Home management of mild to moderately severe community-acquired pneumonia: a randomised controlled trial

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ABSTRACT

Objective: To determine whether community management of mild to moderate community-acquired pneumonia (CAP) is as effective and acceptable as standard hospital management of CAP.

Design: Randomised controlled trial.

Setting: Christchurch, New Zealand, primary and secondary care.

Participants: 55 patients presenting or referred to the emergency department at Christchurch Hospital with mild to moderately severe pneumonia, assessed using a validated pneumonia severity assessment score, from July 2002 to October 2003.

Interventions: Hospital treatment as usual or comprehensive care in the home delivered by primary care teams.

Main outcome measures: Primary: days to discharge, days on intravenous (IV) antibiotics, patient-rated symptom scores. Secondary: health status measured using level of functioning at 2 and 6 weeks, patient satisfaction.

Results: The median number of days to discharge was higher in the home care group (4 days; range, 1–14) than in the hospital groups (2 days; range, 0–10; $P = 0.004$). There was no difference in the number of days on IV antibiotics or on subsequent oral antibiotics. Patient-rated symptom scores at 2 and 6 weeks, median change in symptom severity from baseline to 6 weeks, and general functioning at 2 and 6 weeks did not differ between the groups. Patients in both groups were satisfied with their treatment, with a clear preference for community treatment ($P < 0.001$).

Conclusions: Mild to moderately severe CAP can be managed effectively in the community by primary care teams. This model of comprehensive care at home can be implemented by primary care teams with suitable funding structures.

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Community-acquired pneumonia (CAP) causes significant morbidity, with an overall mortality of 6%–8% in patients admitted to hospital.[1] The hospital-in-the-home care model is safe and effective.[2-4] However, the popularity of hospital in the home for CAP varies, as some doctors consider patients requiring intravenous (IV) antibiotics too unwell for home treatment.[5] A recent study demonstrated that outpatient treatment with oral antibiotics is safe and effective for mild CAP.[6] Although CAP patients have been included in small numbers in some general trials of hospital in the home, there are no randomised controlled trials of hospital in the home versus hospital care of patients with mild to moderate CAP.

Pegasus Health is an Independent Practitioners Association of about 230 (70%) general practitioners in Christchurch, New Zealand. The organisation set up an "Extended Care @ Home" service, providing extended medical and nursing care to patients in their homes. Our hypothesis was that patients with mild to moderate pneumonia could be effectively treated at home by primary care teams using this model.

METHODS

We carried out a randomised controlled trial of home versus hospital (usual) care of mild to moderate CAP. This study was approved by the Canterbury Ethics Committee, Christchurch, NZ.

Eligibility criteria

All patients attending the emergency department (ED) at Christchurch Hospital from July 2002 to October 2003 with a clinical diagnosis of CAP who met the eligibility criteria were invited to participate. CAP was defined according to the British Thoracic Society criteria:

> An acute respiratory tract illness associated with radiographic shadowing consistent with infection on a chest radiograph (CXR) which was neither pre-existing nor of any other known cause.[7]

A formal severity assessment was performed using the CURB-65 score.[7] This simple validated scoring system is practical to implement in a busy ED and enables stratification of patients with CAP into mortality risk groups which might be suitable for different management options.[1,7] Items contributing to the score are confusion, blood urea concentration, respiratory rate, blood pressure and age. Patients with a CURB-65 score of 0–2 have a low mortality (0.7%–9.2%) and were considered for management in the community.[7]

The following additional exclusion criteria were applied: living outside the Christchurch metropolitan area; in hospital-level accommodation or of no fixed abode; living

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alone with no alternative accommodation; serious comorbidity requiring hospital treatment;[7] pneumonia which was not the primary cause for hospital admission, was distal to bronchial obstruction or was associated with pleural effusion; and expected death. Patients who had tuberculosis, bronchiectasis or HIV infection or were immunocompromised were also excluded, along with patients who had been in hospital within the previous 14 days, had pulse oximetry oxygen saturation < 92% on air, or had previously been entered in the study.

Randomisation

Patients were randomly assigned to receive either hospital treatment or home treatment under the Extended Care @ Home (EC@H) program. The randomisation list was produced using SAS code, using randomly allocated block sizes with a maximum of 20. Allocation was obtained by telephone from an independent coordinator.

Baseline data

Patient characteristics, patient-rated symptom severity and general functioning using the SF-12 scale[8] were recorded by the study team at trial entry (the SF-12 yields two summary measures of functional physical and mental health).

