This month Bandolier concentrates on some of the interesting evidence around surgery. Surgery is not an evidence-free zone, and there are many good systematic reviews of randomised trials, and other evidence for surgery and anaesthesia. What we have chosen is a bit eclectic, but it's what's ticked our fancy lately.

There is a randomised trial of different forms of anaesthesia confirming Bandolier's suspicions that it makes not much difference to mortality, and confirming that a systematic review saying that different anaesthetic methods did make a difference was wrong. Policy was changed on the basis of an incorrect systematic review, emphasising that reviews have to get it right. We were also interested in information about our ageing population, and how we need to pull our socks up in making provision for more hip replacements.

As interesting is a study from Glasgow on the reading ability of patients with rheumatoid arthritis. One patient in six would have trouble with patient education material, and 1 in 20 would not be able to read prescription labels. Patients with reading problems required three times as many outpatient appointments for the same clinical result. That was 7,000 extra outpatient visits just for Glasgow's rheumatoid arthritis outpatients.

Studies like that make one think. Helping folk who can't read is good for business, as well as just being a good thing to do.

Electronic updates

The Internet version of Bandolier has added much in the last month. In particular it has a brief review of studies on arthroscopy for osteoarthritic knees, promised in Bandolier 102. It has a completed review of the evidence for the use of Lorenzo's oil for adrenoleukodystrophy adrenomyeloneuropathy. And it begins to pull together evidence on mobile phones, magnetic fields and cancer.

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HIP REPLACEMENT: NEEDS AND RISKS

We're getting older. Not just as individuals, but as a population. And not just in Britain, but across the world. Population pyramids showing the percentage of the population in successive age ranges used to be just that: pyramids that were bigger at the (younger) base and smaller at the (older) summit. That is changing, and in 30-50 years time we will talk of population cylinders. In 2050, about 11% of the population of the UK will be over 80 years old (Figure 1).

If you want to know more about age distributions of populations in the world, there is a great UN website (http://www.un.org/esa/population/unpop.htm). If you want to know how the population of the UK or any other country will change over the next 50 years, there's a terrific US website (http://www.census.gov/ipc/www/idbpyr.html).

Figure 1: UK population 2050, by age

This means that arthritis and the need for joint replacement surgery will increase. Do all those needing joint replacement surgery have the operation? In England, a survey in the 1990s suggested not [1].

Survey

North Yorkshire has about 210,000 persons aged over 55 years. In 1993 about 8% were mailed a questionnaire about activities of daily living, dependency, disability, and existing joint replacement. Also asked were questions about persistent joint problems. Those reporting a problem with hip and difficulty of daily living were sent a second ques-
tionnaire that included an index of severity of osteoarthritis of hip and knee. A score of 14 points out of a possible 24 was equivalent to extremely severe problems. Good responses were achieved for both postal questionnaires, minimizing response bias.

Results

Women and men with existing hip replacements for different age ranges is shown in Figure 2. The overall estimate was 32/1000 people aged 55 and over, but rates were twice as high in women, and with older age.

Rates of those who might benefit from hip replacement are shown in Figure 3. The overall rate was 14/1000 persons aged 55 years and older. Rates for women were higher than for men, and were higher with older age. Currently on a waiting list was 12% (as low as 3% for those over 75 years).

Mortality after hip replacement

People undergoing hip replacement accept that their new hip will probably work very well, but also want to know the downside. Part of that downside, given that many will be older persons, is the risk of dying. A study from the USA [2] suggests that risk to be about 1 in 700.

Study

The Mayo Clinic performed a computer-assisted review of all 31,000 elective operations for hip replacement performed between 1969 and 1997. The records of patients who died were reviewed for relevant clinical information.

Results

Out of 30,714 operations, 90 patients died within 30 days. Four patients died during the operation (0.01%), and 86 during the 30-day follow up. Risk factors for mortality were increased age, being male, and a history of cardiorespiratory disease. Death rates were higher in the 1970s, and fell during the 1980s and 1990s (Figure 4). In the 1990s the mortality rate was 0.15%, about 1 in 700 operations.

