UNCERTAINTIES PAGE

Does home oxygen benefit people with chronic heart failure?

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This is one of a series of occasional articles that highlight areas of practice where management lacks convincing supporting evidence. The series advisers are Rubin Minhas, clinical director, BMJ Evidence Centre, and David Tovey, editor in chief, the Cochrane Library. This paper is based on a research priority identified and commissioned by the National Institute for Health Research's Health Technology Assessment programme on an important clinical uncertainty.
To suggest a topic for this series, please email us at uncertainties@bmj.com.

Patients with chronic heart failure are often prescribed home oxygen therapy for intractable breathlessness, usually via a nasal cannula at a concentration of 24-28% oxygen. A Cochrane Review concluded that long term home oxygen therapy improved survival (although not quality of life) in patients with chronic obstructive pulmonary disease who had severe hypoxaemia (arterial PaO_2 <55 mm Hg (8.0 kPa)).[1] However, little evidence exists that patients with treated chronic heart failure have hypoxaemia. A complicating factor is that a third of patients with chronic heart failure may have episodic hypoxia overnight due to sleep disordered breathing,[2] which might respond to nocturnal oxygen therapy. Sleep disordered breathing can be either obstructive sleep apnoea (common in patients with and without heart failure) or central sleep apnoea (common only in patients with chronic heart failure). Both types of sleep disordered breathing lead to episodic hypoxia, but only obstructive sleep apnoea responds well to continuous positive pressure airways support.[3]

What is the evidence of uncertainty?

A systematic review in 2004 identified only three randomised studies of oxygen therapy for breathlessness in patients with chronic heart failure.[4] We searched PubMed, Medline, and Embase databases for randomised controlled trials comparing oxygen therapy with either placebo or no treatment in adults with chronic heart failure, using the search terms "oxygen", "home" or "domiciliary" or "long-term", and "heart (or cardiac) failure", and we found no further studies.

Thus, despite the wealth of evidence supporting medical treatment in patients with chronic heart failure, unanswered questions remain about the use of oxygen.

What is the prevalence of hypoxaemia in patients with chronic heart failure?

Hypoxaemia affects all patients with acute pulmonary oedema. However, no systematic evidence exists on the prevalence of hypoxaemia during waking hours in patients with chronic heart failure. Observational data from small physiological studies of exercise capacity suggest, surprisingly, that patients receiving drug treatment for chronic heart failure have slightly higher mean arterial oxygen tension than do controls both at rest and during exercise.[5 6] Patients with chronic heart failure seem unlikely therefore to gain from chronic daytime oxygen therapy. However, a study of 700 ambulatory patients with chronic heart failure found that about a third have sleep disordered breathing with its associated intermittent hypoxaemia.[2] Nocturnal oxygen therapy might be of benefit therefore in selected patients.

Does oxygen therapy reduce breathlessness?

Although intractable breathlessness is the most common reason for prescribing home oxygen therapy for patients with chronic heart failure, evidence is mounting that supplemental oxygen does not reduce breathlessness. A large observational study of patients with breathlessness of varying aetiology concluded that oxygen therapy was of no benefit in the absence of hypoxaemia,[7] a finding echoed in a Cochrane review of eight randomised trials of oxygen therapy.[8] A recent randomised, double blind controlled study confirmed that oxygen was no better than room air for the relief of intractable breathlessness in study participants, a few of whom had chronic heart failure.[9] In a small physiological study of 12 patients with chronic heart failure, exercise capacity (used as a surrogate for breathlessness) improved with supplemental oxygen,[10] but the finding has not been replicated.[11]

Is oxygen therapy safe in chronic heart failure?

No evidence exists that long term oxygen therapy is safe in patients with chronic heart failure. After acute myocardial infarction, high dose oxygen therapy is associated with decreased cardiac output.[12] Small, short term observational studies in patients with chronic heart failure suggest that high dose oxygen may also increase left ventricular filling pressure and impair myocardial relaxation.[13]

Is long term home oxygen therapy beneficial in chronic heart failure?

