Reports of Investigation

Epidural analgesia for labour and delivery: informed consent issues

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Objective: Many anaesthetists believe that informed consent for epidural analgesia during labour is inadequate. Patients are perceived to be poorly informed and unable to cope with the information given during labour for informed consent. We reviewed these two hypotheses: A) to define complications for which patients want clear information; B) to quantify the influence of pain, anxiety, opioid premedication, and the importance of level of education, on a patient's level of satisfaction with regard to the consent process; and C) to assess how satisfactory epidural pain relief correlates with satisfaction with the consent process.

Methods: Sixty patients were surveyed during the first two months after vaginal delivery by two interviewers. Questions related to demographics, severity of labour pain, level of satisfaction with the epidural anaesthetic, risk of complications and satisfaction with information received were either categorical or scored on a scale from 0 to 10.

Results: All epidural related complications were considered important to disclose (8.4/10). The level of satisfaction with the consent process was 8.1/10. Patient satisfaction was not affected by opioid premedication, anxiety, pain score, education group or level of pain relief.

Conclusion: Patients indicated they should be informed of all possible complications associated with epidural analgesia, regardless of severity or risk. In contrast to reports in the literature, non disclosure of serious risks during labour was not acceptable to parturients.

Objectif : Plusieurs anesthésistes croient que la façon d'obtenir un consentement éclairé en vue de l'analgésie épidurale pendant le travail est incorrecte. Les patientes semblent mal informées et incapables d'assimiler, pendant le travail, les renseignements fournis au sujet du consentement éclairé. Nous avons révisé ces deux hypothèses dans le but de : A) décrire les complications pour lesquelles les patientes désirent être informées avec précision ; B) quantifier l'influence de la douleur, de l'anxiété, de la prémédication morphinique et l'importance du niveau d'éducation sur le degré de satisfaction exprimé sur le mécanisme de consentement; et C) évaluer le degré de corrélation entre le soulagement par épidurale et la satisfaction avec le mécanisme de consentement.

Méthodes : L'enquête réalisée deux mois après l'accouchement par deux sondeurs visait sur soixante accouchées par voie vacinale. Les questions en rapport avec la démographie, l'intensité de la douleur pendant le travail, le degré de satisfaction avec l'anesthésie épidurale, le risque de complications et la satisfaction avec l'information reçue exigeaient des réponses catégoriques ou graduées sur une échelle de 0 à 10.

Résultats : Il était considéré comme important de révéler toutes les complications potentielles de l'épidurale (8,4/10). Pour le mécanisme de consentement, le degré de satisfaction se situait à 8,1/10. La prémédication morphinique, l'anxiété, l'évaluation de la douleur, le niveau d'éducation et le degré de soulagement n'affectaient pas la satisfaction des patientes.

Conclusion : Les patientes ont montré qu'elles désiraient connaître toutes les complications potentielles associées à l'anesthésie épidurale, indépendamment de leur gravité et du risque encouru. Contrairement à certaines publications, la dissimulation des risques sérieux pendant le travail semble inacceptable aux parturientes.

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IN a 1985 Canadian obstetrical analgesia survey[1] of anaesthetists, 74% indicated that their patients are seldom or never adequately informed, before labour, on the topic of epidural analgesia. In addition, 80% of anaesthetists indicated that it was primarily the anaesthetists' responsibility to educate the patient but, at the same time, believed that it was unrealistic to expect the mother to cope with the informed consent information during labour. To evaluate these results further, we initiated a patient survey questionnaire:

A) to define complications for which patients want clear information;

B) to quantify the influence of pain, anxiety, opioid premedication, and the importance of level of education, on a patient's level of satisfaction with regard to the consent process; and C) to assess how the adequacy of pain relief correlated with satisfaction with the consent process.

Methods

Following Research Ethics Board approval at the Kingston General Hospital in Kingston, Canada, 60 eligible patients (a large enough sample to assume normally distributed data) were systematically sampled over one year. One month of every three months was chosen as our systematic sampling procedure. Systematic sampling is easier to perform in the field (i.e., survey type studies) and can provide greater information per unit cost than simple random sampling.[2]

Eligible patients at these sample periods were only those mothers who had an epidural for an uncomplicated vaginal delivery. All patients were interviewed by survey (in hospital) or were surveyed at home (phone call). Surveying occurred up to eight weeks after delivery. Many patients were discharged within 48 hr after birth, making in-house interviews difficult to obtain. Yet, approximately 50% (29 patients) of our sample were seen and surveyed before discharge from hospital. Interviewers were trained by the first author. Questions from the survey were either categorical (yes/no) or scored on a scale from 0 to 10. (Appendix)

Statistics methodology

Descriptive statistics, histograms, regression/correlations and analysis of variance were used to perform the analyses. Statistics were tested at the 0.05 level for significance.

