidal volume as a surrogate for mask leak.

Level of evidence
LOE 5 – mannequin with flow sensor in mask

Relevance to question
Low – indirectly relevant to the clinical question, as this is use of gas volume measurement during training

Methodological quality
Fair – pre and post design, using staff as their own controls

Outcome(s) assessed
Ability to minimize mask leak after training using gas volume monitoring

Magnitude of any observed effect
 Clinically significant reductions in mask leak after training

Direction of support or otherwise for the question asked
Supportive – training using gas volume measurement improves practical skills