What do we think?
What do we know?
What can we prove?

Bandolier 32
Evidence-based health care
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READING IN BED

One of the joys of writing Bandolier is the impossibility of knowing just what it is that will stimulate our readers. We look for evidence by talking to GPs, purchasers, managers and nurses. Even so, we were surprised at just how many of you enjoyed the small item on reading in bed in Bandolier 31. Many of you wrote with your suggestions and solutions. Some were very funny, and had the Bandolier office laughing out loud, like a good Bryson book. All the letters can be found in the electronic correspondence pages on:
http://wwwjr2.ox.ac.uk/Bandolier/letters/readinbed/all.html

It was a close run thing to judge any one to be better than others. The winner, Dr Welton of Lancashire, gets his prize of a copy of Bandolier - the first 20 issues for a letter with a witty sting in the tail.

Dr Welton’s letter

I read with interest (not in bed) your paragraph under the heading of ‘Reading in bed’, in which you ask for the best suggestions. I am afraid that I fail to see your problem. You suggest that there are problems with reading glasses and that there may be a market for lorgnettes, either with right- or left-armed versions. You idly contemplate the use of swivelling book-rests attached to various places around the bedroom. Next you will be talking of “Head up Displays” on the ceiling, autocues (as used by those nice young men and women on the television) or teletext pages for the bedroom TV set. Really, all this is pure irrelevance. I can hardly understand how it arose.

Put quite simply Jeeves reads the Bandolier to me until I am enveloped in the arms of Morpheus.

R L Welton
Wesham, Lancashire

As the months go by Bandolier worries about the quality of what it reviews for you. Some of our emerging guidelines are on page 3. Bandolier’s interaction with you is important. Many of the topics we cover are prompted by suggestions and questions, but not all can easily be answered (see Dr Down’s letter on page 7). You also entertain us (see reading in bed opposite). Please keep the suggestions coming.

ELECTRON WHIZZ

Bandolier was first published as an Internet version in July 1995. The Internet version has all the 32 Bandolier issues already published in full text, an Internet correspondence section, several other Bandolier publications, and a list of Bandolier’s favourite Internet sites. Also to be found there is a list of all the systematic reviews published with pain as an outcome (just under 200 of them), and information on various international collaborative pain initiatives.

Bandolier had only a vague idea how much the pages were being used. This week our excellent server host, Tim Shaw of the University of Oxford Clinical School Information Management Services Unit, gave us the number of hits for 1996. We were astonished by the growth (up six-fold since January) and the volume of hits (nearly 7,000 a week in August). It must be due to our subtle product placement.

![Total hits on Bandolier pages](image)

There are some sobering lessons here. The first is that in July Bandolier was accessed more by whizzing electrons than through hard copy (our print run is about 21,000 a month). The other is that electronic Bandolier deserves more thought. While fighting to keep the printed version of Bandolier to eight readable pages, we recognise that there is also demand for more information than this. Is it time for a CD-ROM version of Bandolier?
SHOULDERS TO THE WHEEL

Maastricht rules again

Those prolific Dutch systematic reviewers have been at it again. This time they have turned their attention to steroid injections for shoulder disorders [1].

Shoulder problems in primary care

They say that 10% of people have one or more episodes of shoulder pain and/or stiffness during their life, and that 5% of all primary care consultations are about shoulder problems. Of new consultations, they estimate that 23% resolve within a month, 51% within 6 months and 59% within a year.

The figures for usage of injections to treat these shoulder problems seem very high. ‘Twelve per cent of all patient-physician contacts for shoulder disorders involve local steroid injections’ and ‘In the Netherlands, injection therapy is given in 20% of all episodes of shoulder disorders’. Bandolier has a sneaky suspicion that these high proportions reflect payment for item of service.

The way in which steroids work to mend the joint has never been clear to Bandolier. The biology is a bit akin to the label on a can of WD-40 - stops squeaks, drives out moisture, cleans and protects, loosens rusted parts and frees sticky mechanisms. Steroid injections can, however, cause problems, such as the direct hazards of injection, bleed or infection, and effects of the steroid, dermal atrophy and long-term deleterious effects on the joint and surrounding structures. These problems have led to recommendations that steroids should not be injected more than once every six weeks, and not more than three times a year. We should therefore have clear evidence of efficacy if we are going to do these injections.