Results

The demographics for all patients (n=60) with regard to age, education, and occupation are given in Tables I, II, and III respectively. For 38 (65%) patients it was their first epidural.

TABLE I Patient Age (n=60)

<20 years	6	10.0%
20–25 years	12	20.0%
26–30 years	23	38.0%
31–35 years	16	27.0%
>35 years	3	5.0%

TABLE II Occupation (n=60)

homemaker	21	35.0%
student	5	8.3%
employed	31	51.7%
unemployed	3	5.0%

TABLE III Education (n=59) (one patient did not respond)

High School Graduate	14	23.7%
Community College Graduate	31	52.5%
University Graduate	14	23.7%

Pain relief with the epidural was statistically significant ($P = 0.001$) (Figure 1). On average, pain decreased by 70% (6.67 units on a scale of 0 to 10).

All epidural related complications in the questionnaire were considered to be important to be disclosed during the informed consent process (8.4/10 on average). Patients wanted all complications discussed before consenting; particularly, those complications which were associated with the highest morbidity and mortality: convulsions, death/paralysis and effects on the baby (9.3/10; 9.4/10 and 9.4/10, on average respectively). The complication considered to be least important, and different from the others, was "inability to walk once they have the epidural" (7.0/10 on average; $P = 0.0001$). (Figure 2)

Thirty-seven (64%) patients received opioids for pain relief before the administration of the epidural. However, there was no difference between the two groups, receiving opioids and not receiving opioids, with respect to patient satisfaction with the consent process (P = NS). The degree of satisfaction was also not correlated with either anxiety score (r=0.048) or pain score (r=0.013). There was no difference between education group (high school, community college, university) and patient's satisfaction with the information received during consent.

Sixty percent (36/60) of patients, would choose the epidural, even if the risks were high, if the complication was minor (backache, urinary retention). On the other hand, 66% (38/50) would not consider epidural analgesia when the complication was serious, such as death/paralysis, and had a risk > 1/10,000.

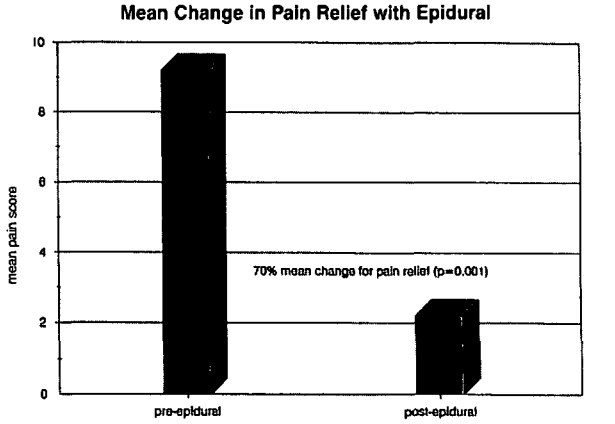

FIGURE 1 Decrease in mean pain score (VAS scale: 0–10) with epidural analgesia. Pain decreased by 70% on average. ($P < 0.001$)

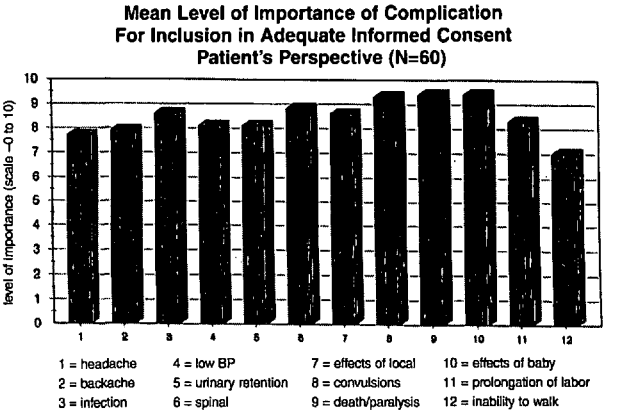

FIGURE 2 Mean level of importance (VAS scale: 0–10), for each possible outcome/complication associated with the epidural, that patients thought should be disclosed during the consent process.

Thirty percent (18/60) of patients perceived side-effects from the epidural. (Table IV) Three patients(5%) had no pain relief with their epidural, six (10%) had backaches after labour and delivery, three (5%) had headaches, two (3.3%) had urinary retention, two (3.3%) had a rash, one (1.6%) had a prolonged (weeks) "deadlike" feeling in her legs, and one (1.6%) had temporary (hours) loss of speech. Patients with side-effects were more likely to score their consent process at a lower level of satisfaction than patients without side effects (3.1/10 *vs* 7.1/10 respectively; $P = 0.001$). However, there was no difference between the group with no side-effects and the patients who had side effects, with respect to disclosure of all possible complications associated with the epidural.