No completed studies have been published of either the efficacy or effectiveness of long term home oxygen therapy administered at a concentration of 24-28% oxygen in patients with chronic heart failure.

Is overnight home oxygen therapy beneficial in chronic heart failure?

A few small studies of short term nocturnal oxygen therapy suggest some benefit in patients with chronic

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- Does home oxygen benefit people with chronic heart failure? (*BMJ* 2011;342:d234)
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- How beneficial is surgery for cervical radiculopathy and myelopathy? (*BMJ* 2010;341:c3108)
- Does avoidance of peanuts in early life reduce the risk of peanut allergy? (*BMJ* 2010;340:c424)
- Should we use bath emollients for atopic eczema? (*BMJ* 2009;339:b4273)

heart failure and central sleep apnoea. For example, 10 of 20 patients with chronic heart failure in an open label study randomised to nocturnal oxygen therapy for three months showed statistically significant but small increases in exercise capacity and left ventricular ejection fraction in the group treated with oxygen, with no change in the untreated group.[14] In the largest available study 51 patients with chronic heart failure and central sleep apnoea were randomised to receive nocturnal oxygen therapy or conventional treatment for one year.[15] The group with nocturnal oxygen therapy had a statistically significant reduction (about 50% compared with no change in controls) in the number of apnoea episodes per hour during sleep; a marginal increase (3.5%; P=0.049, compared with no change in controls) in left ventricular ejection fraction; and a statistically significant increase in daytime activity level (increase of 0.82 in a specific activity scale, compared with no change in controls). However, the study found no reduction in cardiac events.

Is ongoing research likely to provide relevant evidence?

We found only two relevant studies in a search of the World Health Organization's International Clinical Trials Research Platform Portal (Australia New Zealand Trials Registry; clinicaltrials.gov; ISRCTN register) using the terms "oxygen" and "heart failure".

The Oxygen-HF trial (ACTRN12609000103268) is a randomised trial of 285 patients comparing the effects of home oxygen therapy, medical air (placebo), and no treatment (control) on all cause admissions to hospital at six months (primary end point) and symptom assessment and B-type natriuretic peptide. The trial does not have enough power to examine effects on mortality.

The NEON (North-East Oxygen Network) trial, is a randomised trial of 450 patients assessing the prevalence of hypoxaemia in patients with chronic heart failure and comparing the effects of long term oxygen therapy, nocturnal oxygen therapy, or best medical treatment on quality of life (primary end point), exercise capacity, breathlessness, N-terminal pro B-type natriuretic peptide cardiac function, admission to hospital, and cost effectiveness. The trial does not have enough power to examine effects on mortality.

What should we do in the light of the uncertainty?

Although doctors may be under considerable pressure from patients or carers to prescribe home oxygen, long term oxygen therapy should not be prescribed routinely to patients with chronic heart failure as no evidence exists that it reduces breathlessness or the frequency of clinical events (such as admission to hospital or mortality). However, patients with heart failure should be assessed for symptoms of obstructive sleep apnoea, which should be treated according to conventional guidelines.[16] Consider nocturnal oxygen therapy in patients with symptomatic central sleep apnoea as weak evidence of benefit exists.

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Commentary: Research to decrease areas of clinical uncertainty

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Uncertainties abound in healthcare. The 2008 editorial by Chalmers that launched the *BMJ*'s Uncertainties Page series highlighted the enormous harms that can come from failure to identify and reduce them.[1] In the United Kingdom, the National Institute for Health Research's Health Technology Assessment (HTA) programme is charged with producing independent and rigorous research about the effectiveness of different healthcare technologies to resolve important areas of uncertainty. The HTA programme was established in 1993 and is funded by the Department of Health as part of the National Institute for Health Research (www.hta.ac.uk). The article this week in the *BMJ*'s Uncertainties Page series is the first of several articles in this series that will focus on areas of clinical uncertainty being investigated by HTA research.[2]

