

Recurrent pharyngo-tonsillitis

Tonsillectomy has some benefits over watchful waiting, but the net benefit is unclear and research into longer term outcomes is needed



SCOTT CAMAZINE/PHOTOTAKE/ALAMY

In this week's *BMJ*, a randomised controlled trial by Alho and colleagues assesses the effectiveness and safety of tonsillectomy compared with watchful waiting in adults with recurrent streptococcal pharyngo-tonsillitis (three episodes of pharyngitis in six months or four in 12 months).¹ Although the minority of patients presenting to general practitioners with tonsillitis have recurrent tonsillitis, about 12% of the population has recurrent tonsillitis at some stage,² and a substantial familial element exists.² The trial found that tonsillectomy significantly reduced the recurrence of the principal outcome, streptococcal pharyngitis, at 90 days (1/36 (3%) *v* 8/34 (21%); adjusted relative risk 21%, 95% confidence interval 6% to 36%; number needed to treat 5, 3 to 16). A systematic review of tonsillectomy for chronic tonsillitis found limited data to support tonsillectomy in children and no data in adults,³ so the trial is the first to provide evidence to help doctors and patients decide on the best course of action.

Despite these promising results, the trial does have limitations that make it difficult to apply the results to a clinical setting. The main problem is that the follow-up period of six months is relatively short, and people in the watchful waiting group reported considerable improvement during the trial period—after six months the mean number of sore throats was 0.4, and patients had on average had 2.5 days of sore throat. This begs the question of whether the benefit of immediate tonsillectomy would be reduced if the follow-up was longer. Secondly, because of the small size of the trial, the effect sizes were imprecise and confidence intervals were wide. Thus the trial is consistent with as small a benefit as a 3% reduction in episodes of sore throat (number needed to treat 34). A third limitation is that we do not know how severe the episodes of pharyngitis were. The authors provide some data on the number of days with a sore throat, but because patients were encouraged to consult to have swabs taken, it is difficult to judge severity on the basis of consultation data. The episodes of sore throat lasted six days, which suggests that they were shorter than normal episodes presenting to general practitioners (where on average patients have had symptoms for three days before they present and symptoms last for a further five days⁴). Another issue relates to the chosen primary outcome measure of a reduction in streptococcal pharyngitis confirmed by culture, which is perhaps of limited clinical use as patients do not complain of streptococcal pharyngitis

but of sore throats. More useful to clinicians and patients, is that the authors documented a reduction of 25% in episodes of sore throat (56% *v* 31%), and a sore throat for nine days less in the first 90 days of the follow-up period.

Any benefits of the operation must be balanced against potential disadvantages. The major disadvantage documented in the trial is the 13 days of sore throat after tonsillectomy, which can be severe in many patients.¹ Other disadvantages include the risks associated with an anaesthetic, otalgia, dehydration, dental injuries, burns, and soft tissue injuries, and a risk of life threatening complications, such as major haemorrhage or sepsis (mortality rates range from one in 16 000 to one in 35 000).⁵ The trial is underpowered to quantify the risk of these complications accurately, and although only minor bleeding was seen after tonsillectomy, more severe but rarer complications are probably of greater concern to patients.

What is the take home message for clinicians? Until the longer term outcomes in people who do not have surgery are available, and we have more precise estimates of the benefit in terms of the severity of the episodes prevented by surgery, it is difficult to provide firm advice to patients. Until such evidence is available, I would advise patients who have had four episodes of sore throat in one year or three in six months that they are likely to have on average two and a half days of sore throat in the next six months if they decide not to have the operation; if they decide to have the operation they are likely to have about 13 days of severe pain immediately after surgery, and then on average half a day of sore throat in the next six months. I would also make them aware that they might have minor postoperative complications and very rarely life threatening complications.

