

A randomised controlled crossover trial of nurse practitioner versus doctor- led outpatient care in a bronchiectasis clinic

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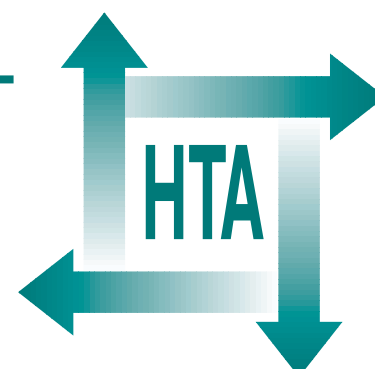
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Executive summary

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Executive summary

Objectives

In the setting of a specialist outpatient clinic for bronchiectasis patients, the study objectives were:

- to assess the feasibility and safety of nurse practitioner-led outpatient clinics and their acceptability to patients and their doctors
- to compare the cost-effectiveness of nurse practitioner-led care with a doctor-led system of care.

Design

The study was in two phases. In the first, the nurse practitioner completed a 6-month training programme to enable her to practise independently. This included tuition in the principles of bronchiectasis and its clinical presentation and management, together with practical experience and skills in clinical assessment and therapeutics. In the second phase, a randomised controlled trial of crossover design was used to compare nurse practitioner-led with doctor-led care in a bronchiectasis outpatients' clinic. Sample size was calculated on the basis of establishing equivalence of the two modes of care.

Setting

The lung defence clinic was introduced at Papworth Hospital in 1995 as a specialist unit with the purpose of streamlining the management of patients with bronchiectasis. Individual management plans are developed for intensive treatment and prophylaxis of endobronchial sepsis. Following initial investigation, patients with minor disease are followed-up in their local hospitals, returning to the specialist clinic annually for review. Patients with moderate to severe disease are seen in the specialist clinic several times a year.

It was in this context that the medical team considered the possibility of expanding the nurse practitioner's role to include outpatient follow-up of bronchiectasis patients. The medical team comprised three consultants and one rotating registrar with 2–3 years' experience of respiratory medicine.

Participants

Bronchiectasis is a chronic, usually progressive, respiratory disease characterised by dilatation and thickening of the bronchi. Patients experience repeated episodes of infection, chronic sputum production and increasing breathlessness, which ultimately progress to respiratory failure. The patients included in the study were over 18 years of age with moderate or severe bronchiectasis confirmed by high-resolution computed tomography scans. A treatment plan was formulated before a patient was considered eligible for the trial. The nurse practitioner did not assess new patients independently.

Interventions

Eighty patients were recruited and for the first year of the study were randomised to receive either 1 year of nurse practitioner-led care or 1 year of doctor-led care. The two groups then crossed over to receive the alternate mode of care for a further year. It was important that patients received each mode of care for a full year since chronic lung disease is subject to seasonal variation.

Main outcome measures

The primary outcome measure was lung function as measured by forced expiratory volume in 1 second (FEV_1). Patients were stratified as stable (decline in FEV_1 over the preceding 12 months $< 5\%$) or unstable (decline in FEV_1 in the preceding 12 months $\geq 5\%$) prior to randomisation.

Secondary measures included walking distance, health-related quality of life, nurse practitioner autonomy, patient and general practitioner satisfaction with communications and care, patient compliance with treatment and resource use.

Results

Of the 80 patients recruited, 39 were randomised to nurse practitioner-led followed by doctor-led

care, and 41 to doctor-led followed by nurse practitioner-led care. The patients' mean age at randomisation was 58 years and 69% of them were female. Baseline lung function and 12-minute walk distance were similar in the two groups.

At the final follow-up, the mean difference in FEV₁ between nurse practitioner-led and doctor-led care was 0.2% predicted (95% confidence interval (CI), -1.6 to 2.0; $p = 0.83$). The mean difference in 12-minute-walk distance between the two methods of service delivery was 18 metres (95% CI, -13 to 48; $p = 0.30$). The number of infective exacerbations experienced by patients during nurse practitioner-led care was 262 in 79.4 patient-years of follow-up, compared with 238 in 77.8 years during doctor-led care. Thus, nurse practitioner-led care resulted in a relative rate of exacerbation of 1.09; however, the difference was not statistically significant (95% CI, 0.91 to 1.30; $p = 0.34$). Of those patients who were using antibiotics and indicated their compliance, 100% were compliant (95% CI, 89 to 100) while receiving nurse practitioner-led care compared with 81% (95% CI, 63 to 93) of patients during doctor-led care, a difference that was statistically significant ($p = 0.024$).

The health-related quality-of-life analysis revealed no significant mode of care effects. However, patients reported less vitality/energy and greater levels of pain following doctor-led care but fewer role limitations because of emotional problems. In the analysis of patient satisfaction with the clinic consultations, there was a statistically significant difference between the two modes of care, in favour of the nurse practitioner, in the areas of communication and time spent with the patient. However, nurse practitioner-led care resulted in significantly increased resource use compared with doctor-led care. The mean difference per patient was £1498 (95% CI, 688 to 2674; $p < 0.001$) and was greater in the first year (£2625) than in the second (£411).

Conclusions

Nurse practitioner-led care for stable patients within a chronic chest disease clinic is safe and as effective as doctor-led care.

There was significant additional patient satisfaction with some aspects of nurse practitioner-

led care and better patient compliance with antibiotic therapy.

There was significant additional resource use related to admissions and antibiotic prescriptions during nurse practitioner-led care. However, this may have been a learning curve effect, as the difference was substantially greater in the first year.

While the treatment and management of the study patients are broadly generalisable to other chronic disease clinics, the authors would not recommend extrapolation of results to acute onset diseases or diseases in which presentation and/or complications are wide-ranging or rapidly changing.

The study design – a randomised, controlled, crossover trial based on equivalence in outcome – proved robust and appropriate for this type of evaluation. Randomisation allowed the most objective treatment assignment over the period of study and ensured that unpredicted differences in hospitalisation and cost were detected; an alternative strategy could have masked these differences.

Recommendations for research

Similar evaluations should be considered as part of the process of introducing nurse practitioner roles, or any role transfer in the health service, as much can be learned from the results in terms of ensuring that their introduction is both acceptable to patients and cost-effective.

To minimise the learning curve effect in future studies of this type, randomisation during training and a formal evaluation of all outcomes immediately after training would help to identify needs and to minimise the learning curve effect during a period of formal evaluation. An alternative approach would be simply to lengthen the trial.

Publication

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NHS R&D HTA Programme

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Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure has been redefined and replaced by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

The HTA Programme continues to commission both primary and secondary research. The HTA Commissioning Board, supported by the National Coordinating Centre for Health Technology Assessment (NCCHTA), will consider and advise the Programme Director on the best research projects to pursue in order to address the research priorities identified by the three HTA panels.

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