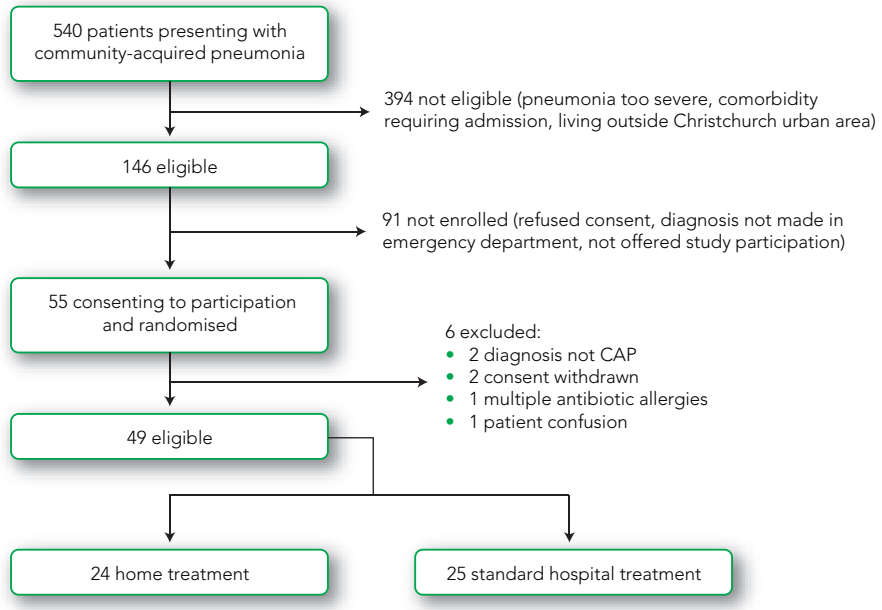
Microbiological samples were obtained, and included sputum where available for Gram stain, culture and sensitivity (including *Legionella pneumophila*), urine for *Streptococcus pneumoniae* and *L. pneumoniae* antigen testing, standard serological testing for *L. pneumoniae* and *Mycoplasma pneumoniae* antibodies, blood cultures and a nasopharyngeal swab for *Bordetella pertussis* culture.

Interventions

EC@H is provided by a GP Medical Director and experienced primary care nurses in conjunction with the patient's own primary care team. It covers a similar range of activities to hospital in the home, providing an IV antibiotic service using standard cannulae, home support services, short-term home nursing care and mobile diagnostic testing.[2,9,10]

All patients in both groups received an initial dose of IV antibiotics while in the ED. Identical antibiotic treatment guidelines were provided, but choice was left to the physicians in both groups. The protocol provided guidelines for recognising failure of treatment or development of complications requiring consideration of secondary care transfer.

1 Participant flow diagram



All patients in both groups completed questionnaires at baseline, at 2 weeks, and at 6 weeks. The numbers of eligible and ineligible patients were estimated from the screening log (which covered 8 of the 15 months). ◆

Initially, patients randomised to home care had a daily visit from a GP and at least twice-daily visits by a nurse. Initial chest x-rays of community patients were reviewed by a respiratory physician, and any requiring follow-up were highlighted.

Home care patients were given a 24-hour emergency contact number and a list of symptoms that should prompt contact.

Outcome measures

The primary outcome measures were duration to discharge from hospital or EC@H program, duration of IV and subsequent oral antibiotics, self-rated symptom severity, and general functioning using the SF-12 scale. Secondary outcome measures were complications and patient satisfaction. Patient-perceived symptom severity was recorded using a previously developed pneumonia symptom score.[11] There were additional questions on sleep and appetite disturbance. Self-rated symptom severity, general functioning and adverse events were recorded daily. Data on duration of admission and antibiotics were extracted from the case records.

Follow-up

Patients were contacted by telephone at 2 and at 6 weeks after presentation to record satisfaction, self-rated symptom severity and functional outcome data using the SF-12 scale. Costs were calculated from a funder's perspective. Direct costs of providing home care were extracted for each patient to align as closely as possible with the hospital costing formula, for which the Victorian diagnosis-related groups (DRGs) system version 4.2 is used,[12] and included actual costs for each study patient for staff time and transport, equipment, pharmaceuticals, and support services such as home help, as well as mean administrative, laboratory and radiology costs per patient for the EC@H service.

Statistical analysis

The study was powered to detect clinically important differences and similarities between the two groups in time to discharge, duration of IV and oral antibiotics and general functioning. With 25 per group, assuming a log-normal distribution, 0.70 coefficient of variation, the study had 90% power to show a 1.5-day difference in time to discharge ($\alpha = 0.05$) and duration of IV antibiotics, and 80% power ($\alpha = 0.05$) to show a clinically significant difference in general functioning of 7 or more units in the SF-12 physical or mental component scores.

