

DETERMINING THE BEST CARE FOR AN INDIVIDUAL PATIENT:
USING THE N-OF-1 CLINICAL TRIAL

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Introduction: Assessment of patient response to treatment may be biased because the caregiver is not blinded, the patient may exhibit a placebo response, or the patient may have improved without treatment. Though not widely seen in nursing literature, N-of-1 trials can be used to avoid these biases when the treatment has a relatively rapid onset of action and the effects cease soon after stopping treatment. In such a trial, a blinded evaluator may assess the responses of an individual patient to repeated exposures to an experimental and a control therapy administered in a random or alternating sequence. **Purpose:** We conducted an N-of-1 trial to assess the response to different levels of PEEP for a ventilator dependent infant with chronic lung disease who had acute episodes of respiratory deterioration. **Methods:** Alternating 3-hour periods of baseline PEEP 6 cm water pressure (P6) with like periods of PEEP 9 cm water pressure (P9) were assessed. The predefined response variables were the number of oxygen (O₂) desaturation episodes and accompanying O₂ saturation as recorded by a computerized monitor. FiO₂ was adjusted to maintain the O₂ saturation between 85% and 95%. Other aspects of patient care were unchanged. The investigator evaluating the monitor record was masked to the level of PEEP. There were a total of fourteen time periods, 7 each for P6 and P9. Analysis of variance (ANOVA) was performed using SPSS 11.5 software. **Findings:** There were 130 and 137 low oxygen saturation alarms in P6 and P9 respectively. The mean interval between occurrences for P6 was 9 min:10 sec (SD ? 11:16), for P9 was 9 min:47 sec (SD ? 11:50) (p=0.767). The mean oxygen saturation for P6 was 59.73% (SD ? 14.8), for P9 was 60.67% (SD ? 15.1) (p=0.137). **Discussion:** Using an N-of-1 trial to minimize bias in assessing a controversial therapy, we found no evidence that different levels of PEEP influenced the likelihood of O₂ desaturation episodes in this patient. Bedside nurses did not believe the study increased their work burden. As for this patient, an N-of-1 trial can be designed and easily implemented by nurses, at all levels, and may be useful in determining treatment response for an individual patient.

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