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Paul Little professor of primary care research
University of Southampton,
Aldermoor Health Centre,
Southampton SO16 5ST
psl3@soton.ac.uk

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Telephone interventions for disease management in heart failure

Such support for patients at home cuts admissions to hospital for heart failure



EUGENE DELUCIE/ALAMY

RESEARCH, p 942

Hugo O Grancelli director of cardiology department
Departamento de Cardiología,
Instituto FLENI, Montañeses 2325
(1428) Buenos Aires, Argentina
hgrancelli@fleni.org.ar

Daniel C Ferrante research projects coordinator
Fundación GESICA, Av Rivadavia
2358 PB 4 (1034), Buenos Aires

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Several randomised trials have established that disease management programmes offering, for example, home visits, heart failure clinics, and telephone interventions result in better adherence to treatment and reduced admissions to hospital for heart failure than standard care for people with heart failure.¹⁻⁴ Current evidence is unclear, however, on the impact of such programmes on mortality, all cause admissions, quality of life, and cost reduction. The most effective components of the interventions and the benefits to different subgroups are also unknown. Moreover, such evidence comes from small trials with short follow-up, performed at single centres, that applied complex strategies to selected high risk populations. These characteristics might affect both the internal and external validity of the trials' findings. In this week's *BMJ*, Clark and colleagues present a meta-analysis that includes 14 trials of telephone interventions in heart failure; it shows an overall 21% reduction in admissions for heart failure (but not in total admissions) and a 20% reduction in total mortality.⁵ The authors also report a benefit of these interventions on quality of life and cost reduction. The two types of intervention—structured telephone support and telemonitoring—were similarly effective.

In this new systematic review by Clark and colleagues only one trial included more than 1000 patients and only two trials had more than 12 months' follow-up.⁶⁻⁷ But previous meta-analyses of heart failure programmes included fewer, smaller trials and did not show a beneficial effect of telephone interventions.⁸⁻⁹

Clark and colleagues reported a reduction in mortality, but this effect was seen in only one structured telephone study (TEN-HMS).⁷ Conversely, in the largest trial done so far, the DIAL trial, in which we were both investigators, mortality was not reduced, although admissions for heart failure were significantly reduced (relative risk reduction 29%, $P=0.005$).⁶ The DIAL trial randomised ambulatory stable patients with previously optimised drug treatment (95% used angiotensin converting enzyme inhibitors or angiotensin receptor blockers and 70% used β blockers) to education and monitoring by nurses by telephone, and all patients were followed up by cardiologists. The reduced mortality seen in the TEN-HMS trial might have been explained by a more effective intervention or by a higher effect because it included sicker patients.

Evaluations of complex interventions with multiple and simultaneous strategies should aim to answer questions about how the interventions work and which of their components are essential. Available evidence suggests that disease management interventions in

heart failure should incorporate education on self care and adherence to diet and medicines; monitoring and surveillance to detect early signs of decompensation; people trained in heart failure to provide the interventions; and facilitated access to specialised care for any clinical deterioration.

The impact of these interventions might be attributed at least in part to the ability to detect early signs of pulmonary and systemic congestion and to allow early consultation with medical specialists before severe decompensation occurs. Other mechanisms might include the effect of education and behavioural advice, as we found in the DIAL trial—patients with improved knowledge of medical treatment and early compliance with diet, daily weighing, and drug treatment (from baseline to the first 45 days) benefited most from the intervention.⁹

Telephone interventions usually need fewer resources than more complex interventions and transcend geographical and transport barriers, allowing wide scale implementation in clinical practice. More complex interventions might be needed in certain situations, such as advanced heart failure or in frail elderly patients. These might still be provided by telephone—for example, through transfer of patient data and other technologies—but such systems are more resource intensive and perhaps less feasible.

Overall, the evidence supports telephone interventions in the management of heart failure. But, as there have been no head to head comparisons of different disease management strategies, any intervention that includes education, monitoring, facilitated access, and trained personnel may be effective, no matter how it is delivered. And, despite these promising data about telephone based programmes in heart failure, we must bear in mind that these interventions cannot substitute for medical assistance for these patients; they simply provide support to the clinician-patient relationship and offer a better way to provide medical care in heart failure.

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Onset of action of antidepressants

Most benefit is evident in the first two weeks, not six, as conventional wisdom says



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Recent guidance from the National Institute for Health and Clinical Excellence (NICE) says that antidepressant drugs should be offered routinely to all patients with depression of at least moderate severity and recommends a selective serotonin reuptake inhibitor as first line treatment.¹ The NICE guidance goes on to state that “Patients started on antidepressants should be informed about the delay in onset of effect.” This reflects conventional wisdom, but is it time to revisit this idea?