Comment

Elective hip replacement is an increasingly safe operation, a tribute to continuous improvement by orthopaedic surgeons, anaesthetists, and the primary care physicians keeping patients fitter for a serious operation. The problem is that we’re probably not doing enough of them. Taking some average figures for the number of people aged 55 years and older in a population of 100,000 in England, the figures from the North Yorkshire survey translate into 379 hip replacements needing to be done (Table 1), of whom only 45 are likely to be on a waiting list.

There could be some quibbles over the accuracy of these figures from the 1990s compared with now, but they are not unrealistic. The average age of the population of the UK will soon reach 40 years for the first time. The demand for joint replacement is going to grow rapidly.

References:
 WHICH ANAESTHETIC TECHNIQUE
- REVISITED

Bandolier 86 was unhappy with a meta-analysis [1] examining the use of neuraxial blockade on mortality after surgery. Although in many respects an excellent review, the conclusion that neuraxial blockade reduced mortality depended on five (out of 141) trials. These trials had death rates of over 10%, had fewer than 100 patients, and had only 6% of the total number of patients.

They were not patients like ours. In the other 131 trials the death rate was about 2% and there was no difference between neuraxial blockade and control. The authors of the review were themselves cautious about the result. A new, large, randomised trial [2] designed specifically to test the hypothesis shows just how sensible they were.

**Trial**

The trial, conducted in Australia, East Asia and the Middle East, randomised highest-risk patients undergoing high-risk major abdominal procedures to intraoperative epidural anaesthesia or general anaesthesia with balanced technique with intraoperative and postoperative opioids. Randomisation was from a central office, but the study was not, nor could be, blind.

The intention was to select a patient population where about half the patients were expected to have a major postoperative complication within 30 days of operation. The outcome was a combined endpoint of death or at least one morbidity endpoint (renal failure, cardiovascular event etc).

**Results**

Over six years, 888 patients were randomised. There were no differences in the proportion of risk factors: 45% had diabetes, 27% myocardial ischaemia, 15% acute myocardial infarction and 12% cardiac failure, as the most common risk factors.

The combined endpoint occurred in 60% of patients. There were no differences between the two procedures for the combined endpoint, death, and all specified endpoints with the exception of the need for prolonged ventilation or reintubation, which occurred less frequently with epidurals. There was only one intraoperative death, and most deaths occurred at least four days after surgery (Figure 1).

**Comment**

This randomised trial confirms the conservative view of the meta-analysis, that anaesthetic technique makes no difference to operative mortality. Another recent large (1,021 patients) randomised trial [3] in a different patient group also found no difference.

The 131 trials in the meta-analysis with death rates of below 10% in controls had 173 deaths with a relative risk of 0.8 (95% 0.6 to 1.1). Adding in the 42 deaths in this study changes the relative risk to 0.9 (0.7 to 1.2). The lesson is that meta-analyses will be wrong if they include trials that are invalid, either because they may be biased, or because their patients are not like ours.

That’s the main reason why meta-analysis and randomised trials sometimes give different results. It’s not that either method is wrong, just that people use them wrongly.

**References:**


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CHRONIC PAIN AFTER SURGERY

Faced with a man with leg amputation and asked what his problem may be, most of us would probably leap to the conclusion that he had phantom limb pain, because that is what we have been conditioned to expect. What is less expected is that chronic pain is a possible, if often overlooked, adverse outcome of surgery. A systematic review [1] has examined the incidence of chronic pain after surgery and suggests that it is very common.

Review

The review searched OVID to January 1999 for articles linking persistent pain to surgery. Authors’ databases and references were also examined. For inclusion articles had to have information about pain 12 weeks or longer after surgery. Generally, studies smaller than 50-100 patients were excluded, apart from amputation studies where studies with 25 patients were accepted.

