CHAPTER 1
Consent for obstetric analgesia and anesthesia

M. Joanne Douglas

Background

Informed consent is based on the ethical principle of autonomy and has several components. The requirements for informed consent are that:

1 it must be given voluntarily;
2 the patient must have the capacity (ability) to understand the information that is presented;
3 the consent must be specific to the person doing the procedure and to the procedure;
4 the risks and benefits of the procedure must be explained and understood; and
5 all questions must be answered.

In addition, the individual should have time to consider the information that is presented, although for the woman in pain that often is a short interval.[1]

The obstetric anesthesiologist often faces a dilemma in obtaining informed consent for neuraxial analgesia/anesthesia in the laboring parturient. Many anesthesiologists consider it impossible to obtain informed consent from a woman who is in pain, and in particular if she has received an opioid, such as meperidine.[2–4] Some women prepare birth plans prior to labor indicating that they do not want an epidural under any circumstances. This presents an ethical dilemma if these women change their minds when confronted with the pain of labor and request an epidural.[1] It can be argued that they prepared their birth plan without full knowledge as to the degree of pain that they might encounter. The anesthesiologist faced with a birth plan that states "no epidural" is concerned that the woman in pain is not fully competent to provide informed consent to the epidural.[5,6] Scott[7] discussed this dilemma in her editorial where she considered it "unethical to withhold pain relief" to a woman in pain because she had previously written a birth plan stating that she did not wish for an epidural.

It is useful to review the literature for studies that explore obtaining informed consent in the laboring parturient, the information to be provided and the most effective way to present that information.

Methods: literature search

Studies included in this review were cohort studies or surveys dealing with the issue of informed consent for labor epidural analgesia. The outcomes of interest were whether women postpartum could recall the risks that were included in the informed consent,[8,9] whether written or oral information was more effective in the consent process,[10,11] and the information women wanted to know prior to giving consent for epidural analgesia.[11–13]

A computer search of the MEDLINE® and EMBASE® databases covering the time period 1980–August 1, 2003 was performed using the key words: [consent], [informed consent], [analgesia], [obstetrics], [obstetric anesthesia/anaesthesia], [labor/labour analgesia], [labor/labour analgesia, epidural] and [ethics]. The search was limited to human studies that were published in English and full text was available from the University of Toronto. The bibliographies of articles that were retrieved were searched for additional references and those articles reviewed. Some studies from the general anesthesia literature were reviewed to contrast the experience of laboring women with that of the general surgical population.[14–17]

Results

Seven studies were found using the above search strategy.[8–13,18] One was a randomized trial,[10] the remainder were prospective surveys or retrospective assessments. No study was excluded (Table 1.1). The total number

Table 1.1 Characteristics of studies.

Authors	Study type & country	Population	Number of subjects	Time data collected	Main outcome	Comments
Swann *et al*.[8]	Survey, Australia	Nulliparas	40	36–48 h postpartum	Recall of risk comparing women who attended epidural antenatal class	Lack of randomization to antenatal classes, no description of population, no consistent provider of information pre-epidural
Affleck *et al*.[9]	Survey, USA	Mixed parity	101	< 24 h postpartum	Recall of risk	Heterogeneous population, 7 had only mild pain
Gerancher *et al*.[10]	Randomized survey, USA	Mixed parity	113/group	5–7 months postpartum	Recall risk: verbal vs verbal + written information	Population not described, 73% followed up, no measure baseline knowledge
White *et al*.[11]	Audit before and after intervention, UK	Mixed parity	100/group	1 day postpartum	Recall risk: verbal vs verbal + written information	25–30% previous epidural, interviewers not blinded, interview of groups separated by time
Pattee *et al*.[12]	Survey, Canada	Mixed parity	60	1–2 months postpartum	What complications parturients want to know, did pain influence ability to give consent	Systematic sampling, retrospective, lack generalizability, 86% postgraduate education, 35% previous epidural, 64% received opioids pre-epidural,variability in time of survey < 4 h–8 weeks
Jackson *et al*.[13]	Prospective survey, Canada	Mixed parity	60	Pre-epidural	What parturients want to know, understand risk	25% previous epidural, 75% postgraduate education, 46% opioids presurvey, epidural only given after survey completed
Beilin *et al*.[18]	Survey, USA	Mixed parity	320	24 h postpartum	Knowledge and concerns re. epidural	Vaginal delivery + cesarean section included

of participants included in the seven studies was 981 parturients.