Data were compared between groups using Mann–Whitney *U* tests, independent *t* tests (SF-12) and the Fisher exact test (satisfaction).

RESULTS

Participant flow and characteristics

The study ran from July 2002 until October 2003. Fifty-five patients met the initial inclusion criteria, consented and were randomised. There were six exclusions after randomisation (Box 1). Complete data for primary and secondary outcome measures were obtained from all remaining patients. The demographic and clinical characteristics of the two patient groups were similar (Box 2). A screening log was kept, covering representative time periods at the beginning, middle and end of the study, which totalled 8 months of the 15-month study period. During this time, 288 patients with potential CAP were identified in ED triage codes and from chest x-ray results. Of these, 208 did not fit the inclusion criteria. These estimates were extrapolated to estimate the eligible population for the entire period (Box 1).

A specific bacterial diagnosis was made in nine out of 24 patients in the home arm and in 13 out of 25 patients enrolled in the hospital arm. *M. pneumoniae* diagnosed serologically was the most common pathogen identified in the patients treated at home (five out of 24 patients), followed by *S. pneumoniae* (in two patients). In the hospital arm, *S. pneumoniae* was the most frequently isolated pathogen (3/25 detected with the urinary antigen detection test and 3/25 isolated in sputum culture), followed by *M. pneumoniae* (3/25) and *L. pneumophila* (2/25), both diagnosed serologically.

Clinical outcomes

Initial treatment was amoxycillin in seven (29%) of the home group and three (12%) of the hospital group. Amoxycillin/clavulanate was the initial antibiotic in 11 (46%) of the home group and eight (32%) of the hospital group. A combination of penicillin and a macrolide was used in five (21%) of the home group and eight (32%) of the hospital group. One patient in each group received clarithromycin alone. Other antibiotics used in the hospital group were cefuroxime (1), clarithromycin/cefuroxime (2), and clarithromycin/cefuroxime/amoxycillin (1). Antibiotics were changed in response to microbiological results or poor clinical progress in six (24%) of the home group and two (8%) of the hospital group.

The median number of days to discharge in the home group was 4 (range, 1–14), compared with 2 (range, 0–10) in the hospital group ($P = 0.004$). There was no significant difference in the number of days on IV antibiotics (3 v 2 days) or subsequent oral antibiotics (9 v 7 days) ($P = 0.22$ for both comparisions).

At 2 weeks, there was no significant difference in the patient-rated symptoms of fatigue, breathlessness, chest pain, cough, sputum production and loss of appetite. There was a significant difference in sleep disturbance, with a median of "never" among the hospital group and "occasional" among the home group ($P < 0.01$). This difference between groups did not persist at 6 weeks.

There was no significant difference in the time to resolution of fever, tachycardia and tachypnoea.

Functional outcomes

There was no significant difference between groups in either the physical or mental functioning components of the SF-12 at either 2 or 6 weeks (Box 3).

Adverse events

There were no deaths in either group. Two patients were transferred from the home care group to hospital. One had a legionella infection and developed empyema; the other failed to improve clinically after antibiotics, and developed bullous myringitis. There was one readmission to hospital from the hospital care group, with clinical deterioration after discharge.

There were nine recorded extrapulmonary infections: five in the home care group and four in the hospital care group. These included urinary tract infections (2), upper respiratory tract infections including sinusitis and pharyngitis (4) and IV site infections (3).

Including the patient with empyema, there were three recorded pulmonary complications (pleural effusions): two in the home group and one in the hospital group. Four patients (two in each group) reported antibiotic side effects of nausea and candidiasis. One patient in the hospital group had a fall that did not result in serious injury.

Patient satisfaction

Patient satisfaction with medical and nursing care was high in both groups, but significantly higher in the home group ($P = 0.001$). In the home care group, all patients reported that they were "very happy" with their care. In the hospital care group, 60% were "very happy", 32% "quite happy" and 8% "neither happy nor unhappy".

