Three versus seven day circuit changes of humidified oxygen circuitry: Pilot study to test the feasibility of conducting a randomised controlled trial.

Abbreviated title: Humidified oxygen circuit changes.

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For Blind Review

Three versus seven day circuit changes of humidified oxygen circuitry: Pilot study to test the feasibility of conducting a large randomized controlled trial.

Abbreviated title: Changing humidified oxygen circuits.

ABSTRACT

Aim: To compare the rate of humidifier-acquired pneumonia between patients in whom circuitry is changed every three days (current practice) with patients in whom circuitry is changed every 7 days.

Background: Published guidelines for the prevention of nosocomial pneumonia state that ventilator circuitry should be changed no more frequently than every 48 hours, there are no recommendations for the optimal length of time humidified oxygen circuits should be used.

Design: Prospective randomised controlled trial.

Methods: Patients receiving humidified oxygen in surgical, medical and infectious diseases units in a 942 bed general teaching hospital in Queensland, Australia were eligible. Those consenting were randomly allocated to either 3-day (control) or 7-day (intervention) circuit changes. The primary outcome measure was rate of nosocomial pneumonia.

Results: Of the 51 eligible patients, 32 were included in the study (17 patients were randomized to the control group and 15 patients to the intervention group; recruitment rate 63%). During the study, four cases of nosocomial pneumonia occurred; two in the intervention group (13.3%) and two in the control group (11.8%)($\chi^2_1 = 0.018$, $p = 0.894$). No patients died during the study period .

Conclusion: Conducting a large-scale randomised controlled trial in this area would be feasible.

Relevance to clinical practice: This study is a first attempt to provide evidence on which to base practice guidelines for the management of humidified oxygen in a

hospital setting.

Keywords: Oxygen inhalation therapy, Humidification, Pneumonia, Randomised controlled trials, Respiratory nursing

INTRODUCTION

Modern health care highlights cost reduction and demands positive patient outcomes. In pursuit of these goals, many hospitals have focused on evaluating high volume practices such as routine equipment changes, as these present significant recurrent costs. Changing humidified oxygen circuits represent one such high volume, routine activity.

BACKGROUND

Impetus for this study arose from the Evidence-based Practice Mentorship Program at our hospital. The program invites Registered Nurses from the district to spend one day per week for twelve weeks, away from the clinical area, attempting to answer a clinical question. The clinician learns database searching and critical appraisal skills under the supervision of an experienced researcher (JW) while developing an evidence-based recommendation, or in the absence of quality evidence, a proposal for funding for further research (Webster, Lloyd et al. 1999).

Humidified oxygen circuits are changed every three days in our hospital and one of the program participants was interested in whether it would be safe to change to weekly circuit changes. A literature review revealed a lack of research on humidifier circuits, although there were a number of studies reporting positive outcomes for weekly ventilator circuit changes (Long, Wickstrom et al. 1996;

Kotilainen and Keroak 1997; Fink, Krause et al. 1998; Han, Liu et al. 2001). Most recent guidelines for the prevention of nosocomial pneumonia state that both ventilator circuits with humidifiers and humidified oxygen circuits should not be changed routinely unless they become visibly soiled (Tablan, Anderson et al. 2004). The guidelines categorise the recommendations in relation to ventilator circuits as 1A, however, the recommendations in relation to humidifier circuits are categorised as level 2 and no relevant references are cited.

Although it seems clear that weekly ventilator circuit changes are safe and efficient, it is inappropriate to base humidified oxygen protocols on research pertaining to ventilator circuitry. Humidified oxygen circuits are configured differently, and are used on a different patient population and for different reasons to mechanical ventilation circuits. Humidified oxygen circuits are open circuits, usually ending in a tracheostomy mask or a face mask. Patients are often disconnected from the circuit, for example, to attend an x-ray, and the circuit is left open and uncovered for periods of time.

THE STUDY

Aim

To conduct a pilot study to compare the rate of humidifier-acquired pneumonia between patients in whom circuitry is changed every three days (current practice) with patients in whom circuitry is changed every 7 days.

Design

A randomised controlled trial, conducted at a 942 bed general, tertiary referral teaching hospital in Queensland, Australia, during a 9-month period between March 2003 and December 2003.