Results

Chronic pain after surgery was common. Many studies had information to one year or longer, and many compared different surgical approaches, or anaesthesia. The results shown in Figure 1 use data from studies closest to one year after surgery, and combine surgical approaches when reported separately. Where several types of chronic pain were reported (like chest pain, arm pain, or phantom breast for breast surgery), the pain at or close to the site of operation was taken. The figures for breast pain include mastectomy, lumpectomy, breast augmentation and reduction. Phantom limb pain was common, but high rates of chronic pain were reported for all surgery. Even in the lowest incidence, hernia repair, rates varied from 0% to 29%.

Predictive factors included pre-operative pain, repeat surgery, a surgical approach with risk of nerve damage, acute and severe post-operative pain, radiation, chemotherapy and a variety of psychological and depressive symptoms.

Functional impairment

More than 95% of all hernia operations performed in Denmark are reported to the Danish Hernia Database. In a two-month period in 1998 1,652 patients had surgery for inguinal or femoral hernia, and 1,443 questionnaires were mailed one year after surgery. The first questionnaire established the incidence of pain, and the second characterised the pain and its effect on function.

Results

There was an 81% response to the first questionnaire. Twenty-nine percent reported having pain in the area of the hernia within the past month, and 11% reported that the pain impaired work or leisure activities. Only 4.5% (1 in 6) had sought medical advice or received treatment for the pain.

Comment

How much pain there is, and its location and nature, determine how important is chronic pain after surgery. Even the lowest figure of 1 in 20 patients needing treatment or advice for pain one year after surgery has large resource implications. Postoperative breast pain occurred not just after mastectomy, but after lumpectomy, and after breast augmentation and reduction, which are elective procedures.

Two issues emerge. The obvious one is to find out more about what influences the incidence of chronic pain after surgery, and do something about it. The other is to make patients aware that surgery can have longer-term consequences.

References:


Figure 1:

Chronic pain after surgery, at about 1 year
Ruptured Achilles Tendons

There will be about 18 Achilles tendon ruptures for every 100,000 people. There is controversy between conservative treatment involving immobilisation, and surgical repair (which also involves immobilisation). All the textbooks you look at strongly recommend surgery. Is this right, and is it sufficient for creating a guideline or purchasing directive? A new meta-analysis [1] cautiously tells you that it is.

Systematic review

This McMaster review did some heroic searching for randomised trials comparing surgery with conservative treatment for Achilles tendon rupture. It also hand-searched journals, textbooks and abstracts. For inclusion studies had to involve patients with closed spontaneous rupture of the Achilles tendon, report re-rupture as an outcome, and be prospective randomised trials.

In addition textbooks of orthopaedics and narrative reviews were identified to assess whether they recommended (strongly or weakly) surgery or conservative management.

Results

There were six trials with 448 patients. Different surgical techniques with 6-8 weeks of casting were compared with different conservative methods, all involving casting of various sorts for 6-8 weeks. Two trials used alternate assignments as the method of randomisation.

Surgery resulted in a significantly lower rate of re-rupture (3.1%) than did conservative management (13%). It also involved significantly more infection (4.7%) than conservative management (0%; Figure 1). There was no difference between the two techniques for return to normal function (about 70%) or spontaneous complaints (about 20%).

Recommendations about treatment of ruptured Achilles tendons were found in 22 review articles and textbooks. Of these 16 strongly favoured surgery, four were noncommittal, and two strongly favoured conservative therapy.

Comment

The best evidence we have is that for every 100 patients treated with surgery rather than conservative management, 10 fewer will have a re-rupture, but five will have an infected wound. The NNT was about 10 (95% confidence interval about 7 to 20) and the NNH was about 21 (13 to 58). There may be other adverse events of surgery not measured in these trials.

Tendon re-rupture is a serious setback, and antibiotics may cure wound infections. But with increasing rates of antibiotic resistance, wound infection may not be a trivial event. The confidence intervals of the benefit and harm overlap. There is certainly room for argument about which procedure is best.