Similarly, most patients were happy with the *location* of their care, but the home

2 Patient characteristics

	Home ($n = 24$)	Hospital ($n = 25$)
Sex		
Male	13	13
Female	11	12
Ethnicity		
New Zealand European	20	13
Other European	2	7
Maori	0	3
Pacific Island	2	1
Other	0	1
Mean age (years)	50.1	49.8
High user health card*	3	2
Community services card†	9	9
Highest education level‡		
Primary	1	1
Secondary	10	18
Tertiary	13	6
Smoking status		
Never	10	10
Current smoker	4	7
Ex-smoker	10	8
Mean pack-years	18.9	20.4
Prior antibiotics	14	10
Other medical conditions (mean number)	0.8	1.1
CURB-65 score		
0	13	14
1	6	8
2	5	3

*Card providing access to sudsidised health care and medicines for frequent users of the health system. †Means tested card providing access to subsidised health care and medicines. ‡Significant difference $P = 0.03$, using χ^2 and combining for tertiary education versus no tertiary education. ◆

3 Mean physical and mental component scores of SF-12*

	Home ($n = 24$)	Hospital ($n = 25$)	P
Physical component			
2 weeks	38.1	40.2	0.45
6 weeks	42.2	45.8	0.18
Mental component			
2 weeks	48.3	48.6	0.91
6 weeks	50.4	51.0	0.81

*A higher score represents better functioning. ◆

group were happier ($P < 0.001$). In the home care group, 92% of patients reported that they were "very happy" with the location of their care and 8% "quite happy". In the hospital care group, 32% were "very happy" with the location, 40% "quite happy", 20% "neither happy nor unhappy" and 8% "very unhappy".

Costs

The mean cost per study patient of EC@H was NZ$1157.90, based on actual costs for each patient for transport, staff time, equipment, pharmaceuticals and support services such as home help, as well as the mean administrative, laboratory and radiology costs per patient for the EC@H service. Based on the Victorian DRGs version 4.2 "uncomplicated pneumonia" DRG E62c, the inlier costweight is 0.6288. In New Zealand, the caseweight price for 2003 was NZ$2475, giving a price per case of pneumonia with CURB score 0–2 to the funder of NZ$1556.28 for hospital care.

DISCUSSION

Our results suggest that home treatment of mild to moderately severe pneumonia, assessed using the CURB-65 scoring system, is an effective alternative to hospital treatment.

Although the duration of IV and oral antibiotics was similar, the time to discharge was significantly longer for patients cared for in the home. This was probably accounted for by the EC@H guideline, which requires patients to have been afebrile for two consecutive readings and observed by EC@H for 48 hours before change to oral antibiotics. In contrast, some patients treated in hospital were discharged before 48 hours. There were no clinically significant differences in median time to clinical sign resolution or in resolution of patient-reported symptoms. General functioning assessed by the SF-12 was similar in both groups, and complications had a similar frequency and pattern. Patients were appropriately referred back to hospital and there were no serious adverse events. The study was not powered to show differences in mortality. Very large numbers would be required for such a study, as patients at low risk of mortality were selected.

This model of care is very acceptable to patients, with a high level of satisfaction with care in the home environment. These are additional outcomes that show advantage, and therefore have the potential to be type I errors, but at the very least they do not show inferiority of the home program.

Caseweight-based costs are a blunt tool for cost comparison. Actual costs of hospital care are not available. However, using this tool, the costs of location of treatment to the funder can be compared. Using this model, the EC@H model of care appears cost effective, with care of the home patients costing the funder around three-quarters of the caseweight-based cost of care for hospital care of these patients.

Some patients potentially eligible for the study were not offered enrolment. This may have been for logistic reasons in the ED or a later diagnosis.

The strength of this study is that it tests a unique model of care for CAP that to our knowledge has never been prospectively evaluated in a randomised controlled trial. This model has previously been tested for cellulitis.[13]

Our results build on recent evidence that outpatient treatment of mild pneumonia is safe.[6] A proportion of patients with the mildest pneumonia in the CURB 0–2 range can be safely treated with oral antibiotics and are likely to require less intense review. Most mild pneumonia is probably already treated in the community with oral antibiotics, and more than half of this group had already had a trial of oral antibiotics before referral. It is important not to treat patients in this group with IV antibiotics if evidence indicates they are suitable for oral antibiotics.

Equally, for people with more severe pneumonia, the careful selection and close monitoring described in this study are very important, and our findings cannot necessarily be extrapolated to less intensive models.

Community-based care of serious conditions such as pneumonia has traditionally been organised by secondary care programs. These have generally involved admission under a medical team with early discharge to the community. EC@H is the first model where the full clinical responsibility for patients with CAP is taken by primary care teams. This not only allows patients to remain at home, but also increases the skills and experience of the GP workforce in managing acutely unwell patients in the home environment.

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COMPETING INTERESTS

None identified.

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