The HTA programme aims to meet the information needs of the NHS and works by consulting widely to identify topics for research. Suggestions are made through a web based suggestion system (www.hta.ac.uk/suggest); the HTA also identifies topics by reviewing reports and systematic reviews from bodies such as the National Institute for Health and Clinical Excellence and the Cochrane Collaboration. A priority setting exercise is conducted to decide which research to commission. Requests for research into these topics (commissioning briefs) are framed using the PICO structure (Population (what is the population of interest?), Intervention (what are the interventions of interest?), Comparison (what are the comparisons of interest?), Outcome (what are the outcomes of interest?))[3] to emphasise their relevance to patients and clinicians. The commissioning brief asks for evidence synthesis or new primary research, usually in the form of a randomised trial. Researchers can also apply directly to the HTA programme for funding, but the topics proposed are first assessed for NHS importance; only if the topic meets this criterion will the proposal proceed for scientific assessment. When the research is complete, the findings are published in the journal series *Health Technology Assessment* (www.hta.ac.uk/project/htapubs.asp), providing a record of the research that complements shorter articles in journals such as the *BMJ*.

Most HTA trials seek to establish the benefit of a treatment or investigation in routine practice rather than under ideal conditions. Trials are therefore usually conducted in a clinical setting, with interventions delivered wherever possible as they would be in routine clinical practice. Measures, including independent randomisation and intention to treat analysis in randomised trials, are needed to avoid bias. The key outcomes sought in such studies are patient outcomes, not surrogates, as measures of effectiveness and cost effectiveness.

Many research projects commissioned by the HTA programme have been highly influential in changing clinical practice and healthcare policy. The Cooksey review, which has guided much of the recent development of NHS research policy, identified the HTA programme's success in providing NHS decision makers with a high quality evidence base and suggested that much of the escalating information needs of the NHS could be met by expanding the programme.[4] Individual trials commissioned by the HTA programme have also helped to resolve uncertainties around specific issues. For example, the Venus II trial showed that larval therapy is effective as a debridement agent in leg ulcers, although it did not speed up healing.[5] The CRASH-2 trial showed that a short course of tranexamic acid, a low cost treatment, in the management of trauma patients reduced the percentage of people dying from 16.0% to 14.5%.[6] The DiGEM trial highlighted the lack of evidence for clinical benefit from routine self monitoring of blood glucose for people with type 2 diabetes not treated with insulin.[7] Although primary research may take many years, it can if necessary be delivered quickly—for example, in response to the recent influenza pandemic, information about the spread and prevalence of the condition was rapidly available to clinicians and policy makers.[8]

We hope that the *BMJ* series, in highlighting HTA projects that have been commissioned in response to clinically important uncertainties, can achieve three objectives. Firstly, raising awareness of the current uncertainty can encourage clinicians and patients in relevant areas to support the research and take part where possible. Secondly, the series will help to ensure that when the results are published they can be rapidly taken into clinical practice. Finally, we hope that by making the process of funding research more transparent we can encourage individuals to identify new areas of clinical uncertainty and report them to the HTA programme, so that these topics can enter the commissioning process, helping to resolve that uncertainty and improve the care received by patients.

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SAFETY ALERTS

Essential care after an inpatient fall: summary of a safety report from the National Patient Safety Agency

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As many as one million patient falls are estimated to occur in hospitals each year in the United States, with similar rates reported from most other developed countries.[1] In England and Wales about 280 000 patient falls are recorded annually from acute hospitals, community hospitals, and mental health units.[2] This is likely to be an underestimate, as all reporting systems are known to under-report.[3] Although over 96% of these falls result in only minor or no physical harm, 1390 caused fractures (including 840 hip fractures) and 30 led to intracranial injuries (mostly subdural haematomas).[2]

Inpatients are particularly vulnerable to falling owing to acute medical problems such as delirium, stroke, systemic infections, and cardiovascular and musculoskeletal conditions and to adverse effects from medications. In addition, the unfamiliar hospital environment may exacerbate the impact of conditions such as dementia and problems with continence, balance, strength, mobility, or eyesight.[1]

Prevention of falls is a crucial element of patient safety, and resources to help identify and reduce risk factors for falls are widely available.[4] However, what happens after a fall is equally important. In particular, early detection and treatment of any injuries sustained, such as subdural haematoma[5] and hip fracture,[6] may affect outcome critically.