22 studies

The reviewers found 22 studies which met their inclusion criteria. They put these studies through their tough quality scoring system, and no study scored more than 60 out of the maximum of 100, with only three scoring more than 50. This is a clear signal that definitive conclusions are unlikely to be possible from the available studies.

The second complexity is that the studies looked at many different treatments, not just at injections. Only three studies compared steroid injection with saline injection, and five compared steroid injection with injection of local anaesthetic. The studies also used different outcome measures.

Results

Not surprisingly then the reviewers decided that discretion was the better part of valour, and did not pool the data from the studies. They did not mince their words in their conclusions - ‘the evidence in favour of the efficacy of steroid injections for shoulder disorders is scarce... The few studies that appear to be credible do not provide conclusive evidence about which patients at what time in the course of shoulder disorders benefit most from steroid injections.’

Onward, ever onward

As ever brave on your behalf Bandolier did probe the results a little further. Taking the crude criterion of success at four weeks or later after injection, the NNT for such success with steroid injection compared with saline injection (three studies) was 17, with a confidence limit which includes no benefit to any patient. For steroid plus local anaesthetic injection versus local anaesthetic alone (five studies), the NNT for success at four weeks or later was 33, again with a confidence limit which includes no benefit to any patient. On this basis one patient in 17 would achieve ‘success’ with a steroid injection compared with an injection of saline, and one patient in 33 would achieve ‘success’ with a steroid plus local anaesthetic injection compared with an injection of local anaesthetic alone.

Where does this leave us?

Our Dutch colleagues’ conclusions seem fair. Those (and there is one on the Bandolier team), who might be pejoratively described as hawks because of their needle-waving tendencies, have a problem. The evidence that steroid injections for shoulder problems are worthwhile is less than compelling. The onus is on those who wish to continue to offer steroid injections to the shoulder to produce convincing evidence - a starting point would be to use a study design which scored closer to the maximum on the Dutch scale.

Chasing the evidence for our favourite interventions does sometimes result in a negative like this. The reaction to the review can become a hostile reaction to the reviewers - ‘Very threatening’ - ‘if they go on like this I’ll be out of a job’. Surely the professional agenda should be to provide a package of care which includes interventions which do more good than harm. Don’t blame the messenger.

A last chastening point is that the fact that 40% of the patients still had their shoulder problem after a year means that a considerable proportion of these (common) shoulder problems are not self-limited. We need good control of these symptoms if we (or time) cannot cure them.

Reference:


NITROGLYCERIN PATCHES FOR SHOULDER PAIN

Continuing the shoulder pain theme, Bandolier came across an interesting RCT from a group in Santander [1](though see the one-report reflex in Bandolier 27). They assembled some biologically plausible evidence for nitroglycerin being effective in inflammation and vasodilation though a nitric
oxide mechanism. They claim to have shown that nitroglycerin patches (NTG) were effective in thrombophlebitis syndrome.

**Study**

Patients had shoulder pain of less than 7 days duration, with tenderness in the supraspinatus region and limited motion on movement. Randomisation was between a 5 mg NTG transdermal patch and an identical placebo applied in the most painful area. A new patch was applied for each of three days.

**Outcomes**

At the start, and after 24 and 48 hours, pain intensity was measured on a 10-point scale, together with the duration of pain in the previous 24 hours and restriction of joint movement.

**Results**

By 48 hours there were significant (and large) improvements in pain, its duration, and improvement in shoulder movement.

At 48 hours, pain intensity was 2 or less (out of 10) in 9/10 patients given NTG compared with 0/10 given placebo. There was no reduction in pain intensity in placebo patients. The NNT for pain intensity of 2 or less for NTG compared with placebo was 1.1 (0.9 - 1.4).

At 48 hours, duration of pain was 1 hour or less per day in 9/10 patients given NTG compared with 0/10 given placebo. In placebo patients the duration of pain was between 1 and 12 hours. The NNT for pain duration of 1 hour or less per day for NTG compared with placebo was 1.1 (0.9 - 1.4).

At 48 hours, joint motion was unrestricted in 8/10 patients given NTG compared with 0/10 given placebo. In placebo patients joint motion was restricted by 25%-50%. The NNT for unrestricted joint motion for NTG compared with placebo was 1.3 (1.0 - 1.8).

**Comment (credibility strain)**

These results look great, don’t they. Yes, it was a randomised trial, with double blinding. But it was only 10 patients per group, and the random play of chance may be bigger than we think with these small numbers. Statistical significance does not transfer directly into clinical practice.

Given that there is a sort of Bayesian drift here, with some biological foundation and clinically plausible results, what is needed is a larger, pragmatic trial in primary care.

Reference:

The season of mists and mellow fruitfulness is upon us, bringing with it the runny nose, sneezes and other symptoms of the common cold. *Bandolier* has its own remedy (trade secret), so was impressed to see two large randomised controlled trials of things that, while they do not promise an end to suffering from the common cold, show that good research is going on to help with the paracetamol, hot lemon, whisky and bed.

Reading the papers was enlightening. According to references in them, the average US adult has two to four colds a year, while children have an average of six to eight a year. The mean duration is seven days (but with a standard deviation of 6 days, so that some can last three weeks).

**Nasal spray for runny noses**

One study examined intranasal ipratropium bromide (84μg / nostril, up to four times a day) versus placebo vehicle or no treatment in 411 patients (137 per group) with common cold for no more than 36 hours [1]. Patients had to have moderately severe rhinorrhea, defined by visual analogue scale and by collection of at least 1.5 g of nasal discharge over a one hour baseline period. Randomisation and its concealment well done, and the assessments were double blind except for the no-treatment group.

**Outcomes - silver sleeves**

Outcomes were collection of nasal discharge for up to six hours on days 1 and 2, visual analogue scales, and categorical assessments on days 1 and 2, with a global assessment on day 5.

**Results**

Because common colds are self-limited, amounts of nasal discharge collected and self-reporting of symptoms improved on days 1 and 2 in all groups. The improvements were greatest in patients treated with ipratropium and least in the no-treatment controls. Patients given the control vehicle (mostly saline) had intermediate improvements.

NNTs could be derived from patient scores on days 1 and 2, and globally on day 5. How good ipratropium bromide looked depended on whether the comparison was with the vehicle control or no treatment. Best estimates were against no treatment, suggesting that intranasal saline itself was having an effect. The best interpretation was from the global (5 day) comparison with no treatment, which produced an NNT of 1.6 (1.4 - 1.9).

Adverse effects were also noted, among them blood-tinged mucus, nasal dryness and headache producing significantly increased incidences. Nose bleed was a rare problem.

**Zinc lozenges to cure the cold**

There are several biologically plausible reasons why zinc may help in ameliorating symptoms of the common cold. One is that zinc apparently combines with the negatively charged carboxyl termini of the rhinovirus coat to prevent it entering cells. This stops the virus reproducing further.

This second paper [2] was a delight to read for several reasons. Firstly the authors state up front that they determined that a 50% reduction in the duration of symptoms was what they considered a significant clinical effect. What follows can be judged by that. More interesting was that they encouraged recruitment by entering patients who completed the study into a raffle for one of two prizes: dinner for two or a trip for two to the Bahamas! Even better was to see the restaurant in Cleveland acknowledged at the end of the paper.

It was a randomised study of 100 patients given identical lozenges which contained 13.3 mg zinc (as the gluconate trihydrate). Patients with cold symptoms (a median of eight out of ten symptoms) for 24 hours or less were given a pack of lozenges and told to suck one every two hours while awake.