Participants

All patients receiving humidification in the surgical, medical and infectious diseases units were assessed for elligibility (LH). Exclusion criteria were age < 18 years; an inability to give consent, (for example, the patient was mentally incompetent and relatives were either unknown or unable to be contacted); or cessation of humidification prior to 48 hours after admission to the ward. Patients entered the trial only after 48 hours had elapsed since arriving in the ward. This 'window period' was allowed so that pre-existing but undiagnosed infections could be detected prior to commencement on the trial.

The randomisation schedule was generated by a researcher otherwise uninvolved with the implementation of the trial (JW). The project officer (LH) was responsible for enrolling participants, gaining consent, and collecting data. A third researcher (DG) kept the computer-generated randomisation schedule at all times. This researcher (DG) was a clinical expert involved in conceptualising the trial, but who was not involved in daily implementation of the trial. The researcher enrolling participants (LH) would phone (DG) with demographic details of the potential

participant who would advise of the participant's study group. We proposed an a priori hypothesis that participants from intensive care would be more likely to develop nosocomial pneumonia so groups were stratified according to whether or not patients had been admitted to the ward from the intensive care unit.

Intervention

For all study patients, the following characteristics were prospectively collected: age, sex, smoking history, prior location before admission to the ward (eg intensive care unit, home etc) diagnosis at hospital admission, ward in which the patient was being treated, indication for humidification therapy, presence of chronic obstructive airways disease, number of circuitry changes done and reasons for the changes, duration of humidification therapy prior to pneumonia, total duration of humidification therapy (until death or weaning), peak temperature.

Changing the humidifiers after patients were enrolled in the trial remained the responsibility of the registered nurses employed in the clinical area. We placed a sticker on the patients' humidifiers and placed documentation in the patients' bedside charts to alert the nurses caring for these patients to the study group and date on which the humidifier circuit should be changed. Both nurses and participants were aware of the participant's allocation. The nurses changed circuits at any time if visible soiling appeared, irrespective of the patients' study group.

The treating physician, who was not blinded to the patients' study group but not

part of the research team, diagnosed pneumonia using the following criteria: a new localized chest radiographic infiltrate; fever; white cell count of < $4x10^9$/L or > $11x10^9$/L; isolation of a pathogenic organism >3+ on semi-quantitative culture of a tracheal aspirate or sputum sample, and clinical signs such as changes in sputum (increased production, changed appearance or increased quantity) and increased respiratory rate. The diagnosis of pneumonia was extracted from the patients' medical records by the project officer. Any ambiguity about the patients' diagnoses was clarified with the patients' treating physicians.

Sample size calculation

The sample size for the study was based on the reported nosocomial pneumonia rate for patients in the intensive care unit of the hospital which was 18%. We assumed that the pneumonia rate would be less among patients receiving humidification therapy rather than mechanical ventilation, so an arbitrary rate of 10% was applied. Using an $\alpha = 0.05$, $\beta = 0.02$ (i.e. power = 0.8), and a change in pneumonia rate from 10% to 5% as clinically significant, an estimated sample size of 110 patients in each group was required.

Outcome measures

The primary outcome measure was nosocomial pneumonia and the secondary outcome measures were death and length of humidification therapy.

Analysis

Patients were monitored until 48 hours after the cessation of humidification therapy. Outcome analysis was by original allocation and is expressed as the number of patients with the outcome of interest in each group (%). Baseline characteristics such as age and weight were not normally distributed and were compared using Mann-Whitney test and were summarized using the median [range]. Categorical variables were compared using the chi-square statistic with Yate's correction and were summarised as proportions (%).

Ethical considerations

The study was approved by the hospitals' Human Research Ethics Committee. Data was recorded in a durable manner and will be kept in a safe location for at least 5 years. A member of the research team approached patients in the designated wards and gave them written information and a verbal explanation of the trial. In the event that patients were unable to give consent, a family member was approached and asked to consent on the patients' behalf. Participation was voluntary and patients were informed that refusal to participate would not affect their care. Patients were able to withdraw from the study at any time.

RESULTS

The pilot study took place between March 1st 2003 and November 30th 2003. During that period, 51 patients were approached to participate in the study. Of

these, nineteen patients were ineligible for inclusion. Reasons for exclusion are shown in Figure 1. Of the 32 patients recruited into the study, seventeen patients were randomized to the 3-day change group and fifteen patients were randomized to the 7-day change group, giving a recruitment rate of 63%. Baseline characteristics for patients in the two groups were comparable at randomisation (Table 1).

Primary outcomes

During the study, four cases of nosocomial pneumonia occurred; two in the intervention group (13.3%) and two in the control group (11.8%)($\chi^2_1 = 0.018$, $p = 0.894$).