Speed of onset of the actions of antidepressants is clinically important for several reasons. Delayed onset means that depression, its associated disability, and for some patients the potential risk of suicide continue. Early onset of effects may improve future compliance and thus outcomes.

When tricyclic antidepressants were first introduced in the 1950s delays in antidepressant effects were not reported. Indeed, researchers on early tricyclic antidepressants asserted that they usually started to work within the first few days of treatment.²⁻³ Later clinical experience suggested, however, that the drugs did not act immediately. The ensuing debate continued into the 1970s. By the mid-1970s, animal models suggested that the dissociation of acute biochemical changes induced by antidepressant treatment and the therapeutic action were due to the development of subsensitivity in the postsynaptic monoamine receptor.⁴⁻⁵ In animal models, these changes became apparent only after dosing with antidepressants over a similar period to that taken for clinical efficacy to develop. In the 1980s, a series of pooled clinical studies seemed to confirm this delayed onset of action.⁶ Since then, increasingly refined neurobiological theories of the action of antidepressants have incorporated this delay.⁷

This message is largely unchanged, despite the development of newer antidepressants, such as the selective serotonin reuptake inhibitors, and even though newer antidepressants can often be started at a therapeutic dose, rather than titrated upwards over two to three weeks, as is necessary with the older tricyclic antidepressants to minimise adverse effects.

Research on this question is hampered by lack of an agreed definition of onset of action.⁸ This is par-

ticularly true in clinical practice, where it may be difficult to distinguish between signs of response and side effects. For example, sedation may relieve symptoms but it is not directly related to the medicine's antidepressant properties. Recently, however, several studies have challenged the assumption of a delay in the onset of antidepressant action.¹⁰⁻¹¹

A meta-analysis of 76 double blind placebo controlled trials of antidepressant treatment for depression in 2005 found that 60% of overall improvement occurred during the first two weeks and that half of all patients who respond to a six week trial respond in the same period.⁹ More recently, a meta-analysis of placebo controlled trials of selective serotonin reuptake inhibitors suggested that therapeutic response is greatest in the first week, with a gradual decline in the size of benefit over successive weeks of treatment.¹¹ One third of the total effect seen at six weeks was apparent in the first week.¹¹ As the studies were placebo controlled trials, this improvement was unlikely to be a placebo effect.

These recent findings raise further questions. Is speed of therapeutic benefit with antidepressants a class effect, and do differences occur within classes? Do some symptoms respond quicker than others? Does early response predict future response and, if so, should we routinely review response earlier and change treatment if no response occurs in the first week or two? Does this phenomenon apply only to a subset of the population and is it genetically determined? Should we be encouraging patients to anticipate early relief from symptoms and, if so, is there a risk of disappointment if benefit is delayed?

Until studies are specifically designed to measure the onset of action of antidepressants, results from meta-analyses of studies not designed for this purpose should be treated with caution. We suggest that future studies should look for subsets of symptoms that may be ameliorated earlier than others and seek to discover how this is mediated. In the meantime, if these findings are correct it is good news for many patients with depression treated with antidepressants. But these results are unlikely to alter clinical practice until these additional questions are answered.

Andre Tylee professor of primary care mental health
NIHR Biomedical Research Centre,
Institute of Psychiatry, King's
College, London SE5 8AF
a.tylee@iop.kcl.ac.uk

Paul Walters Medical Research
Council fellow

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Euthanasia in neonates

Should it be available?



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Euthanasia for newborn babies with lethal and disabling conditions is illegal worldwide. However, in reality its acceptance and practice vary between different countries.¹ In the Netherlands, about 200 000 live births occur annually; of these, 10-20 babies—mostly with severe congenital malformations—are thought to be actively killed, yet between 1997 and 2004 only 22 such deaths were reported to the authorities.²

To regulate neonatal euthanasia, clinicians in the Netherlands have argued that all cases should be reported. In collaboration with lawyers, they have developed and subsequently published guidance,³ which defines criteria that must be fulfilled before euthanasia can be considered and which would subsequently be examined by the statutory legal authorities (see box). Doctors who follow this guidance are not guaranteed freedom from prosecution, but to date no paediatrician in the Netherlands has been prosecuted.