Overall, the evidence provided in the studies is not strong (Table 1.1). In many there was no full description of the individuals surveyed in the population (e.g. educational status), although most described the number of multiparas and nulliparas. There was no indication as to how the number of women surveyed was determined and most of the surveys were conducted at varying time periods following delivery.

Other design issues lead to difficulties in interpreting the results. For example, if the woman cannot recall risks during a postpartum interview or questionnaire, this does not exclude the possibility that she understood the risks at the time of consent. Therefore, a survey that relies on the recall of risk may be meaningless. A woman's postpartum assessment as to her competency at the time of the consent may be influenced by the outcome of the labor (healthy or ill baby, vaginal or operative delivery, postpartum pain from an episiotomy or tear). Yet none of the surveys stratified for the obstetric outcome. The woman's response to a survey might be biased if she did not want an epidural but agreed to it because of the severity of her pain. Similarly, it is difficult to rely on responses to questionnaires or interviews that women

Table 1.2 Risks discussed by Affleck *et al.*[9]

Infection
Bleeding
Nerve damage
Urinary retention
High spinal block
Block failure
Nausea and vomiting
Respiratory depression
Pruritus
Intravenous injection (with cardiovascular collapse)
Postdural puncture headache
Local anesthetic toxicity (potential seizure)
Hypotension

completed before being given analgesia because her answers might have been influenced by her desire to obtain analgesia as rapidly as possible.

In addition to the problems listed above, other characteristics of the studies make interpretation difficult. Some of the surveys combine the results of mixed populations of parturients (multiparas who had received an epidural with a previous pregnancy and nulliparas). It may be difficult to generalize the results to parturients of different ethnic and educational backgrounds when the majority of participants were well educated. Many of the surveys were small, leading to a lack of precision in the findings. Finally, and possibly most importantly, none of the studies describe a rigorous process to determine whether or not their questionnaires produce reliable and valid results.

Postpartum recall of risks

In an effort to determine the effectiveness of the consent process, Swan and Borshoff[8] assessed postpartum recall of epidural risk explanation in 40 laboring women who had an epidural. Prior to insertion of the epidural, a brief, detailed explanation of the risks of the procedure was given focusing on backache, postdural puncture headache (PDPH) and "more serious" complications. "More serious complications" were explained in general terms. Women were then surveyed 36–48 h postpartum for recall and a comparison was made as to recall of risk between those who had the antenatal education classes offered at their hospital and those who had not.

Sixty-five percent had attended antenatal classes but only 40% attended the session on epidural analgesia. All 40 women recalled having an epidural but only 67% recalled that risks were discussed. Recall of all three areas of risk (PDPH, backache, serious complications) was higher in the group that had received antenatal education; median score 2.31 (maximum 3) vs 0.92. Those who had received epidural antenatal information had significantly better recall of each specific risk.

Affleck *et al.*[9] administered a standardized oral discussion of anesthetic risks to 101 laboring women prior to epidural catheter insertion (Table 1.2). The women could discuss any concerns. Postpartum (< 24 h after consent) they were surveyed and asked to:

1 verbalize any risks they could recall; and

2 identify the risks they could recall from a printed list of eight risks, five of which were real and three were false. Descriptive analysis was used.

All women recalled the informed consent discussion and insertion of the epidural. Patients recalled an average of 2.0 ± 1.3 risks with 13% recalling no risks, 22% one risk, 29% two risks and 25% three risks. When only one risk was recalled the most commonly recalled risk was PDPH (64%). The five true risks were identified by more than 50% of the women. In contrast to Swan's study there was no difference in risk recall between those who attended prenatal classes and those who did not.

