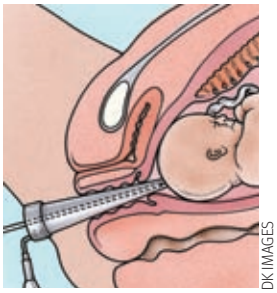
Fetal scalp sampling in labour

Lactate measurement has benefits over pH estimation



DK IMAGES

RESEARCH, p 1284

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Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

BMJ 2008;336:1257-8
doi: 10.1136/bmj.39567.480972.80

In the linked randomised controlled trial, Wiberg-Itzel and colleagues compare the effectiveness of two methods of diagnosing hypoxia in the fetus during labour—scalp pH analysis and scalp lactate analysis.[1]

Fetal wellbeing during labour depends on several factors—an adequate supply of oxygenated maternal blood reaching the placental intervillous space, gas exchange across an undamaged placenta, supply of oxygenated blood to the fetus through an open umbilical vein, and sufficient metabolic reserve in the fetus to withstand the hypoxic effects of uterine contractions. The fetus may be compromised by maternal hypotension, prolonged uterine contractions, placental abruption, umbilical cord occlusion, and fetal growth restriction. Distress may also occur for no obvious reason in apparently normal labours.

The traditional mainstay of fetal assessment during labour is monitoring of the fetal heart rate—either by intermittent auscultation (using a Pinard stethoscope or hand held Doppler device) or by continuous electronic monitoring. Compared with intermittent auscultation, continuous electronic monitoring has the disadvantage that it restricts the woman's movement. It also increases the need for caesarean section (relative risk 1.66, 95% confidence interval 1.30 to 2.13) and instrumental vaginal delivery (1.16, 1.01 to 1.32), but is less likely to result in the neonate having seizures because of hypoxic brain insults (0.50, 0.31 to 0.80).[2] A trade-off therefore exists between the benefits and harms of the two methods. If 628 women had continuous electronic monitoring there would be one less neonatal seizure and 11 more caesarean sections compared with intermittent auscultation.[2]

Both approaches to monitoring fetal heart rate lack specificity. Intermittent slowing of the heart rate does not necessarily indicate serious compromise. In particular, "variable decelerations"—caused by cord compression—may be associated with marked and audible drops in the fetal heart rate but are often benign. Adjunctive methods of fetal assessment are therefore needed in the presence of worrying features that are not severe enough to warrant immediate delivery. Fetal scalp sampling to measure capillary blood pH has provided that function for decades.[3] The baby's scalp is visualised through a tapered cylindrical amnioscope that is inserted into the vagina, and capillary blood is obtained via a stab wound.

However, the procedure is awkward, intrusive, and uncomfortable. A recent study found that it takes longer to perform than most obstetricians realise. Of 100 consecutive attempts at scalp sampling, 11 failed completely. The mean time between making the decision to sample and obtaining a pH result was 18 minutes. The median time to take a sample after preparations were made and the woman positioned was 14 minutes. The median time to abandoning the procedure in cases of failure was 26 minutes.[4]

The value of estimating capillary blood pH is also uncertain. A recent review on fetal heart monitoring found no evidence that access to scalp sampling reduced the risk of neonatal seizures or of caesarean section.[2] The intrapartum care guideline issued by the National Institute for Health and Clinical Excellence in 2007 acknowledged the lack of a satisfactory evidence base, but it concluded that clinical experience and indirect research comparisons justified a recommendation that fetal scalp sampling should be used when the fetal heart trace was pathological.[5] Consequently, and because this is a procedure that features prominently in an expensive medicolegal arena, anything that improves the ease of scalp sampling or provides a less invasive alternative is welcome.

Wiberg-Itzel and colleagues report a multicentre Swedish randomised controlled trial of almost 3000 women, which compared scalp pH analysis with scalp lactate analysis.[1] Lactate concentrations reflect tissue hypoxia and consequent anaerobic metabolism. Measurement of fetal capillary lactate concentrations during labour was described in the early 1980s,[6] but the technique failed to catch on in clinical practice. With technological advances, lactate can be reliably measured using small amounts of fetal blood (5 µl).[7] In contrast, pH analysis requires 30-50 µl of blood.

Wiberg-Itzel and colleagues found no significant difference between rates of metabolic acidaemia at birth after use of lactate analysis or pH analysis of fetal scalp blood samples to determine hypoxia during labour (0.91, 0.61 to 1.36 *v* 0.84, 0.47 to 1.50). However, significantly more protocol violations occurred for pH estimation (10.4%) than for lactate estimation (1.2%), mainly because of failed sampling. The authors did not record the time taken to perform sampling, but it was thought to be shorter for lactate estimation because of the smaller samples needed. Economic data were not reported. This study, together with a smaller earlier trial,[8] supports the use of lactate measurement rather than pH estimation at fetal scalp sampling.

Do less invasive alternatives exist? The most promising is analysis of the ST segment of the electrocardiographic signal obtained from an electrode attached to the fetal scalp. The adjunctive use of ST segment analysis along with cardiotocography decreases the need for

scalp sampling and instrumental vaginal deliveries compared with cardiotocography alone.[9] The logical next step is a head to head comparison of the two adjunctive methods—fetal scalp sampling versus ST segment analysis. This trial is ongoing in the Netherlands.[10]

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Assessing patients' improvement in clinical trials

Should the doctor or patient judge improvement, and does it matter?

RESEARCH, p 1287

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Provenance and peer review: Commissioned; not externally peer reviewed.

BMJ 2008;336:1258-9
doi: 10.1136/bmj.39570.393218.BE

Doctors need to understand the benefits of new treatments from patients' perspectives, because they must judge the relative risks and benefits of offering such treatments to patients. The field of health status assessment has evolved to meet this need, and several patient completed instruments have been developed that are valid, reliable, and sensitive to treatment.[1] Such tools can provide invaluable insights into how a treatment affects outcomes such as function and quality of life, which can be more important to patients than survival.[2-4] For some conditions, however, measures of disease specific health status are not available, and global assessments of clinical change are used.

Although valid approaches are available for measuring global change experienced by patients,[5 6] simple ad hoc measures are often used and can be assessed from the perspective of the patient or the doctor. In the linked survey of trials included in systematic reviews, Evangelou and colleagues determine whether patients and doctors differ in their assessments of global change after experimental treatments.[7]

Given the reliance of studies on global assessments of clinical change and the convenience of the doctor doing the assessment, the correlation between patients' assessments and doctors' assessments is important. The studies included in Evangelou and colleagues' review were mostly from the fields of rheumatology and psychiatry. The authors found a close correlation between the two assessments, which suggests that either should suffice when measuring the benefits of treatment from the patient's perspective. However, although they performed a thorough and methodologically sound literature review, their findings may provide false reassurance.

In the field of cardiology, doctors' assessments have been shown to be biased and unreproducible. The New York Heart Association (NYHA) classification of functional status in heart failure is meant to measure patients' symptoms and functional limitations on a four point scale. But interobserver variability is high—agreement between independent assessors is only 55%.[8 9] Similarly, clinical investigators' and objective interviewers' assessments of the severity of angina have been shown to be biased.[10] If reproducible assessments cannot be determined at a single point in time, it is unlikely that doctors will be able accurately to represent changes over time. Yet, as Evangelou and colleagues note, such formal investigation of doctors' ability to measure change has rarely been performed.

Rather than rely on such crude assessments, clinicians need clinical trials to investigate patients' perspectives of their disease through the serial assessment of valid, reliable, and responsive disease specific health status questionnaires.[11] For example, the Kansas City cardiomyopathy questionnaire, a disease specific measure for patients with heart failure, is more sensitive to clinical change than the NYHA,six minute walk test and several generic instruments.[12] Moreover, such measures can identify which domains (for example, symptoms, physical function or social function, etc) are most affected by treatment. This information allows patients to have a more realistic expectation of the benefits from a proposed treatment. When disease specific measures do not exist, generic measures of health status should be considered. Only through the use of psychometrically sound measures can clinicians obtain an accurate assessment of how a treatment affects a patient's disease process and effectively communicate that information to the patient.

Several possible explanations exist for the discrepancy between Evangelou and colleagues' findings and the well documented limitations of doctors' assessments of patients' health status. Firstly, because the authors used summary data from reviews rather than raw data from clinical observations, they had to rely on group means and may not have appreciated the individual variability of each doctor's assessment. Secondly, the clinical manifestations of the diseases studied may correlate better with patient's quality of life than other conditions such as cardiovascular disease. Thirdly, the different measurements of clinical change used in the studies included in the reviews may minimise important differences in perspectives of clinical change that would have been more evident with better assessment measures.[5 6]

Interestingly, failure to control for variability in the duration of the studies and the potential for recall bias regarding patients' original health status is more likely to have introduced biases that produce greater differences between patients' assessments and doctors' assessments. Finally, because patients are often at a nadir in their disease when enrolled in a clinical trial, a background trend for improvement may have artificially accentuated the similarities between the patients' assessments and the doctors' assessments.

Researchers should be encouraged to study the correlations between alternative methods of assessing patients' clinical status in other diseases and clinical settings. More importantly, however, serial changes in patients' health status, as assessed by patients themselves, should increasingly be used to document the benefits of treatment. This would obviate the need to rely on global assessments from either the patients' perspective or the doctors' perspective.

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Patient consent—decision or assumption?

New guidance from the General Medical Council urges a change in approach

ANALYSIS, p 1281

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Competing interests: None declared.
Provenance and peer review: Commissioned; not externally peer reviewed.

BMJ 2008;336:1259-60
doi: 10.1136/bmj.a155

The process of obtaining consent from patients for procedures such as surgical operations has been described as "the modern clinical ritual of trust,"[1] although its real meaning and performance are still debatable.[2] Last week, the General Medical Council released new guidance on the subject, *Consent: Patients and Doctors Making Decisions Together*, that will be implemented in June 2008.[3]

To caricature, obtaining consent often involves a junior member of the clinical team being charged with obtaining a signed piece of paper declaring that the patient has understood the nature of the procedure and its consequences. Consent is often completed a few hours before the intended procedure, and patients seldom have time to read, never mind reflect on, information about possible harms and benefits—rare or otherwise.

Although the consent discourse has hardly been studied in depth, many clinicians report the process of obtaining consent from patients as a perfunctory chore—to be accomplished in a superficial albeit efficient way—to ensure a smooth transition from preoperative assessment to preparation for the operating theatre. In the real world of rapid throughputs and turnaround times, consent is—and often has to be—assumed. Evidence shows that patients want to be given more relevant information about risks and consequences.[4] This emphasises the fundamental aim of informed consent—that patients should be neither coerced nor deceived.[2]

The new GMC guidance urges doctors to re-think their approach.[3] It advocates the communication of risks; it advises what should be done when patients refuse treatment; and it notes changes in the law, including the new legal safeguards for patients who lack capacity to make their own decisions. It encourages doctors and patients to be actively engaged in discussions about investigations and treatment, to enable patients to make informed decisions that are tailored to their individual circumstances and beliefs. The guidance stresses that obtaining and giving consent should not be a "tick the box" exercise but should be based around nine fundamental points (see box on bmj.com).[3]

So what are the implications for what clinicians do in practice? At first reading, the guidance seems radical and seems to signal a cultural change in how informed consent should be achieved. Yet closer reading reveals broad brushstrokes—details are sparse and the advice remains non-specific. For example, the guidance provides no detail about suggested risk thresholds for specifying the probability of harm; in addition, it makes no suggestions on how to achieve balance, how to tailor information, or how to explore personal preferences.

Considerable progress has been achieved in many of these areas in the related fields of risk communication, shared decision making, and decision support.[5] Guidance on how to communicate risk—using graphics, negative framing, and positive framing; describing both absolute (baseline) and relative risk estimates; and deploying natural frequencies rather than percentages—have been published.[6] Although the GMC's guidance looks like a manifesto for shared decision making,[7] it stops short of describing how clinicians could achieve these challenges

in busy clinical settings.[8] The lack of detail might prevent many clinicians from making major changes to their practice, perhaps just introducing patient information material, which may be of dubious quality.[9] Nevertheless, the arrival of new guidance signals the need for an overhaul of how informed consent needs to be achieved for clinicians who are keen to make improvements.

What needs to happen before the guidance can be implemented? Systemic and cultural change is needed to move shared decision making beyond interactions between health professionals and patients into the realm of becoming a requirement at the organisational level, integrated into the way multidisciplinary teams are set up to provide care. Rather than remain a bureaucratic task, consent would become a step-wise conversation conducted over numerous contacts.[10] Information would be provided early, preferably as soon as intervention is a possibility. The task of obtaining consent would be a distributed responsibility, conducted and documented by a series of clinicians working to a common goal. The process would become a consent pathway, with clear steps where information and patient preference would be considered and documented.

A signature on a consent form would no longer be sufficient evidence that the patient had been given accurate and tailored information. New materials will be needed that contain data about the intervention being considered, the likely outcomes, and their probabilities, complete with guidance on how to clarify patients' preferences and deliberate about options. Generating these materials will require considerable investment and expertise, both in the synthesis of evidence and in the presentation of the information. There is, however, much experience in producing such tools—decision support technologies, also known as decision aids, are on the increase.[11]

The international patient decision aids standards collaboration is working to ensure that quality assurance criteria exist.[12] These tools did not originate as methods to ensure informed consent—they were devised to help patients consider tough decisions, where clinical equipoise exists. However, as consent becomes increasingly regarded as a form of choice that involves a deliberated decision rather than just acceptance of professional advice, the shift to adopt decision support technologies as a means of achieving informed consent seems not only necessary, but inevitable.

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The carers of people with dementia

Want high quality services and have compelling reasons to get them

RESEARCH, p 1295

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Competing interests: None declared.
Provenance and peer review: Commissioned; not externally peer reviewed.

BMJ 2008;336:1260-61
doi: 10.1136/bmj.39567.647072.80

Carers of people with dementia have a hard time; not only do they have to contend with the illness but they also receive limited support and poor services. A recent UK parliamentary committee report criticised the whole range of dementia care.[1] It highlighted poor diagnosis (only a third of people with dementia receive a formal diagnosis), fragmented home support, untrained staff in care homes, and a failure to recognise or manage dementia in general hospitals. This leaves difficult decisions for those redesigning services. Who will offer long term support? What will be the role of the voluntary sector? In the accompanying paper, Charlesworth and colleagues tackle these questions in a randomised controlled trial of a scheme for befriending carers of people with dementia.[2]

Carers have high rates of anxiety, stress, and burnout. Their life expectancy is reduced, and up to a third of carers of people with dementia are depressed.[3 4] During the course of dementia, the stresses for carers change. Across Europe, fewer than a quarter of carers say that services are sufficient to meet their needs.[5]

Care of dementia in the United Kingdom costs more than £17bn (€22bn; $34bn) a year. Breakdown in support from carers is a major cause of people moving into care homes, and accommodation accounts for more than 40% of the total financial cost of dementia.[6] Carers already save UK tax payers £6bn a year so they are vital for keeping down spiralling costs. Carers face considerable financial costs themselves because many have to give up work or reduce their hours.[6] By supporting carers we may be able to help people with dementia to stay living at home for longer and free up money to spend on other parts of the service.

So how can we support carers? A range of support has been evaluated, including telephone information, education, mutual support, cognitive behavioural therapy, problem solving, and case management.[7] One randomised controlled trial in carers of people with dementia found that six counselling sessions, group support, and the availability of telephone counselling reduced the rate of placement in a nursing home by

28%.[8] However, overall, interventions aimed at supporting or providing information to carers of people with dementia have produced disappointing results, and high quality trials are sparse. Research into dementia is under-represented and accounts for only a 20th of the number of research papers on cancer.[6]

Charlesworth and colleagues tested access to befriending schemes as support for family carers of people with dementia.[2] The befriending schemes were run by local voluntary bodies. The study found no significant difference in mood or quality of life at 15 months' follow-up between carers who had access to a befriender compared with those who did not. However, only half of those offered befriending used the service, and only a third completed six months of befriending. Those who used the service tended to have little existing contact with family or friends.

What are the implications of these results? At face value they might suggest that resources should not be used to fund access to befriending. However, befriending is a personal activity that works well for some carers at certain times. The trial shows that this is important because most of the carers who completed six months of befriending were still in contact with the befrienders one year after the start of the trial. Existing supports and the quality of services may influence the effects of befriending.

So, how can we provide carers with high quality services? Several randomised controlled trials have shown better models of care. In the United States, providing a senior nurse to coordinate services—such as treatment and education—in primary care reduced distress in people with dementia and improved depression in carers.[9] Another trial in the US found that a disease management programme led by care managers improved quality of life for the person with dementia.[10] In the Netherlands, a detailed clinic based assessment by doctors, nurses, and other professionals which was sent to primary care also improved quality of life for people with dementia.[11] The UK government has launched the first national dementia strategy, which should be published at the end of this year.[12] Its priorities are improved awareness, early diagnosis and intervention, and better quality of care for dementia.

The UK parliamentary committee made several recommendations to improve the care of dementia.[1] One of these is to offer everyone with dementia and their carer a single health or social care professional contact point. Although this will require extra resources, the reasons to implement a fully funded strategy are compelling.

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Vertebroplasty for osteoporotic vertebral fracture

Consensus on the indications is needed to avoid indiscriminate use

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Competing interests: None declared.
Provenance and peer review: Commissioned; not externally peer reviewed.

BMJ 2008;336:1261-2
doi: 10.1136/bmj.a178

The first percutaneous injection of bone cement into the spine was performed in 1984 to treat a 54 year old woman with extreme pain caused by a haemangioma in the second cervical vertebra. Surprisingly, pain relief was complete.[1] After the case was published, indications for percutaneous vertebroplasty quickly expanded to include treatment of chronic back pain caused by metastases and osteoporotic fracture.

Since then, many case series have indicated that vertebroplasty is an effective way to control the pain of vertebral compression fracture caused by osteoporosis. The immediate relief of pain is often dramatic and, especially for the chronically debilitated patient, it may seem miraculous. The results are fairly consistent, and in one large case series of 552 patients, improvement in pain and disability persisted throughout two years of follow-up.[2] Unfortunately, in the only published randomised controlled trial of vertebroplasty, almost all patients in the control group—who received conservative care—crossed over to the intervention group two weeks after randomisation, so the results were difficult to interpret.[3]

At present, guidelines for selecting which patients to treat with vertebroplasty are vague. The National Institute for Health and Clinical Excellence (NICE) interventional procedure guidance 12 states that "the procedure should be limited to patients whose pain is refractory to more conservative treatment." With respect to efficacy, "the opinions of the specialist advisors were divided."

Standards of care for debilitated patients

vary greatly between jurisdictions as a result of differences in home support, insurance coverage, or access to private care. Rigorous supervision of non-hospital care before vertebroplasty may be difficult for the specialist physician trying to ensure that all patients undergo "adequate trial of optimised conservative treatment." The problem is exaggerated if patients have difficulty in travelling to and from appointments—in Canada and the United States home visits by doctors are rare.

In some centres in North America, patients with "failure of conservative treatment" can be directly referred for vertebroplasty by emergency departments. In this setting, the effects of the procedure may be exaggerated for several reasons—patients are very appreciative of rapid pain relief; doctors' perceptions of results are positively reinforced by the immediacy of the effect and early discharge from hospital; and the hospital administration may benefit financially. The problem is compounded in health systems that reward action rather than observation and in clinical services that compete to provide "better care." In this context, failure of conservative treatment could become a euphemism for inadequate care.

So what constitutes failure of conservative management? No definition of a standard approach for initial conservative treatment can be found in the literature. No agreed guidelines exist for the minimum duration of conservative management or whether this should vary according to age or condition. Options for conservative care are seldom described in any meaningful way. For example, high dose calcitonin for controlling pain of bony origin is rarely considered, even though it is a highly effective analgesic for osteoporotic vertebral fracture.[4 5] Only occasionally is advice given about bed rest.[6] Furthermore, few publications stress the palliative nature of vertebroplasty, especially in osteoporosis, and that the procedure does have risks. Serious complications of vertebroplasty include paraplegia, pulmonary cement embolism, and death.[7]

A recently published position statement on percutaneous vertebral augmentation with vertebroplasty or kyphoplasty (balloon vertebroplasty) discussed the evidence for the poor prognosis of chronic pain and disability in elderly people. This evidence is used as a justification for vertebroplasty, and the statement concludes that this procedure is "established therapy and should be reimbursed by payors as a safe and effective treatment for painful compression fractures."[8] However, although early follow-up results of two non-randomised controlled studies showed significant improvement in pain in the vertebroplasty group, three or six months later the differences between groups were not sustained.[9 10] There is no good evidence that vertebroplasty has a better long term outcome, and it may even accelerate the rate of new fractures.[11 12] Also, because vertebroplasty does not treat the underlying condition, if immediate pain relief detracts attention away from the seriousness of the osteoporosis, might this constitute an adverse effect?

Although evidence is currently lacking, immediate access to vertebroplasty could be more effective than conservative treatment. Conservative measures such as narcotic analgesia and bed rest have side effects that are often magnified in elderly debilitated people. Hospital care is expensive and faster rehabilitation may be preferable. However, without high quality evidence, selection criteria for the procedure may become less clear over time as new devices and instruments are developed to expand the application of the technique. Competition between manufacturers is more likely to cloud rather than to clarify these matters.

With good training and equipment, vertebroplasty is a relatively simple interventional procedure; its immediate effects are well documented; and its use is perhaps justified as a treatment for severe chronic debilitating pain caused by osteoporotic vertebral fracture. Of course these decisions should be made by a multidisciplinary team of clinicians experienced in osteoporosis, pain and rehabilitation, and vertebroplasty, who would be responsible for management and follow-up. Randomised controlled trials are essential to define the minimum conservative treatment that patients should receive before vertebroplasty, and to develop clear guidelines on the use of vertebroplasty that would help to prevent its indiscriminate use.

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