And two of the six trials with 155 (35%) of the patients used randomisation methods which we know to be associated with some degree of bias. Judgement is more balanced than textbooks and reviews would lead us to believe. Of course, since the first randomised trials were published in 1981 techniques may have improved, and local skills may be different. But clear cut this decision is not, and we learn again that recommendations not based on evidence can lean towards the optimistic.

There is another point to be made. In Bandolier 102, the way in which guidelines still tended to be relatively light on evidence was examined. Most guidelines rely on opinion, and do not quote systematic reviews or randomised trials. If guidelines were written on Achilles tendon treatment to reflect textbooks and narrative reviews, they would over-emphasise surgery compared with conservative management.

The real lesson is to follow the best evidence we have. Good systematic reviews should be the bedrock of guidelines, decisions, and future research.

References:

Figure 1: Re-rupture and infection after Achilles tendon surgery or conservative management
**INTRATHecal BACLOfen for Severe Spasticity**

Health service purchasers are often faced with the problem of making decisions in the absence of evidence on benefit and cost. Evidence is most often lacking in rare but severe conditions, and in early applications of new technology. The example of intrathecal baclofen for severe spasticity [1] shows that even in these difficult circumstances sufficient evidence may be garnered to inform decision-making.

Intrathecal baclofen needs to be used on a continuous basis. This involves not just demonstrating that it is effective in the individual patient, but complex neurosurgery to implant a continuous infusion device delivering baclofen to the head, or cord, or both. The device needs to be refilled several times a year, and the operation re-done every five or six years when batteries need replacing.

**Systematic review**

This set out to gather several different types of information. Information on benefits of continuous intrathecal baclofen was sought through a literature search (to end 1999) using four electronic databases, including the Cochrane Library. Any type of study was eligible, if patients had one of five conditions (cerebral palsy, multiple sclerosis, hypoxic brain injury, traumatic brain injury, or spinal cord injury). Studies had to describe some functional benefit, like bed-bound patients being able to sit in a wheelchair, or improved ability to perform activities of daily living, or reduction in spasm-related pain. In all the included trials patients had to have severe disabling spasticity refractory to oral medicines, and in addition they must have shown a response to a bolus dose of baclofen.

A separate search was for economic analyses or cost studies. Cost information identified from the literature was supplemented by semi-structured interviews with clinicians. Quality of life was estimated from the evidence review, supported by clinical opinion. Three simplified scenarios were used, which concentrated on mobility and pain as the criteria most likely to be affected. The scenarios were:

1. **Bed-bound patients with severe spasm-related pain**
2. **Bed-bound patients not in pain**
3. **Wheelchair users with moderate spasm-related pain.**

**Results**

There were 17 studies published between 1985 and 1997, with information on between 7 and 70 patients. Follow up was between about six months and six years. A summary of the outcomes is in Table 1.

Quality of life improvement estimates were 0.27 for a bed-bound patient not in pain, to 0.5 for a bed-bound patient experiencing severe spasm-related pain. The cost was estimated at about £12,000 for assessment, test dose and implantation procedure, with follow up costs of up to £1,200 a year for refills. Over five years, the total discounted cost was £15,400. The cost per quality adjusted life year ranged from £6,900 to £12,790 for the three scenarios (Table 2).

**Table 2: Cost/QALY estimates**

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Cost/QALY (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bed-bound patients experiencing severe spasm-related pain</td>
<td>6,900</td>
</tr>
<tr>
<td>Bed-bound patients not in pain</td>
<td>12,790</td>
</tr>
<tr>
<td>Wheelchair users with moderate spasm-related pain</td>
<td>8,030</td>
</tr>
</tbody>
</table>

**Comment**

The authors are justifiably cautious, but their conclusion was that intrathecal baclofen produces functional benefits and is likely to be an appropriate use of resources in carefully selected patients. They specified that patients had to have severe disabling spasticity refractory to oral medicines, and have shown a response to a bolus dose of baclofen. Methods employed included systematic searches for evidence of effectiveness and cost, backed up with sound clinical opinion, and restricted to a particular scenario. The process results in a reasonable quantification of cost/benefit, which we can compare with other things we purchase.