Other outcomes

Both groups were similar in terms of the mean number of humidified days per patient (Intervention 12.8 [23.90]; Control 13.7 [13.6]; p = 0.89). There was a statistically significant difference in the median number of circuits used per patient (Intervention [range 0 to 14]; Control 3 [range 0 to 17]; Z = 2.72; $p = 0.02$). No patients died during the study period. Due to insufficient numbers of participants we were unable to investigate the effect of previous ICU admission on the primary and secondary outcomes.

DISCUSSION

The purpose of this study was to assess the feasibility of conducting a large scale randomised controlled trial to test the safety of extending the period between humidified circuit changes from three to seven days. We were able to recruit 63% of eligible patients but, even so, we only recruited 32 patients in a 7-month recruitment period. A number of issues prevented us from obtaining a larger sample. We received sufficient funding to employ a research assistant for only one day per week for a period of 12 months. We originally planned that the research assistant would manage data and that nurses on the study wards would recruit participants. This plan was based on an understanding that two nurses from each of the six study wards would act as resource persons for the study and would assist other nurses on the ward with recruiting patients. These nurses had expressed an interest in research and evidence-based practice. We explained the recruitment process to the resource nurses, recruited a patient together and left a resource folder for the study on the ward. However, it soon became clear that nurses on the study wards were unable to recruit patients into the study because of work pressures. As a result, recruitment was left to the research assistant and occurred on only one day per week; hence, many potential participants were missed. Although these problems meant that the study was under-powered to show real differences, the high recruitment rate indicates that recruitment would not be an issue in an adequately funded study.

Four patients developed nosocomial pneumonia while enrolled in the study. All of

these patients were admitted to the respective study wards from an intensive care unit (ICU), all received enteral feeding and all remained in hospital for extended periods; all factors associated with increased risk of nosocomial pneumonia (Tablan, Anderson et al. 2004). One of the participants was an elderly victim of a motor vehicle accident and later died after re-admission to the intensive care unit. After an extended stay of more than 98 humidified days, another participant was later transferred to another hospital for a double lung transplant. The third patient to have developed nosocomial pneumonia continued to see a speech pathology department for ongoing management of swallowing difficulties, hence this patients' pneumonia was most likely due to aspiration. The fourth patient, although now well, was also an elderly victim of a motor vehicle accident, and was fully nursing-care dependent and immobile when enrolled in the study. Therefore, all of the patients who developed nosocomial pneumonia had in common a number of factors known to be associated with higher incidence of pneumonia such as, critical illness and endotracheal intubation; enteral feeding; extended length of stay and immobility (Brooks 2001) and were unlikely to have developed the pneumonia as a result of contaminated humidified oxygen tubing.

While not statistically significant, an important clinical finding of the study was the difference between groups in the number of circuits used per patient. Patients in the control group used a median of 3 [range 0 to 17] circuits per patient. Patients in the intervention group, who were having their circuits changed only every 7 days, used a third of the number of circuits of the control group with a mean of 1 [range

0-14] circuit per patient. This difference between groups seems more important when converted into cost savings. Our hospital spends $98,733 on 3,098 humidifier circuits per year for non-ICU wards only. A practice change to 7-day humidifier circuit changes could reduce current expenditure to one third of the current figure, for a potential cost saving of approximately $66,000 per annum. During the study we halved the usage of humidified circuits for 15 patients during the data collection period, resulting in an actual cost saving of $930.

Further study of the safety of 7-day versus 3-day changes of humidified oxygen circuits would be feasible, but would require a research assistant to be employed full-time for the purposes of participant recruitment, data collection and data entry. Recruitment processes are now quite lengthy and involve specialised knowledge of consent procedures. Expecting clinical nurses to undertake this role is no longer an option in busy clinical settings.

CONCLUSION

Potential cost savings involved in extending the time frame between humidifier circuitry changes indicate that a large scale randomized controlled trial is both feasible and important.