In this study, patients also indicated (8.8/10) that the distress they experienced during labour was great; but this discomfort did not interfere with their ability to hear and comprehend the information associated with the consent process. When asked if the discomfort of labour interfered with their comprehension of the consent process, the average score was low (3.0/10).

The most useful information received, with regard to the epidural, was from either the doctor who administered the epidural, (24) 40%, or from a prenatal education course, (23) 38%. Further details are given in Table V.

All patients agreed the consent process should be done well before labour begins (9.4/10 on average) and there was no difference among any subgroups of patients with regard to this aspect of the consent process.

TABLE IV Perceived Side Effects (n=60)

No Pain Relief	3	5.0%
Backaches	6	10.0%
Headaches	3	5.0%
Urinary Retention	2	3.3%
Rash	2	3.3%
"Dead" feeling in legs	1	1.6%
Loss of speech ability	1	1.6%
No side effect	42	70.0%

TABLE V Useful Information Received with Regard to Epidural

Anaesthetist	24	40.0%
Prenatal Education Course	23	38.0%
Family Doctor	3	5.0%
Obstetrician	6	10.0%
Obstetrical Nurse	1	1.6%
Reading Material	3	5.0%

Discussion

This study demonstrated that obstetrical patients like to know about all possible complications of epidural analgesia during the consent process, regardless of how small the risks are, and preferably before the onset of labour. It was particularly important for patients to know about complications with greatest morbidity and mortality before consenting to the epidural. In addition, the discomfort of labour was not reported to interfere with their ability to comprehend information associated with the consent process. This result is in contrast to the report that 80% of anaesthetists felt that it was unrealistic to expect the patient to cope with information regarding complications during labour.[1] Sixty-four percent of our patients had received opioids before the administration of the epidural and hence

before the informed consent process. This may affect the validity of the informed consent process and may make it inadmissible in court.[3] This study also indicated that the degree of satisfaction of patients may be dependent upon outcome as there was a difference between the group of patients who perceived a complication and the group who perceived no after effects from the epidural, with regard to their respective mean levels of satisfaction with the consent process.

The evidence from this survey indicates that patients are not consistently satisfied with the oral consent process that is typically used prior to the epidural. The Canadian Medical Protective Association (CMPA) clearly states,[4] that "Although orally expressed consent may be acceptable in some circumstances, frequently there is need for WRITTEN confirmation. As physicians have often observed, patients can change their minds or may not recall what they authorized." In these cases, the literature states that these patients will be supported in a court of law.[3] Thus, we would support the view that it may be prudent to obtain written signed consent, after full disclosure of risks, for epidural analgesia during labour and preferably before the onset of labour.

In Canada, the present required legal standard of disclosure requires a physician to disclose all those consequences and risks which would be material to a reasonable patient (i.e., the full disclosure standard).[5] There may be however, some uncertainty as to what in fact does constitute a material risk. The Supreme Court of Canada defines a material risk as follows: even if a risk is a mere possibility, yet if it carries with it serious consequences, such as paralysis or death, it should be regarded as material and therefore requires disclosure.[5] The results of this survey study clearly demonstrate that this is the standard patients want.

With regard to the literature which suggests that patients who are more educated are those who may wish for maximum explanation of risks,[1] our results indicated that the level of education cannot be used to identify those who desire greater explanation of possible complications associated with the epidural for labour and delivery. Similar results have been reported elsewhere.[6]

The retrospective nature of this study introduces the aspect of recall bias. We are presently initiating a study designed to document what the patient's preference is regarding receiving information regarding informed consent immediately prior to initiating epidural anaesthesia.

Conclusion

In summary, obstetrical patients stated they wanted to be informed about all possible complications of epidural analgesia regardless of severity or risk and preferably before the onset of labour. This study found that patients do not agree with non-disclosure of serious risks because of apparent distress and did not report that pain, anxiety or previous opioid analgesia interfered with their ability to comprehend the informed consent process. Nevertheless, 36% of patients were not satisfied with the oral informed consent. Our results suggest that our centre may be advisable to introduce a standardized written informed consent process for obstetrical epidurals before the onset of labour or as early in labour as practical.

References

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ANAESTHESIA SURVEY

We are interested in finding out your level of satisfaction with the epidural anaesthetic you received for your recent labour and delivery. We would also like to know if you felt you received adequate information to help you decide if you wanted an epidural or not.

Demographic data: Circle all that apply.