Twelve months of reports to the National Patient Safety Agency before 25 March 2010 indicate that about 200 patients who sustained fractures or intracranial injuries after a fall in hospital experienced some shortfalls of care after their fall. This is likely to be an underestimate owing to under-reporting and minimal detail in many reports on care after the fall. The reviewed incidents suggest that failure to recognise the risks and the potential for harm after falls are common. A typical report reads: "Patient suffered head injury on ward previous day. Found 11.30 unconscious (GCS [Glasgow coma score] 3/15) bleeding from nose and aspirating blood. Fixed and dilated pupils. Significantly abnormal cardiovascular and respiratory observations. Coagulopathy on background of alcoholic liver disease. ISSUES . . . No neuro obs [neurology observation] being carried out after injury."

Problems identified by the National Patient Safety Agency

- Delayed diagnosis of fractures, ranging from several hours to several days after the fall. This seemed to relate predominantly to patients being assessed only superficially or not at all by medical staff, rather than to injuries that were difficult to detect or x ray images that were difficult to interpret. Patients with delirium or dementia who could not give a coherent account of the fall or their symptoms appeared particularly vulnerable to delayed diagnosis
- Neurological observations not recorded often enough, or not at all, with failure to recognise the greater vulnerability of patients receiving anticoagulant treatment or patients with coagulopathy. These problems resulted in delayed diagnosis of intracranial haemorrhage
- Sling hoists used to move patients despite symptoms of limb fracture or spinal injury, causing intense pain and even fracture displacement
- Delay in access to urgent investigations or surgery (particularly orthopaedic advice and beds for patients who fell in non-orthopaedic, acute hospital wards).

This summary is based on a safety report (known as a rapid response report or RRR) issued by the National Patient Safety Agency in January 2011.[7]

What can we do?

As serious injury occurs in only about 1% of inpatient falls, staff need to be vigilant. Key clinical considerations are:

- Before moving a patient off the floor, stop and think if there could be serious injuries, including checking for signs or symptoms of limb fracture and potential for spinal injury
- If the patient shows signs or symptoms of serious injury, know how to access "flat lifting" equipment and get help from colleagues who are trained in its use (or in isolated units, keep the patient immobile while awaiting emergency services)
- Ensure that all patients with features of serious injury, and those who are more vulnerable to serious injury, are rapidly assessed by a doctor
- Ensure that all patients receive a detailed and documented medical review within an appropriate timescale. Medical staff should return regularly to review the patient if there are any concerns, with further review at the next consultant or general practitioner ward round
- After suspected head injuries, base the frequency, duration, and components of neurological observations on national guidance (box).[5] Abnormal findings such as lateralising signs, seizures, or a drop in the Glasgow coma score should trigger prompt action. Hospitals should use only charts that allow recording of the standard 15 point version of the Glasgow coma scale[8]
- Carefully document a history of the fall, collected from any witnesses as well as the patient, as this may point towards underlying causal factors. Report all falls and investigate these via local systems, and where applicable inform relatives and carers of the fall
- Assume that a patient who falls is at high risk of further falls, triggering action on secondary prevention[1] and consideration of bone health[6]
- Note that falls are often an ominous "red flag" for underlying deterioration, which may itself merit urgent medical review regardless of any actual injury.[1]

Following a Department of Health review in July 2010, the National Patient Safety Agency will be abolished and some of its functions transferred to a patient safety subcommittee of the new NHS Commissioning Board. Reports of incidents are, however, still encouraged at www.npsa.nhs.uk.