The benefits and costs are still estimates, though. They can be modified as more evidence emerges on benefit, on cost, or, crucially, on the quality of life improvements obtained.

**References:**


**Table 1: Outcomes after intrathecal baclofen for severe spasticity**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number benefiting/total with complaint</th>
<th>Percent benefiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved ease of nursing care</td>
<td>83/90</td>
<td>92</td>
</tr>
<tr>
<td>Bedridden patients able to sit in a wheelchair</td>
<td>50/76</td>
<td>66</td>
</tr>
<tr>
<td>Reduction in spasm-related pain</td>
<td>55/62</td>
<td>89</td>
</tr>
<tr>
<td>Improved ability to perform ADL</td>
<td>45/62</td>
<td>73</td>
</tr>
<tr>
<td>Ambulatory patients improving ability to walk</td>
<td>18/45</td>
<td>40</td>
</tr>
<tr>
<td>Improved ability to sit comfortably in a wheelchair</td>
<td>31/36</td>
<td>86</td>
</tr>
<tr>
<td>Wheelchair bound becoming ambulatory (assisted)</td>
<td>4/36</td>
<td>11</td>
</tr>
<tr>
<td>Improved ability to transfer</td>
<td>25/26</td>
<td>96</td>
</tr>
<tr>
<td>Improved skin integrity</td>
<td>19/23</td>
<td>83</td>
</tr>
<tr>
<td>Improved wheelchair mobility</td>
<td>13/18</td>
<td>72</td>
</tr>
</tbody>
</table>
READING AND RHEUMATOID ARTHRITIS

Many of us will have seen British television advertisements for people with low reading or numeracy skills. Most of us immediately forget them. A survey of illiteracy in rheumatoid arthritis patients in Glasgow [1] suggests that we need to pay the subject more attention.

Survey

A tertiary referral centre for rheumatic diseases invited attendees of four consecutive clinics for rheumatoid arthritis patients to participate. All gave verbal consent for participation after a prepared consent form had been read to them (important this).

Patients were asked to complete the REALM questionnaire. This is the Rapid Estimate of Adult Literacy in Medicine [2], a screening instrument of 66 routinely-used lay medical terms arranged in three columns of increasing difficulty and number of syllables, ranging from ‘fat’ and ‘flu’ to ‘jaundice’, ‘medication’ and ‘inflammatory’. A patient is asked to read the words aloud, scoring one point for every word read correctly and zero if the word is mispronounced or not attempted. The maximum possible score is 66 and scores can be translated into reading ages of school grades (Table 1).

Other information on patients was obtained at the interview and from medical records.

Results

Of 127 patients asked to take part, four declined. Three said they were unable to read. The remaining 123 were aged 19 to 77 years, and had had rheumatoid arthritis for 1-60 years. Most (97) were women. Eighteen of the 123 had a REALM score of 60 or below, indicating functional illiteracy (Table 1). Together with the three patients who could not read, 21/126 patients (17%, or 1 in 6) would at best struggle with patient education material and 1 in 20 could not read prescription labels.

Comparing the literate with the illiterate group, there was no difference in age, disease duration or number of disease modifying drugs prescribed. Illiterate patients were more likely to be socially deprived, be anxious or depressed, and be unemployed. Illiterate patients had three times more outpatient visits and visited twice as many hospital departments.

Comment

This is important stuff. If patients don’t understand their medicines, that’s bad, and more time and effort is going to be needed to address comprehension in patients with inadequate literacy skills. When even the most competent of us have problems with taking it all in, how much worse is it to be cut off from the written word?

Time and effort may be worth it just for efficiency. If time and effort reduced the increased rate of outpatient attendance associated with illiteracy to that for literate patients, then just under 7,000 visits might be avoided in Glasgow alone, just for patients with rheumatoid arthritis.