**Effectiveness and adverse effects of intranasal ipratropium in common colds**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>NNT against vehicle</th>
<th>NNT against no treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient assessment of effectiveness on day 1 (better or much better)</td>
<td>7.1 (4.3 - 22)</td>
<td>3.3 (2.5 - 5.0)</td>
</tr>
<tr>
<td>Patient assessment of effectiveness on day 2 (better or much better)</td>
<td>7.1 (4.0 - 34)</td>
<td>5.6 (3.5 - 15)</td>
</tr>
<tr>
<td>Patient global assessment of effectiveness on day 5 (better or much better)</td>
<td>6.3 (3.8 - 17)</td>
<td>1.6 (1.4 - 1.9)</td>
</tr>
<tr>
<td>Blood-tinged mucus</td>
<td>7.7 (5 - 16)</td>
<td>6.7 (5 - 13)</td>
</tr>
<tr>
<td>Nasal dryness</td>
<td>12 (7 - 56)</td>
<td>8.3 (6 - 16)</td>
</tr>
<tr>
<td>Headache</td>
<td>14 (8 - 46)</td>
<td>13 (8 - 32)</td>
</tr>
</tbody>
</table>
Effects of zinc lozenges on resolution of common cold symptoms

<table>
<thead>
<tr>
<th>Day of treatment</th>
<th>Cold completely resolved with zinc lozenge</th>
<th>Cold completely resolved with placebo lozenge</th>
<th>NNT (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>16/50</td>
<td>7/50</td>
<td>5.6 (2.9 - 53)</td>
</tr>
<tr>
<td>6</td>
<td>34/50</td>
<td>19/50</td>
<td>3.3 (2.1 - 8.8)</td>
</tr>
<tr>
<td>9</td>
<td>47/50</td>
<td>30/50</td>
<td>2.9 (2.0 - 5.3)</td>
</tr>
<tr>
<td>12</td>
<td>49/50</td>
<td>35/50</td>
<td>3.6 (2.4 - 6.8)</td>
</tr>
<tr>
<td>15</td>
<td>50/50</td>
<td>41/50</td>
<td>5.6 (3.5 - 14)</td>
</tr>
</tbody>
</table>

**Outcomes**

Symptoms were scored daily by using diaries. The main outcome was complete resolution of the cold symptoms.

**Results**

The median time to resolution of all symptoms was 4.4 days for the zinc treated group, compared with 7.6 days for those treated with placebo. The NNTs for complete resolution with zinc compared with placebo at various times is shown in the table. Between days 6 and 12, the NNT was about 3, meaning that for every three patients treated with zinc lozenges, one had cold symptoms resolved who would not have had they been given placebo.

There were some adverse effects. Patients given the zinc lozenges reported bad taste and nausea more frequently.

**Comment**

The common cold has no definite or simple cure, and over-the-counter medicines will be the first line treatment for almost all sufferers. Both these trials were pharmaceutical company sponsored, at least in part. Knowing that nasal sprays will benefit some patients with excessively running noses may help in some cases. Zinc gluconate is not in the British Pharmacopoeia, so far as Bandolier can ascertain at the time of going to press, though it may be a health shop product.

Zinc gluconate would appear to be a useful addition to the bathroom cabinet, but can anyone tell us where to get it? Alternatively where can we enrol in a study which at least gives us a chance for a trip to the Bahamas?

**References**


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**The GPs guide to home birth**

Many GPs are fearful of any involvement or even discussion of home birth, despite the Changing Childbirth [1] philosophy of choice. Yet continuity and control for women is increasingly becoming part of mainstream practice.

A recent statistical review found “There is no evidence to support the claim that the safest policy is for all women to give birth within hospital” ... and “For some women it is possible but not proven that the iatrogenic risks associated with institutional delivery may be greater than any benefit conferred” [2].

**The numbers**

Home births accounted for only 1.8% of all deliveries in 1994. The perinatal mortality rate for all these home births in 7.8 per 1000 live births; that for hospital is 8.9 per 1000 live births [3]. A survey to determine the intended place of delivery at the onset of labour of all births occurring at home in 1979 found that, of these births, only two thirds had been booked for delivery at home. The perinatal mortality rate for planned home deliveries was 4.1 per thousand births while for births at home which were planned to occur in consultant units was significantly higher at 67.5 per thousand births [4].

But it is difficult to compare - directly the perinatal mortality rates for home and hospital as more complex deliveries occur in hospital. A feasibility study into conducting a randomised controlled trial on hospital versus home births showed that only 2% of women were considered suitable by the obstetricians and would consent to randomisation [5]. So it is unlikely to be much clearer in the future.