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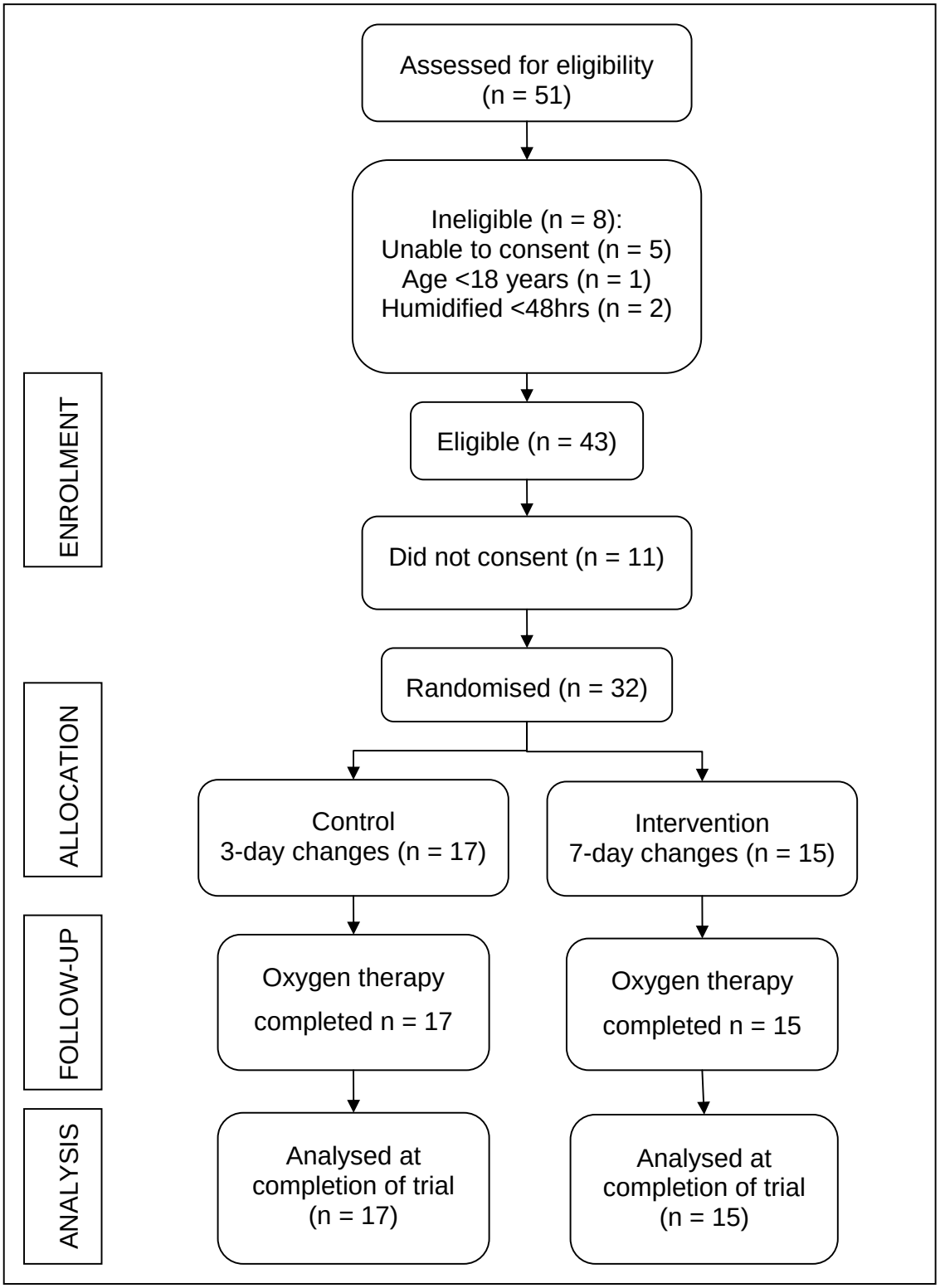

Figure 1: Flow of participants through each stage of the study

Table 1. Demographics of patients in a pilot randomized controlled trial of 7-day versus 3-day changes of humidified oxygen circuitry. The data are median [range] or proportions (%).

	7-day change n = 15	3-day change n = 17
Age (years)	63 [31 to 78]	72 [23 to 90]
Sex (male)	13 (86.7)	14 (82.4)
Weight (kgs)	70.3 [19.1]	65 [60 to 95]
Admitted from ICU	10 (66.7)	10 (58.8)
Patient type:		
Medical	7 (46.7)	5 (29.4)
Surgical	6 (40.0)	8 (47.1)
Infectious diseases	2 (13.3)	4 (23.5)
Smoking history (current or within last 12 months)	4 (26.7)	5 (29.4)
Presence of COAD	6 (40.0)	7 (41.2)
History of pneumonia	6 (40.0)	11 (64.7)
Presence of tracheostomy	9 (60.0)	15 (88.2)
Antibiotics on admission	10 (31.3)	15 (46.9)