Content and frequency of neurological observations

The NICE guideline on the triage, assessment, investigation, and early management of head injury[5] includes the following advice on frequency of neurological observations:

- (From point 1.7.2.1 in the guidance) For patients admitted for head injury observation, the minimum acceptable documented neurological observations are Glasgow coma score, pupil size and reactivity, limb movements, respiratory rate, heart rate, blood pressure, temperature, and blood oxygen saturation
- (From point 1.7.3.1 in the guidance) Observations should be recorded every 30 minutes until the Glasgow coma score of 15 has been achieved. The minimum frequency of observations for patients with a score of 15 should be (starting after the initial assessment in the emergency department):

-Every 30 minutes for two hours

-Then every hour for four hours

-Then every two hours thereafter

- (From point 1.7.3.2 in the guidance) If a patient with a Glasgow coma score of 15 deteriorates at any time after the initial two hour period, revert to observations every 30 minutes and follow the original frequency schedule.

The rapid response report requires NHS organisations to support frontline staff through system changes, including producing and disseminating local protocols for actions after a fall and reviewing training, equipment, and bedside documentation. Units without resident doctors are required to agree on criteria and timescales for access to emergency ambulance services and medical review. Acute hospitals should review their referral and transfer systems to ensure that patients with serious injuries from falls receive the same quality and speed of access to specialist investigations and treatment as that provided to people in the community.

What else do we need to know?

The challenge both for falls in hospital and for falls in the community is consistent, reliable implementation of the existing evidence on the care that will optimise patients' chances of making a full recovery and reduce the risk of further falls.[9]

How will we know when practice has become safer?

NHS organisations are asked to make the system changes outlined in the rapid response report by July 2011. In 2011, the Clinical Effectiveness and Evaluation Unit of the Royal College of Physicians will pilot a national audit of inpatient falls, including elements to assess progress in implementing the recommendations of the rapid response report. Organisations can also check progress locally—for example, by taking a sample of patient notes to check the quality of medical assessments done after a fall and recording of neurological observations, or by asking a sample of staff members if they know how to access local "flat lifting" equipment.

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The talisman effect

Early most mornings I shuffle into the kitchen to make coffee for the family. You may visualise the cupboard in our kitchen above the counter to my right. This is where the family's store of vitamins is kept. There are numerous bottles of vitamins and minerals labelled from A all the way to Z. There is vitamin C and lots of vitamin Bs and then a whole lot of minerals such as zinc and magnesium and even selenium. Our kitchen cupboard may hold the whole of the periodic table for all I know.

A cursory inspection of members of the family arriving at breakfast reveals no obvious evidence of scurvy, pellagra, or beriberi in the consumers of their vitamin enriched cereals, so I have conducted a family focus group to find out the reason for this profligate consumption of food supplements. The answers have ranged from "Because they are good for you" and "They prevent me from getting colds" to "They will stop me getting Alzheimer's like you, father."

I have rejected their conclusions with the contempt that medicine reserves for non-believers of the scientific method. There is no hard evidence, I have cried, futilely, to the ranks of the opposition. This is why I have come to the conclusion that the multibillion dollar vitamin business is based on what I call the talisman effect. A talisman is a protection against evil or disease. It usually takes the form of a piece of jewellery or a pendant hung round the neck to provide magical protection (from the Greek *telesma*, to consecrate). Almost all cultures and religions have signs, figures, or artefacts that are thought to protect the wearer against misfortune and disease. The crucifix, St Christopher medals, the sign on the door, the black ribbons on the trucks, the amulets and the ankle and wrist bands on babies in the traditional worlds.

The talisman effect of vitamins and many other modern interventions in providing protection against illness seems to be cryptically embedded in the human psyche. How does the ritual of the medication, the belief in efficacy, and the feeling of protection affect the outcome of illnesses? The interventions may indeed have some benefits, but, like the placebo effect in treatment, the talisman effect in prevention may be more difficult to identify and measure in our deeply atavistic belief systems.

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