1 Age:
  1) under 20
  2) 20–25
  3) 25–30
  4) 30–35
  5) over 35

2 Occupation:
  1) Homemaker
  2) Student
  3) Disabled
  4) Unemployed
  5) Employed: Type of work

  _____

3 Education: _____

4 Previous epidural: Yes ____ No ____

5 How severe was your labour pain prior to receiving your epidural? (Place an X on the line at the point of corresponding to the severity of your pain.)
Worst pain _____ No pain

6 How severe was your labour pain after receiving your epidural?
Worst pain _____ No pain

7 How satisfied were you with the pain relief from the epidural?
Very Satisfied _____ Very Dissatisfied

8 How anxious were you during labour prior to your epidural?
Very Anxious _____ No Anxiety

9 How anxious were you during labour after receiving your epidural?
Very Anxious _____ No Anxiety

10 How pleasant did you find the experience of having the epidural inserted?
Very Unpleasant _____ Very Pleasant

11 How pleasant did you find the interpersonal manners of the physician who gave you your epidural?
Most Unpleasant _____ Most Pleasant

12 Are you aware that you experienced any unpleasant side-effects from the epidural?
Yes ____ No ____

Explain _____

13 How did the epidural compare to your expectations?
Better than I expected _____ Not as good as I expected

14 How satisfied were you overall with your epidural?
Very Satisfied _____ Very Dissatisfied

15 How badly did you want to have an epidural?
Very Badly _____ Not at all

16 Would you desire to have an epidural for a subsequent delivery?
Strong Desire _____ No Desire

The following is a list of possible complications of epidural anaesthesia. Please indicate how important it is to you that you be informed about the existence of the risk of this complication.

17 Headache:
Extremely Important _____ Not at all

18 Backache:
Extremely Important _____ Not at all

19 Infection:
Extremely Important _____ Not at all

20 Lowered blood pressure:
Extremely Important _____ Not at all

21 Inability to pass water:
Extremely Important _____ Not at all

22 Spinal Anaesthesia:
Extremely Important _____ Not at all

23 Side effect of Local Anaesthetic:
Extremely Important _____ Not at all

24 Convulsions:
Extremely Important _____ Not at all

25 Death/Paralysis:
Extremely Important _____ Not at all

26 Effects on baby:
Extremely Important _____ Not at all

27 Effect on course of labour:
Extremely Important _____ Not at all

28 Inability to walk during labour:
Extremely Important _____ Not at all

For each of the complications listed below circle one response to indicate how satisfied you were with the information you received.

a) Not discussed, but I would have liked to
b) Not discussed, but I don't care
c) Discussed: Very satisfied
d) Discussed: Moderately satisfied
e) Discussed: Unsatisfied

29 Headache: a b c d e

30 Backache: a b c d e

31 Infection: a b c d e

32 Lowered blood pressure: a b c d e

33 Inability to pass water: a b c d e

34 Spinal anaesthesia: a b c d e

35 Side effects of local: a b c d e

36 Convulsions: a b c d e

37 Death/Paralysis: a b c d e

38 Effects on baby: a b c d e

39 Effects on course of labour: a b c d e

40 Inability to walk during labour: a b c d e

For each of the complications listed below indicate the level of risk that you would consider significant.

a) A risk greater than one in ten
b) A risk greater than one in a hundred
c) A risk greater than one in a thousand
d) A risk greater than one in ten thousand
e) A risk greater than one in a million
f) Don't consider the complication significant
g) Consider the complication significant but don't want to be told the actual number.

41 Headache: a b c d e f g

42 Backache: a b c d e f g

43 Infection: a b c d e f g

44 Lowered blood pressure: a b c d e f g

45 Inability to pass water: a b c d e f g

46 Spinal Anaesthesia: a b c d e f g

47 Side effects of Local Anaesthesia: a b c d e f g

48 Convulsions: a b c d e f g

49 Death/Paralysis: a b c d e f g

50 Effect on baby: a b c d e f g

51 Effects on course of labour: a b c d e f g

52 Inability to walk during labour: a b c d e f g

53 The distress I was feeling during labour decreased my ability to comprehend fully the information I was given about the epidural.

Strongly Agree _____ Strongly Disagree

54 I believe that women should receive information about the option of epidural anaesthesia well before labour begins:

Strongly Agree _____ Strongly Disagree

55 The most useful information regarding the epidural was given to me by: (Circle all that apply.)

a) my Family Doctor
b) the doctor who gave the epidural
c) the obstetric doctor
d) the nurses on the labour ward
e) family/friends
f) Prenatal class
g) other

56 Even though I was distressed during my labour I feel I was able to fully understand the information I was given regarding the epidural.

Strongly Agree _____ Strongly Disagree

57 How satisfied are you with the information you were given by the doctor giving your epidural?

Very Satisfied _____ Very Dissatisfied

58 In general, I feel that I received the information that I needed in order to make a decision about having an epidural.

Strongly Agree _____ Strongly Disagree

59 I didn't want to have an epidural but felt I was forced into having one by other people.

Strongly Agree _____ Strongly Disagree

60 Are you aware if you received any pain killers prior to having the epidural?

Yes ____ No ____

Unsure _____