Is recall of risk better when written information is provided?

Two studies examined the best way to present information prior to epidural analgesia. Gerancher *et al.*[10] enrolled 113 consecutive laboring women during the daytime over a 1-month period. All women had a structured preanesthetic interview by one of the investigators. This interview was carried out prior to administration of any form of labor analgesia, including parenteral medications. The interview included questions regarding the woman's medical condition and a verbal presentation of anesthetic options, risks and procedures (total time 10 min). A written 10-point check list was used to ensure that all topics were covered.

The women were randomly assigned to receive the interview as documented above (verbal group) or the same interview plus a written informed consent form containing the same information (verbal + written group). The "informed consent" form was

simultaneously reviewed by the investigator and signed by the woman, and the investigator and women in this group received a copy of the consent form. The verbal group did not review, receive or sign a similar consent form. The women were contacted 5–7 months later at which time 10 objective questions (five true risk questions, two false risk questions and three situational questions) were asked to assess their degree of recall.

Eighty-two of the original 113 women (72.5%) were contacted postpartum; 44 in the verbal + written group and 38 in the verbal only group. Seventy-five percent in the verbal + written group and 78% in the verbal only group had received epidural analgesia. Median recall scores were 80 (70–90) in the verbal only group and 90 (80–100) in the verbal + written group ($P < 0.01$). Seventy-six responded that written consent would help them remember the different options, risks and procedures. Six (one verbal + written, five verbal only) considered it unhelpful and four of the six felt that written consent would be alarming. Two of these four (both verbal group) felt they were unable to give informed consent.

White *et al.*[11] performed an audit prior to (control group) and following adoption of the use of an epidural written information card (subject group) which was prepared following consultation with antenatal and postnatal women, midwives and anesthesiologists. This information card was given to the subject group to read prior to a verbal discussion of the risks involved with epidural analgesia. Both groups had structured interviews on the first postpartum day to discover what the women understood when they gave consent. Eleven questions about epidurals were asked, mainly focusing on potential complications.

Two hundred women participated: 100 in the pre-written information group (control) and 100 in the post-written information group. There was a statistically significant improvement ($P < 0.05$) in the number of correct answers to eight of the 11 questions when the information card was used.

What do women want to know?

In the past many anesthesiologists felt that it was unrealistic to expect the laboring woman to cope with information regarding epidural complications when she was having pain. As an essential ingredient of informed consent is providing information regarding the risks and benefits of the proposed procedure, one must ask the question "How much does the patient want to know?" Two studies addressed this issue.

Pattee *et al.*[12] surveyed 60 women during the first 2 months postpartum. One month of every 3 months was chosen for systematic sampling and eligible women were those who received epidural analgesia for an uncomplicated vaginal delivery. Approximately 50% of the women were interviewed by survey in hospital and those who were discharged early, at home via telephone call. All of the interviewers were trained by the first author. Questions were either categorical (yes/no) or scored on a 0–10 scale. The questions covered demographics as well as epidural complications that were included in the discussion prior to obtaining consent.

Sixty-five percent of the women responded that it was their first epidural. Sixty-four percent of the parturients had received opioids prior to the epidural but they were as satisfied with the consent process as were the women (34%) who had not had opioids. Women wanted all epidural complications disclosed as they considered them important. If a major complication such as death or paralysis had a risk of more than 1 : 10,000, 66% would not have an epidural. Women did not feel that distress, even though they had considerable pain (8.8/10), interfered with their ability to give consent nor did it affect their comprehension of the information provided (3.0/10). Useful information regarding the epidural came from the anesthesiologist (40%) or from prenatal courses (38%). All patients felt that information with respect to epidural anesthesia should be provided well before labor began (9.4/10).