This paper is worth a read. There’s a good review of issues around literacy and patients, and it tell us that they could find no other UK surveys in rheumatoid arthritis or other chronic diseases. Given the high rate of adverse drug reactions in the population (Bandolier 101), and the emerging evidence of the problems of illiteracy on health care use, this is a prime topic to learn more about. As with so many problems, though, it’s not tackled because no-one has bothered to look for it. Three cheers for Glasgow for pointing out this important point. Young professionals everywhere should see this topic as one for immediate research.

References:
1 MM Gordon et al. Illiteracy in rheumatoid arthritis patients as determined by the rapid estimate of adult literacy in medicine (REALM) score. Rheumatology 2002 41: 750-754.

Table 1: REALM scores, reading age equivalents in the UK and USA, and results from 126 rheumatoid arthritis patients in Glasgow

<table>
<thead>
<tr>
<th>Raw score</th>
<th>Description</th>
<th>Glasgow RA patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>No test, said could not read</td>
<td>3/126</td>
<td></td>
</tr>
<tr>
<td>0-18</td>
<td>UK reading age 8-9 years (US third grade and below)</td>
<td>1/126</td>
</tr>
<tr>
<td>19-44</td>
<td>UK reading age 9-12 years (US fourth to sixth grade)</td>
<td>2/126</td>
</tr>
<tr>
<td>45-60</td>
<td>UK reading age 12-13 years (US seventh and eighth grade)</td>
<td>15/126</td>
</tr>
<tr>
<td>61-66</td>
<td>UK reading age 16 years (US high school)</td>
<td>105/126</td>
</tr>
</tbody>
</table>

www.ebandolier.com
In many parts of the world a major problem with health care delivery is capacity – just not having enough hospitals, or doctors, or nurses to do the jobs needed. In the UK we have our own version of this. One way to deal with capacity constraints is to make “better” use of the staff we have, by using them more “efficiently”. The quotation marks here signify the difficulty of knowing what is best, and what is most efficient. One of a series of studies on outcomes in intensive care [1] suggests that more “efficient” may not mean better (or even more efficient).

Study

Throughout Maryland information is collected on all patients discharged from the 52 non-federal short-term stay hospitals. Retrospective information was obtained for all patients aged 30 years or older who had abdominal aortic surgery in 1994-1996. At the end of this period all ITU directors were questioned about nurse staffing, with specific questions about the nurse-patient ratio. Information about complications and co-morbid conditions was obtained from the database. Other variables sought were hospital and patient characteristics.

Results

Of the 52 hospitals, 46 performed abdominal aortic surgery, and 38 were able to provide information. Seven hospitals with 478 patients had one nurse to one to three or four patients (fewer nurses per patient) and 31 hospitals with 2128 patients had one nurse to one or two patients (more nurses per patient). The average number of hospital beds and number of abdominal aortic surgery cases was the same for hospitals with more and fewer nurses.

Patients looked after by more or fewer nurses were similar in age, ethnicity, sex, co-morbidity and nature of admission. Slightly fewer were operated on in hospitals with larger numbers of cases of this type, but more were operated on by surgeons performing more of this type of operation. Mortality was similar, but patients in hospital with fewer nurses spent one extra day in intensive care.

Patients looked after in ITUs with more nurses had lower rates of postoperative complications than did those patients looked after in ITUs with fewer nurses (Figure 1). After adjustment for various possible confounders, all the complications in Figure 1 had adjusted relative risks of between 1.5 and 4.5.

Comment

Less is more. Fewer nurses may be more efficient according to one definition of efficiency, but it meant more complications and longer patient stay in ITU. One extra day in intensive care per patient adds at least £2,000 to the cost of care of each patient.

The evidence about what makes a quality service is not extensive. From Maryland, other studies have looked at intensive care organisation and outcomes [2], or have taken a wider look at the topic of staffing [3]. Initiatives to improve both safety and value of healthcare in the United States include the Leapfrog group, at www.leapfroggroup.org, which is worth a visit.

References: