

Informed consent for epidural analgesia in labour

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ABSTRACT

Consent for epidural analgesia for labour is unique. The issues of patient autonomy and competence are controversial because of the limited antenatal education that most South African patients receive, and the absence of a culture of structured birth planning. Frequently, such patients are first encountered by the anaesthetist when in advanced labour and limited time is available for explanation. Overall, this represents the most extreme example of obtaining consent in compromised circumstances.

Introduction

The purpose of this review is to:

- Discuss the difficulties associated with informed consent for epidural analgesia in labour in healthy parturients,
- Outline a reasonable explanation to the patient concerning the benefits and risks of epidural analgesia,
- Present some of the evidence from recent literature that supports the explanation conveyed to the patient.

1. Informed consent

The concept of informed consent was introduced by the courts during a famous legal case in the United Kingdom in 1957. A patient had suffered paraplegia following translumbar aortography and maintained that he had not been informed of the dangers of the procedure. Following this case, it became the responsibility of the physician to explain the risks and benefits of the intended procedure, and the alternatives. From 1957 to 1998, the so-called Bolam Principle applied, which stated that a doctor is not guilty of negligence if acting in accordance with a practice accepted as proper by a reasonable body of medical men skilled in that art. In 1998, following Pearce versus the United Bristol Health Care Trust, the premise was adopted for the first time that it was the opinion of a reasonable *patient*, and not that of the court or the medical profession, that was crucial. The demise of medical paternalism and the acceptance of patient autonomy consequently would have to become part of daily clinical practice.¹

The General Medical Council's advice to practitioners is somewhat non-specific, stating that the amount of information the clinician gives to each patient will vary according to factors such as the complexity of the treatment, the risks associated with the procedure, and the patient's own needs. The doctor should take appropriate steps to find out what the patient wants to know and ought to know about his or her condition and treatment.

The guidelines of the Health Professions Council of South Africa on informed consent appear in Booklet 15 of their Ethical Practice Guidelines series. These guidelines have now been

drafted into and promulgated in the National Health Act (Act 61 of 2003), which became law in May 2005 (Website: <http://hpcs.co.za>).

Consent for epidural analgesia (EA) for labour is unique. The procedure is invasive and common (in the National Health Service in the UK, 160 000 patients received epidural analgesia during 2001 and 2002), and the intervention may be regarded as non-essential. Patients are young, healthy, highly motivated and have access to increasing amounts of information. In state hospitals in South Africa, by contrast, patients are poorly informed and emotionally unprepared for the pain of labour.² The issues of patient autonomy and competence become even more controversial because of the limited antenatal education that most South African patients receive, and the absence of a culture of structured birth planning.^{2,3} Frequently, such patients are first encountered by the anaesthetist when in advanced labour and limited time is available for explanation. Overall, this represents the most extreme example of obtaining consent in compromised circumstances. In this situation, particularly when dealing with cultures with strong traditional beliefs, clinicians should be acutely aware of their biases when informing patients of the various options for pain relief, and avoid coercive behaviour.⁴

It is now accepted that neither severe pain nor the prior administration of appropriate doses of sedatives and/or opiates invalidates consent,^{5,6} but that the recall of information presented immediately before or during labour is poor.^{7,8} By contrast, the antenatal distribution of an information booklet has been found to be very beneficial in improving recall.⁹ In extreme cases, for example, where pain is excruciating due to the impending delivery and the patient clearly cannot understand, retain or weigh up information, the anaesthetist may deny epidural analgesia if it is demanded. If the patient is incompetent for any reason, a decision must be taken in the patient's best interests – this is the ultimate test of 'necessity'. Expert opinion is that this may apply to up to 35 000 women per annum in the United Kingdom.¹⁰ Should a patient with an advance birth plan that either does not include, or even specifically excludes, EA change

her mind due to extreme pain, EA may be provided on the basis that it is part of 'basic care', which includes the alleviation of severe pain.¹¹

As yet there are no strict legal guidelines as to what is required of the practitioner. A recent legal view from the United Kingdom (UK) is that "the general contours of the law are firmly in place", that "disclosure of risk is one of the few remaining areas of uncertainty", and that "the ultimate test is what the court itself thinks was a reasonable amount of information to give the patient".¹²

According to the Association of Anaesthetists of Great Britain and Ireland, 'material risk' is one to which a reasonable person in the patient's position would be likely to attach significance. Traditionally, complications with an incidence of 1% should be mentioned but, in a recent obstetric survey in the UK,¹³ 64% of patients wanted to know about complications with an incidence as low as 1/1000, and 20% wanted information on complications as rare as 1/10.⁶ In a further study, all the participants wanted to know all the potential epidural complications, but not necessarily the incidences of all the complications.¹⁴ Anaesthetists should consider carefully how a particular situation influences risk, and present relative everyday risks to help place potential complications in perspective. Table 1 summarises a recommended guide to various risk categories.^{15,16}

Some clinicians believe that 'full disclosure' may be somewhat bewildering to some patients, but this is not supported in the literature.¹ This issue has not yet been resolved fully, as is evident from a recent in-depth debate.^{11,17} In particular, full disclosure is no guarantee against litigation.¹⁷ Overall, it appears that most patients want more information than is usually divulged, and that supplying this information does not dissuade women from consenting to epidural analgesia.^{14,18}

2. Explanation to the patient

The anaesthetist should obtain written consent from the patient. A minor who is pregnant is often competent and able to understand, and her opinions on the matter of analgesia should be honoured.³

Table 1: Everyday risk guide

Risk category	Relative risk	Everyday occurrences
Negligible risk	<1/1 000 000	Death due to lightning strike
Minimal risk	1/100 000 -1/1 000 000	Death in a railway accident
Very low risk	1/10 000 -1/100 000	Death in accident at home or work
Low risk	1/1 000 - 1/10 000	Annual risk of death in a traffic accident
Moderate risk	1/100 - 1/1 000	Annual risk of death due to natural causes for patients over 40 years of age
High risk	>1/100	Risk of diarrhoea after antibiotics

The following information should be made available to the patient, optimally in the antenatal period, *couched in terms that each individual can understand*:

- The patient will require an IV line before the procedure and a urinary catheter afterwards.
- Concerning *pain relief*, the patient can expect that, in experienced hands, 90% of epidural catheters will provide excellent pain relief at the first attempt, and this method is of a better quality than any other employed in labour. In 10% of cases, either a patchy block or poor analgesia may arise, requiring intervention in the form of withdrawal of the catheter by 1 to 2 cm, or a top-up with the patient lying on the affected side; failing these manoeuvres, the catheter would be re-sited. There may be some discomfort during the second stage of labour. Only rarely is it impossible to obtain effective pain relief.
- Some degree of *motor block* may occur (usually minimal with 0.1% bupivacaine continuous infusions, unless administration is prolonged). The patient will be mobile, but it is not the policy of all units to perform 'walking' epidurals. The motor block associated with 0.1% bupivacaine should not affect the ability to 'push'.
- Minor side effects include:
 - *Hypotension, nausea/vomiting, pruritus and transient respiratory depression*, which are usually treated easily.
 - *Sedation, shivering and an increase in body temperature* may also occur.
- Rare major side effects are:
 - *Inadvertent high spinal block or IV injection of local anaesthetic agents*, resulting in *arrhythmias, convulsions or cardio-respiratory arrest*. (Emphasise that the anaesthetist is well equipped to deal with these complications).
- EA does not increase the likelihood of *Caesarean section*. The second stage may be slightly prolonged, and assisted delivery may be more common.
- EA results, on average, in better *neonatal blood gas* values than systemic opiate analgesia.
- *Headache* may arise due to inadvertent dural puncture – in <1% of cases in experienced hands. A combination of conservative management and epidural blood patch, should severe headache arise, may be required to treat the discomfort.
- No new *backache* will arise as a consequence of EA *per se*.

Should the patient develop backache, nerve root pain, bladder dysfunction or weakness, with or without fever and neck stiffness, this should immediately be reported to the maternity centre so that epidural haematoma/abscess can be excluded.

- The risk of permanent *neurological damage* is very low.
- The risk of *sepsis and/or abscess formation* is very low.

The patient should be informed that, if a Caesarean section is required after conventional epidural or a combined spinal-epidural (CSE) technique, general anaesthesia is usually not necessary, since local anaesthetic may be added via the epidural catheter to allow for surgery.

After the above information has been conveyed, the patient should be given the opportunity to ask further questions.

3. Selected evidence from the literature to validate the above explanation

Quality of pain relief

Many randomised trials and a major meta-analysis attest to the superiority of EA over other methods of pain relief.¹⁹ EA employing combinations of local anaesthetics and phenylpiperidines has been found to produce consistently reliable analgesia.¹⁹ Non-opioid additives to epidural analgesia, such as clonidine and neostigmine, have narrow therapeutic ranges and have not achieved widespread acceptance.²⁰

Although inferior to EA, Entonox does have some analgesic benefit.²¹ The use of parenteral opioids has been extensively studied. Pethidine has modest analgesic effects when compared with a placebo.²² Patient-controlled intravenous remifentanyl has been shown to be more effective than IV pethidine, with a low crossover rate to epidural anaesthesia.^{23,24} However, remifentanyl crosses the placenta, and close monitoring is required of both mother and fetus.²⁵ Kappa agonists have been extensively researched and, although they have shown promise in the laboratory, clinical studies have been disappointing.²⁶

Motor block

The anaesthetist should aim to give the lowest possible concentration and dose of local anaesthetic to provide effective analgesia. This limits side effects, particularly motor block. When the anaesthetist interprets information from the literature, it is important to realise that the potency of the local anaesthetic agents differs. In this regard, the term "minimal local anaesthetic concentration (MLAC)" is the minimum concentration of local anaesthetic in a 20 mL volume that will produce effective analgesia in 50% of patients in the first stage of labour (ED₅₀).²⁷ Thus, ED₅₀ = 20(mL) X MLAC (mg/mL). MLAC is determined using the up-down sequential allocation method, in which the dose of the subsequent patient is determined by the response of the preceding patient. Using this method, the relative potencies of epidurally administered lignocaine versus bupivacaine, ropivacaine versus bupivacaine, and ropivacaine versus levobupivacaine have been determined as 5.7, 0.6 and 0.98

respectively. Alleged benefits of one local anaesthetic compared with another in terms of motor block should only be accepted if equi-analgesic concentrations are studied. MLAC only represents one point on the dose response curve, therefore if the slopes of the dose response curves differ, ED₉₅s for two agents may be different even if their ED₅₀s are similar. MLAC comparisons therefore do not always correlate with relative clinical potencies, and MLAC values do not allow for the effects of continuous infusions. MLAC is a useful tool for within-population comparisons, and allows for the study of combinations of local anaesthetics and opiates. It is difficult to study the cumulative effects of epidural local anaesthetics in labour, since MLAC increases as labour progresses,²⁸ and local anaesthetic requirements increase if there is cephalopelvic disproportion.²⁹ If one extrapolates from the non-obstetric literature, it is likely that prolonged continuous infusions of low concentrations of bupivacaine cause gradually increasing motor block.

Other side effects

An important recent addition to the literature on labour EA is the recognition that EA *per se* is associated with an increase in maternal temperature. This pyrexia is independent of infection, and may be due to altered thermoregulation or activation of the inflammatory response. Clinical pyrexia develops in 6-23% of patients, at a rate of 1°C for every seven hours of analgesia. There is a five-fold increase in neonatal encephalopathy if maternal temperature exceeds 37.5°C.³⁰

Effects on the progress and outcome of labour

EA does not increase the incidence of caesarean section, as shown by meta-analyses^{19,31} and a convincing before/after study.³² This is independent of cervical dilatation at the time when EA is initiated.^{33,34,35}

EA may prolong the duration of the first stage of labour by, on average, 30 minutes.¹⁹ Combined spinal-epidural anaesthesia (CSE) probably confers no benefits in this regard.³⁶ Most evidence suggests that EA prolongs the second stage of labour.¹⁹

Many systematic reviews report that EA is associated with an increased rate of instrumental deliveries when compared with systemic opiates.^{19,37} Patients receiving high concentrations of local anaesthetic may develop motor blockade, and these patients have been shown to have an increased rate of instrumental delivery when compared with low-concentration epidural techniques³⁸, or with CSE analgesia maintained with low bupivacaine concentrations.³⁹ There currently is insufficient evidence to support the hypothesis that discontinuing EA analgesia during the second stage of labour reduces the incidence of instrumental delivery. Furthermore, this practice would be likely to result in poor analgesia.⁴⁰

Neonates whose mothers received EA have better one-minute Apgar scores than after other analgesic regimens.¹⁹ The fetal base deficit is significantly lower, and pH tends to be higher following epidural analgesia than after systemic opiates.⁴¹

Neurological outcome following epidural analgesia

When considering new neurological deficits following EA for labour, the clinician should be aware that deficits may be secondary to labour and delivery, that spontaneous neurological deficits may occur, and that retrospective reports often result in under-reporting.⁴²

Early non-randomised studies suggested the possibility that epidural analgesia was associated with an increased incidence of new backache. Long-term follow-up in a randomised trial suggested no differences between epidural and non-epidural analgesia. The study was limited by crossover to epidural analgesia, but the findings appear statistically valid.⁴³

For post-dural puncture headache, epidural blood patch (EBP) provides persistent relief in 61 to 75% of cases. There is recent evidence that prophylactic EBP is probably not indicated, although this may reduce the duration of the symptoms.⁴⁴ Intrathecal saline administration may reduce the requirement for EBP.⁴⁵ Delaying EBP for 24 hours is probably not indicated. The optimal volume of blood is probably 15 to 20 mL. Two hours of bed rest is optimal after EBP.^{46,47}

The overall incidence of neurological complications is 0 to 36.2 per 100 000 blocks,^{42,48} and is made up as follows:

- Neuropathies, usually radiculopathies involving a single spinal nerve root, are by far the most common lesion (81%). There is usually a history of pain or paraesthesia on injection.
- Next most common are cranial nerve palsies (11%). The abducens is most commonly affected, but cranial nerves 2, 5, 7 and 8, may also be involved. These almost always recover within a period of 20 minutes to five months.
- Epidural abscess, characterised by backache, nerve root pain, weakness and finally paralysis, is rare (2% of neurological deficits). There is associated fever, neck stiffness, headache and leucocytosis. The presentation occurs two to 16 days postpartum, usually after the catheter has been in place for more than 24 hours. The organism is usually *Staphylococcus aureus*.
- Spinal epidural haematoma usually presents earlier (two hours to three days postpartum). Symptoms are similar to those for abscess. There have been four reported cases of spontaneous epidural haematoma in pregnancy, resulting in paraplegia.⁴⁹
- Three cases of anterior spinal artery syndrome are described (2% of neurological deficits), of whom two had permanent paraplegia.
- Of six cases of cranial subdural haematoma (2% of neurological deficits), all after inadvertent dural puncture, four patients died, one had persistent visual disturbances, and one recovered.
- Meningitis is approximately 15 times less common following epidural than spinal anaesthesia in labour. The organism is most commonly *Streptococcus viridans*, but aseptic meningitis may be difficult to distinguish. Most or all patients recover fully.
- In a series of 505 000 patients, no cases of arachnoiditis

following labour epidural analgesia were described; this complication is probably related to the use of preservatives or vasoconstrictors added to the local anaesthetic.^{50,51}

Should a combined spinal-epidural (CSE) technique be envisaged, the following additional points should be explained to the patient:

- CSE produces effective analgesia five to 15 minutes sooner than conventional epidural analgesia.⁵²
- CSE may be advantageous in late labour, when analgesic requirements are considerable.⁵³
- Motor block is no different from that of conventional low concentration continuous infusion epidural techniques.⁵⁴
- Balance is well maintained after the spinal component of CSE.⁵⁵
- The risk of meningitis is very low, but still higher than that following conventional epidural analgesia.⁵⁶
- The risk of fetal bradycardia shortly after initiation of the spinal component is significant, but has not been associated with an increased incidence of caesarean section.⁵³

Some units practise patient-controlled epidural anaesthesia (PCEA) during labour. The use of small boluses of local anaesthetic without a continuous background infusion is associated with higher patient satisfaction, improved quality of analgesia, reduced total local anaesthetic consumption, reduced motor blockade, and a decreased number of anaesthetic interventions.⁵⁷

4. Conclusions

The philosophy behind informed consent has changed considerably. The legal status of informed consent is established in South Africa. Consent for EA in labour is unique and an evolving field that provokes fierce debate amongst practising obstetric anaesthetists. Some areas of controversy have been rigorously studied, and scientifically valid answers are emerging. In addition, specific risks of EA in labour have been better defined, as reported in the recent literature.

An antenatal education brochure outlining the options for intrapartum analgesia in the first language of the patient would greatly reduce the ethical and practical difficulties associated with detailed explanations to patients in excruciating pain. The onus is on the anaesthetist to individualise the explanation of EA for each patient. The concept of 'material risk' should be explored with every patient. Full information should be available, unless a patient specifically indicates a desire to be kept ignorant of the relevant risks. Anaesthetists should have at their disposal up-to-date literature on the risks and benefits of epidural analgesia for labour.

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