Jackson *et al.*[13] prospectively surveyed 60 laboring women between May 1 and October 1, 1999. A single individual interviewed each woman immediately after the request for an epidural was made. All surveys were completed during the daytime and all women requesting an epidural were considered eligible. In addition to brief demographic data, a visual analog score (VAS) was completed regarding pain, anxiety and desire to have an epidural. The goals of the study were to determine what the laboring woman wanted to know before consenting to epidural analgesia and if she felt that she could understand the risks. The survey then gave a list of possible epidural complications and asked the importance of each (Table 1.3). This was followed by a series of questions (Table 1.4).

Table 1.3 Possible epidural complications discussed by Jackson *et al.*[13]

1	Headache
2	Backache
3	Infection around the spine
4	Temporary low blood pressure
5	Inability to urinate
6	Spinal anesthesia (temporary total body paralysis)
7	Convulsions
8	Death or permanent paralysis
9	Effects on baby
10	Prolongation of labor
11	Inability to walk during labor

Table 1.4 Questions asked by Jackson *et al.*[13]

1	Level of risk considered significant
2	Where they had obtained epidural information
3	Level of agreement as to whether pain/anxiety affected their ability to understand the information given
4	Whether a relative or friend would be helpful in their decision
5	Whether they felt pressure to have an epidural
6	Whether they had received a "painkiller" in labor prior to the epidural

Four women could not complete the survey: three because of labor pain and one because of the birth of her baby. Four patients did not understand what was meant by the "level of risk considered significant." Most of the women (75%) had some college or university education and 25% had epidural analgesia for a previous labor. Eighty percent realized that epidurals were not risk free and knew of alternatives and 46% had received an opioid earlier in labor. All had a high degree of pain (7.5/10) and anxiety (7.2/10) and the median length of labor prior to the request was 6 h (SD 14 h, range 1–76 h). All wanted to hear about all potential epidural complications but felt that knowing the complications would not stop them from having an epidural. They considered headache, confinement to bed and prolongation of labor as less important side-effects while seizure, death or paralysis and effects on the baby were of greater importance. Of interest, 52% of women did not want to know the incidence of the complications. The women in this survey felt less able to understand the information because of pain and anxiety (4.9/10) than those in the study by Pattee *et al.*[12]

Beilin *et al.*[18] wanted to know whether pregnant women want to have an interview with an anesthesiologist before the start of labor. On postpartum day 1, a 17-item questionnaire was given to 407 consecutive women who had given birth either vaginally or by cesarean section. The questionnaire took 10–15 min to complete. Three hundred and twenty women completed the questionnaire (79%). Fifteen percent (26) of 174 women felt that they did not receive sufficient information and 11 of these felt that the pain of labor interfered with their ability to concentrate.

Consent for anesthesia in other contexts

Overall, there are few studies involving consent for epidural analgesia for labor. However, the results from these few studies are similar to those in the general surgical population. Clark *et al.*[19] studied the risk information retained before and after either a verbal or verbal + written consent process in consecutive non-obstetric inpatients. Surprisingly, the verbal only group retained more information about anesthetic risk than did the verbal + written group. In contrast, Garden *et al.*[14] found that full disclosure of risks in 45 patients about to undergo cardiac surgery significantly increased knowledge about anesthesia. Provision of written information did not increase the level of anxiety.

There have been several studies looking at what the non-obstetric patient wants to know prior to anesthesia for surgery.[14–17] Most found that patients under the age of 50 years wanted to know more about potential complications than those over 50 years.[17] Patients in these studies wanted the opportunity to meet their anesthesiologist preoperatively and discuss their anesthetic. The studies by Pattee *et al.*[12] and Jackson *et al.*[13] also found that laboring women wanted to have all complications discussed but were reluctant to know the incidence. Because of the education level of the women in Jackson's study the results may not be applicable to all laboring women.

Although a majority of patients wish to know about complications, a survey of Canadian anesthesiologists, published in 1985, found that 48% of anesthesiologists identified at least one complication that they never discussed with their patients.[20] This complication was considered very important by the anesthesiologist. Twenty-one percent of anesthesiologists identified four or more such complications that they did not discuss.

At the same time 74% felt that their patients were seldom or never adequately informed prior to labor and over 80% felt that it was the anesthesiologist's responsibility to educate the women. It would be interesting to repeat this study today to see if the results would be similar.

Current anesthesia practice

Is a separate written consent necessary to document that informed consent has been obtained? In Canada, a written consent form does not necessarily indicate that an informed consent was obtained.[4] In the UK, the majority of obstetric anesthesiologists obtain verbal, rather than written, consent for epidural analgesia.[3] In a survey with a return rate of 60%, more American anesthesiologists indicated that they obtain separate written consent for obstetric anesthesia (for labor and cesarean section). This is in contrast to UK anesthesiologists (47% vs 22%).[21] Written consent for epidural analgesia for labor was obtained by 33% of American and 11% of UK anesthesiologists, even if the woman was judged to be mentally impaired by pain or analgesic drugs. More risks and benefits of epidural analgesia are discussed by American anesthesiologists. Royal College of Anaesthetists' tutors in Great Britain and Northern Ireland were surveyed with respect to their practice in providing information and obtaining consent.[22] There was a 77% response rate. Sixty-two percent of departments provided information on obstetric analgesia and anesthesia and 80% stated that it was possible for a woman to discuss anesthetic techniques with an anesthesiologist.

Conclusions

What can we learn from these studies? First, many laboring women want to know the risks that are involved with an epidural before they give consent. Second, knowledge of the risks does not appear to deter women from consenting to the procedure. Third, provision of written information increases the chance that a woman may recall the complications that are associated with an epidural in the postpartum period. Lastly, the studies by Pattee *et al.*[12] and Jackson *et al.*[13] found that most women wanted all of the risks associated with epidural analgesia explained prior to insertion of an epidural and that these women felt that neither pain nor previous opioid altered their ability to understand those risks. However, there still is a low rate of recall of the informed consent discussion. It is important to realize that failure to recall risk does not indicate that the informed consent process was inadequate or that the woman did not comprehend the information given at the time of the consent. It simply indicates that after a period of time the patient could not remember the information that was provided.

All of the studies are limited by small numbers, heterogeneous populations, dependency on recall of a discussion that took place when the woman was in pain and generalizability of the studies to all women requesting epidural analgesia during labor. Information provided prior to labor will allow women to make a more informed choice.

How do we deal with the woman who has a birth plan that states "no epidural" but then asks for an epidural during labor? Many anesthesiologists would withhold epidural analgesia for fear of legal repercussions. The literature does not deal directly with this issue other than in letters to the editor. Just as one can give consent, one can also change one's mind when confronted with the pain of labor. Ideally, the anesthesiologist will have seen the woman in early labor or prior to labor to ensure that she has all of the facts, understands the possible complications, has adequate time to consider her decision and is not being influenced by her caregivers, her partner or others in her room. However, if suddenly faced with a woman who had a birth plan and who has now changed her mind because of severe pain, I would insert an epidural after a discussion with the woman. I agree with Scott who stated: "It is unethical, I would maintain, to withhold pain relief from a greatly distressed woman, actually begging for an epidural, solely because of a statement written in her Birth Plan at a time of 'not knowing', which states 'I do not wish to have an epidural in labor'."[7] The only possible legal ramification may arise if a woman's birth plan states that: "Even if I change my mind when confronted with labor pain I am not to have an epidural." Known as the Ulysses directive, it may be ethically sound to administer an epidural but legally it could be interpreted as a battery.[1,23] Many anesthesiologists would argue that the woman who has written a Ulysses directive has capacity and can change her mind. Under these circumstances they would administer an epidural.[5,6] Whether an epidural is administered or not, it is important to see these

women postpartum and have a frank discussion about the issues surrounding the decision. Some women, who had indicated that they did not want an epidural and who then change their mind and receive an epidural, may feel that they have failed in that they were unable to cope with labor pain. A postpartum discussion may allay their anxiety and ensure that any questions they may have are addressed.

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