**Perceived risks**

Although we have seen that home birth does not appear to be high risk in terms of perinatal mortality for women with normal pregnancies, there is evidence that women who request home birth are indifferent to any increased risk compared with those who do not seek it [6]. The GP should present the information regarding local options for place of birth to the woman in a clear, understandable and balanced manner. In order to fully inform the pregnant woman, the GP must be fully informed. Also, it is important that the women un-
stand just what their GP could do, or could not do at a home birth.

GPs who do not wish to provide care for home births should refer women to a community midwife, supervisor of community midwives at the district maternity unit, or to a GP who provides full maternity services, solely for maternity services. It is important to remember that midwives are professionals and personally accountable for their own actions and decisions. There is no question of vicarious liability for the GP for the actions of any midwife.

If a GP is involved in intra partum care, and an unfortunate event proceeds to litigation, the GP would not be judged by the standards of a consultant obstetrician, but by those of a GP with similar skills and standing (the Bolam Test).

GPs do not have to attend a home birth even when the woman has been accepted by them for full maternity care unless asked to do so by the midwife. However even if a GP has not accepted a woman for maternity services, he or she is obliged to attend an obstetric emergency if requested, even if the woman is no longer on his list, just as he or she would be for any medical emergency.

Where the midwife feels that the GP is supportive, the likelihood of transfer to hospital is reduced [7].

**GP’s role in home births**

What then is the GP’s role in home births? Most GPs already involved in home births feel that their role is primarily to support the woman and the midwife, to spot early deviations from the normal course of labour along with the midwife, and effect early transfer into the obstetric unit.

One of the greatest worries for GPs contemplating home birth is that of the situation where they are faced with a neonate needing resuscitation. The anxiety is fired by the fear of the development of cerebral palsy in the baby, as a result of anoxia. The incidence of cerebral palsy is 0.2% and has not altered in four decades. Swedish evidence indicates that only one baby in 5000 full term normal deliveries needs intubation [9]. “What little evidence exists suggests that less than 2% of cerebral palsy could be attributed to sub optimal care” [10].

Changing childbirth is not about actively promoting one place of delivery above another one, but allowing the woman to make her own choices on balanced information given to her. Home birth should be one of the options presented. For women with uncomplicated pregnancies it is not a high risk option.

Dr Mary Keenan  
GP Advisor
Changing Childbirth Implementation Team

References:
7 Report of the Northern Region Home Birth Survey 1993. Northern & Yorkshire Health Authority

**Rules for bullshit detection**

Manure can vary from a lot of straw with a little ordure, to a lot of ordure with a little straw. Bandolier would like to advocate this evolving checklist for sniffing out the good from the bad when it comes to single trials of effectiveness.

1 Is the trial randomised and double-blind? If not, why am I reading it?
2 How many patients in each treatment group? The smaller the number, the less credible the result.
3 How big is the effect? If there are small differences which are only of statistical significance, forget it.
4 Context. Are the patients in the trial like yours?
5 Is there any pre-existing biology to explain the effect? - the Bayesian drift.
6 Connoisseurs of manure will always avoid post-hoc sub-group analysis.
7 Goal post moving should worry you. Examples are failure of treatment explained by not treating the disease early enough, and if lots of adverse effects are associated with a particular intervention, the protagonists then argue that of course they have now improved their technique.
**SHOPFLOOR EPIDEMIOLOGY**

*Bandolier* gets asked for all sorts of help. Sometimes we can help. Often we can’t. Dr Down from Surrey has a particular problem in his practice, whose population lies in a pocket surrounded by the M25 and A3. Most of the population lives within a couple of miles of these roads. He has seen a rising incidence of respiratory complaints (asthma, otitis media, Eustachian tube dysfunction and allergic rhinitis). With a proposed new service station planned, can anyone help with evidence linking symptoms with roads and service stations?

**Dr Down’s letter**

Dear Dr Moore,

I am writing to ask whether *Bandolier* has access to any data relating to the prevalence of respiratory tract disease in and around motorways and motorway service areas. In particular whether such data analysis exists linking air pollution - especially PM10s to the prevalence of respiratory tract disease. The Department of Transport has I believe admitted that PM10 pollution is an area that needs to be further investigated whilst not yet being able to establish clear links between other indices of air pollution and the prevalence of asthma.

The graph illustrates the monthly consulting frequency of common respiratory tract disease over the last five years. Whilst our practice population has not varied by more than 2%, the monthly consulting incidence for asthma, Eustachian tube dysfunction, serous otitis and allergic rhinitis has more than doubled during that time. (Data is recorded in consultation using Read codes for the presenting complaint. Our practice population is drawn from villages situated to the north and north-east of the M25.)

I would be most interested to hear from you on the matter especially now that a Motorway service area to the south of the practice is the subject of a public enquiry.

Yours sincerely,

Dr N A C Down
Oxshott Medical Practice
Holtwood Rd
Oxshott
Surrey KT22 0QL Fax 01372 842558
GRIT IN THE WORKS

Frogs in a jam-jar

Three BBC programmes have reviewed the impact of the NHS changes of the last decade. They did not emphasise the extent to which these changes are being watched round the world, as other governments look at ways of ‘increasing the efficiency’ of their state-funded health care [1].

A Welsh correspondent of Bandolier described the change in primary care of feeling like being “frogs in a jam-jar”. Add to this the fact that the world is watching ... Bandolier was struck by the way in which the programmes seemed to follow the frog metaphor. Once the decision had been made to make changes, effort swung into the process of managing the change while minimising the fall-out. Not the fact of the change, not the effects on health care delivery, but the political fall-out. The programmes implied that the effects of the changes would not be studied, because it was felt that to set up such studies would be perceived as a sign of weakness.

Among the original rules for hospitals wishing to become Trusts was one that Trust status would only be ‘granted’ if the staff voted in favour. That rule did not last long. Once the changes were in place it was rapidly obvious that Trusts would fall over financially unless the rules were bent. All water under the bridge you say, and quite right. Except that the echoes of our Welsh friend’s feelings of jam-jar impotence ring in our ears.

Growing old

How many of us understand the minutiae of paying for long-term health care? At what point do you ‘leave’ the NHS, where care is free, and enter the territory of the local authority where care is not free? Who makes the decision, and what is the basis of the decision? Bandolier has been struck (Bandolier is struck so often it is tantamount to abuse) by the level of collective ignorance in this important area.

Lest you think it cannot happen to you, Young [2] cites the 1989 OPCS disability survey estimating that 4.3 million people over 60 in Britain are disabled. That is 70% of all disabled people and 46% of all older people. ‘Most (over 90%) older disabled people live in their own homes, and most (over 80%) have only “mild” disability but many have several types of disability’. Perhaps our interest will perk up when we have to pay a 1.5% tax towards our own demise.

We hope that our clouds of ignorance will be dispelled by reviewing Health Authorities’ response to HSG (95) 8, NHS responsibilities for continuing health care.

Reference:

DOWN THE GARDEN PATH

Once upon a time an elderly woman living in the rural wilds of West Oxfordshire received through the post her appointment for a bowel X Ray. With the appointment came the laxative. It was winter and very cold. The only lavatory was beyond the vegetable patch, down the garden path.

The instructions didn’t tell her what would happen when she dutifully took the laxative in the evening, and the fact that she lived through the hypothermia was due entirely to guardian angels.

Bandolier was therefore delighted to read a report of two laxative regimes given before colonoscopy [1]. A questionnaire was given to 165 patients, given either sodium picosulphate or polyethylene glycol. Nine adverse effects were listed on the questionnaire, and patients were asked to score each of them on a scale of 0 to 2 depending on severity. All the patients (mean age 60, range 22-86) replied. Twenty-two patients (13%) had faecal incontinence, and forty-two reported sleep disturbance. Interestingly younger patients complained significantly more often than older patients about taste disturbance, nausea, fullness and cramp.

I can see clearly now ...

The colonoscopist could not see clearly in 5 of the 165 patients, despite the bowel preparation. On a ten point rating scale (0 = least favourably, 10 = most favourably), patients rated sodium picosulphate significantly higher than polyethylene glycol.

The authors conclude that, although two previous publications said that polyethylene glycol gave better results, in their view both preparations were satisfactory for colonoscopy and patients preferred sodium picosulphate.

Reference:

Watchdog