In 2006 it was reported in the national press in the United Kingdom that, in response to a consultation undertaken by the Nuffield Council on Bioethics on the ethics of prolonging life in fetuses and the newborn, the Royal College of Obstetricians and Gynaecologists (RCOG) had proposed considering “active euthanasia” in UK practice. Recurrent themes run through any debate about neonatal euthanasia. One is the tension seemingly felt by some clinicians as a result of the fact that in UK law the fetus becomes a legal entity only at the moment of birth. Because of

this, the RCOG can recommend that late termination of pregnancy for fetal anomaly should be preceded by fetocide, but any clinician who injected a similar severely malformed newborn baby with potassium chloride moments after birth would be guilty of murder. Another theme is the fine line between the practices of withholding life support, actively withdrawing life support, and intervening to deliberately kill the baby. The first two options, when undertaken because of apparent unbearable suffering or because treatment is futile, are seen as acceptable practice and are widespread; the last option is active euthanasia and anyone undertaking such an act should expect to be prosecuted.

The only babies for whom active euthanasia might be considered are those destined to survive and able to support their own ventilation, but who will have a very poor quality of life with no prospect of improvement. This group includes children with malformations such as some severe forms of spina bifida and a smaller group of ex-preterm babies, whose extensive disabilities become apparent only after recovery from early respiratory problems. Extrapolation of the experience in the Netherlands indicates that there would be around 50 such cases each year in the UK.

The report of the Nuffield Council of Bioethics on “Critical care decisions in fetal and neonatal medicine,”⁴ published after widespread consultation in November 2006, “unreservedly” rejected the possibility of neonatal euthanasia in the context of UK practice even when life is intolerable. Why was this, and why was it apparently received with relief by most paediatricians in the UK?

Parents entrust their newborn babies to intensive care services, often for many weeks—the length of stay is typically much longer than that for adult or paediatric intensive care. They do this because they are confident that clinical decisions, often made in response to unpredictable life threatening emergencies, will be made in the child’s best interest and based

Kate Costeloe professor of paediatrics Barts and the London, Queen Mary’s School of Medicine and Dentistry, University of London, London E1 2AD
k.l.costeloe@qmul.ac.uk

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Box 1 | Essential criteria to be considered in neonatal euthanasia³

The diagnosis must be accurate and the prognosis hopeless

The baby’s quality of life must be poor and he or she must be experiencing unbearable suffering despite optimal treatment

Both parents must give informed consent

An independent doctor must agree with the decision

Euthanasia must be carried out to an accepted medical standard

on the principle that, within reason, the main objective of care is to preserve life.

One of the reasons the UK is resistant to adopting the Dutch recommendations is that active killing as a therapeutic option is seen as a “slippery slope” towards its wider use, although some reject this argument.² Another reason is the fear that active killing may have a negative impact on the psychology of professional staff, and that parents may feel pressured to accept the option of euthanasia so that they do not become a burden on medical and social services.

Euthanasia can only be an option if the futility of continued treatment is certain. While this may be clear for some congenital malformations and genetic conditions it is often unclear for preterm infants. Older patients may decide themselves that their life is intolerable and request euthanasia or assisted suicide, whereas carers and family must judge the quality of life of a baby. This decision is extremely difficult because indicators that a very preterm baby is likely to be severely disabled are not foolproof. Clinicians who have led discussions that have resulted in active withdrawal of care have to live with the probability that they have occasionally allowed a baby to die who would have thrived.

Health professionals are frequently challenged by the press with deluding themselves by drawing a distinction between the withdrawal of active life support (euthanasia by omission) and active killing of a baby. In practice, experienced neonatologists and neonatal nurses feel comfortable with this distinction; they can discuss it openly with families and help them to understand, for example, the acceptability of infusing

opiates at a dose that controls pain and distress but the impossibility of increasing the dose further with the primary intention of hastening death. Neonatal nurses have great expertise in assessing suffering in tiny babies and in providing palliative care.

Acts by neonatologists in the UK undertaken with the purpose of ending life seem to be rare.¹ Guidance provided by the Royal College of Paediatrics and Child Health⁵ around end of life decisions has provided a framework within which UK neonatologists feel comfortable. We have a service that has become progressively more transparent, with parents increasingly involved in making clinical decisions.

The availability of active euthanasia as a therapeutic option would undermine this progress and be a step backwards. However, we must look at how to provide for babies who might be candidates for euthanasia elsewhere in the world—to control their pain and to support their families. Sadly, too often, parents have to battle for essential services that ensure the best outcome for their disabled child, and that also make their own lives more tolerable.

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Health and welfare of older people in care homes

Improvements will depend more on reform of the whole system rather than on commissioners and champions

Marion E T McMurdo professor
Ageing and Health Division of
Medicine and Therapeutics,
Ninewells Hospital and Medical
School, University of Dundee,
Dundee DD1 9SY

Miles D Witham clinical lecturer
m.e.t.mcmurdo@dundee.ac.uk

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The welfare of older people who live in care homes has raised concern for decades in many countries.¹ Scandals surface on a depressingly regular basis, and although these enter the public consciousness, none provokes the outcry caused by reports of abuse of vulnerable people at the opposite end of the age range—children.

Two recent campaigns by the charity Age Concern England and partners focused on lack of respect for the dignity of older people. “Hungry to be heard” examined the problem of malnutrition in older people in hospital,² and it called for more help for those needing assistance with eating and drinking. But protecting patients’ meal times from interruption will prove a difficult goal for frazzled staff in many acute hospital units. “Behind closed doors” campaigned for people to be able to use the toilet in private in all care settings and argued that this was a general

marker of whether human rights and dignity were being respected.³

Both reports bring fresh impetus to important topics but deal with issues that have been around for a discouragingly long time. The landmark study on malnutrition in hospital was published in the *BMJ* as long ago as 1994, yet problems persist and solutions remain elusive.⁴ Of course, both illness and dependency pose threats to dignity, but people of all ages have a fundamental right to be respected. So why is dignified respectful care for older people still lacking, and what might restore it?⁵

Legislation, regulation, and standard setting are widespread in the health and care home sectors, and more of the same seems unlikely to alter attitudes and prejudices. There is a current vogue to appoint champions and commissioners for older people. Such appointments may allow a degree of self congratulation



that something is being done for older people, but risk simply being a way of avoiding the difficult business of system change. Older people are the core business of the care sector; thus, what is needed is not just individual advocates but rather a long overdue and major change in culture and practice to reflect the central position of older people in systems of care.

How might this be achieved in care homes? Firstly, we need to stop blaming individual practitioners and care homes. Good people working in poor environments with poor systems of care will inevitably produce poor quality care, as has been shown in health care.⁶ A whole systems approach is much more likely to succeed; for example, changing infrastructure, procedures, management techniques, and staff training.⁷ Such an approach is beginning to reap dividends in terms of patient safety in health care.⁸ Frontline care staff should not be made scapegoats; instead, their dignity should also be assured.⁹ Being valued (in financial and non-financial terms) and able to work in a system, atmosphere, and culture that recognises and rewards good quality, informed, thoughtful care is much more likely to be effective than merely providing more training.⁹

Secondly, access to good quality medical care should be readily available. Older people in care often have complex medical problems, yet their care is mostly provided by general practitioners, rather than specialists in the medicine of old age.¹¹ Most older people in care are unable to initiate a referral for a medical review. They depend utterly on care staff to recognise that any abrupt change in their condition—for example, a sudden loss of mobility—is likely to be a marker of underlying illness, which should be assessed, diagnosed, and managed. While some general practitioners relish the challenges of their role in care homes, others lack the skills, support, or inclination to fulfil this unsought but demanding role. Primary care teams need to be supported by secondary care specialists and should be given time, money, incentives, and training in comprehensive geriatric assessment. Such an approach would improve the quality of care for people in institutional

care. It would also enable more elderly people to live successfully in the community without the need for institutional care.¹²

Older people have an important part to play too. The political impact of older people as a lobbying force is weak in many, but not all, countries. When older people become politically organised they are a large and formidable force that has real power to campaign for change, as has been shown by the American Association of Retired Persons. Older people need to demand that carers are paid a decent wage and are well trained, that managers are responsive to their needs, that buildings are fit for purpose, and that vulnerable older people are not denied the expert health care that they are entitled to. All of this costs money, and those of us in affluent countries need to pay more to ensure that care for older people is of a standard that we ourselves would be happy to receive.

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