Anaesth Intensive Care 2006; **34:** 254-260

Issues of Consent for Regional Analgesia in Labour: A Survey of Obstetric Anaesthetists

J. D. B. BLACK*, A. M. CYNA†

Department of Women's Anaesthesia and Department of Obstetrics and Gynaecology, Children's Hospital and University of Adelaide, Adelaide, South Australia, Australia

SUMMARY

Anaesthetists are legally obliged to obtain consent and inform patients of material risks prior to administering regional analgesia in labour. We surveyed consultant members of the Australian and New Zealand College of Anaesthetists with a special interest in obstetric anaesthesia, in order to identify and compare which risks of regional analgesia they report discussing with women prior to and during labour. We also asked about obstetric anaesthetists' beliefs about informed consent, the type of consent obtained and its documentation. Of 542 questionnaires distributed, 291 responses (54%) were suitable for analysis. The five most commonly discussed risks were post dural puncture headache, block failure, permanent neurological injury, temporary leg weakness and hypotension. Obstetric anaesthetists reported discussing a mean of 8.0 (SD 3.8) and 10 (SD 3.8) risks in the labour and antenatal settings respectively. Nearly 20% of respondents did not rank post dural puncture headache among their top five most important risks for discussion. Seventy percent of respondents indicated that they believe active labour inhibits a woman's ability to give 'fully informed consent'. Over 80% of respondents obtain verbal consent and 57 (20%) have no record of the consent or its discussion. Obstetric anaesthetists reported making a considerable effort to inform patients of risks prior to the provision of regional analgesia in labour. Verbal consent may be appropriate for labouring women, using standardized forms that serve as a reminder of the risks, and a record of the discussion. Consensus is required as to what are the levels of risk from regional analgesia in labour.

Key Words: informed consent, labour pain, analgesia, epidural, intrathecal, obstetrical, disclosure, pregnant women

Consent for labour regional analgesia has been a source of confusion and concern for anaesthetists, due to a number of actual and perceived difficulties. Anaesthetists are legally obliged both to obtain consent and to inform the patient of material risks prior to administering a procedure[1-3]. In the situation of regional analgesia during labour, anaesthetists have a duty to obtain consent to the same standards demanded for a surgical procedure. Failure to do so might constitute assault[1]. Issues that have caused concern include: the question of a woman's capacity (to give consent) while in labour; the urgency with which some women demand the procedure; the presence of any 'anticipatory directives' made by the woman; and external pressures on the woman to accept or refuse a regional technique[1,3,4]. These issues have been examined by a number of commentators[1,3,5-7]. Material risks of regional analgesia during labour, and the significance placed on each risk, have been examined from the patient's point of view[5,6]. The High Court of Australia has provided guidelines for determining which risks are 'material'. These include the nature of the risk and the degree of urgency[8]. The use of low-dose local anaesthetic epidural techniques has changed the risk profile of regional analgesia in labour[9]. The current attitudes and practices of anaesthetists obtaining consent for regional analgesia in labour have not been examined. We aimed to identify and compare which risks of regional analgesia anaesthetists report discussing with women in the labour and antenatal settings. In addition, we asked whether obstetric anaesthetists (OAs) believed it was possible to obtain informed consent and how consent is obtained and documented.

METHODS

A questionnaire, based on the regional analgesia risks discussed by Kelly et al[6], was piloted by ten OAs working in our tertiary level maternity unit. The

* M.B., B.S., Anaesthetic Senior Registrar, Department of Women's Anaesthesia, Women's and Children's Hospital, Adelaide, South Australia.
† D.R.C.O.G., Dip.Clin.Hyp., F.R.C.A., Consultant Anaesthetist, Department of Obstetrics and Gynaecology, University of Adelaide, Adelaide, South Australia.

Address for reprints: Dr Allan M. Cyna, Dept Women's Anaesthesia, Women's and Children's Hospital, 72 King William Road, Adelaide, S.A. 5006, Australia.

Accepted for publication on November 11, 2005.

final version of the survey was approved by the Chair of the Obstetric Anaesthesia Special Interest Group (OASIG) of the Australian and New Zealand College of Anaesthetists (ANZCA), the Australian Society of Anaesthetists and the New Zealand Society of Anaesthetists. It was then published on the Internet (see Appendix). In order to maintain respondent anonymity, access to our survey was emailed by an administrative officer of ANZCA to all 542 members of the OASIG with a current email address. Each member was allocated an ID number and password by the College and invited to visit the survey website, where the survey could be completed online or by downloading a paper version. Three follow-up emails were sent to non-respondents over an eight-week period during September and October 2004.

The survey asked for demographic information relating to the OA's practice, years of experience, number of sessions practised in the field of obstetric anaesthesia and their preferred method of regional analgesia in labour. We then asked respondents to consider two scenarios regarding the information they discuss with a '23-year-old primip' while gaining consent for regional analgesia in labour. These were, respectively, during labour (Scenario L) and in the antenatal clinic (Scenario A) (see Appendix). For scenarios L and A, anaesthetists were asked to indicate whether they would usually discuss each of 20 risks identified. Respondents were asked to give risk frequencies if routinely mentioned. They were also asked to rank, from their point of view, the five 'most important' risks to discuss prior to performing regional labour analgesia. In addition, respondents were asked whether they believed it were possible to gain fully informed consent under each scenario. In the case of a 'No' response to the second scenario (A), they were asked to consider the consent of a multiparous woman in the antenatal setting (Scenario AM). Lastly, they were asked to indicate whether they obtain verbal or written consent and whether they document the discussion and consent process. Consent was defined as the patient agreeing to undergo the procedure. Reasons for excluded surveys are detailed below. For each item on the survey the denominator was taken as the total number of responses to that question. Duplicate surveys were identified and conflicting data were excluded from analysis. Comparative data are presented.

RESULTS

A total of 342 responses was received from 319 OAs (59%) with 291 responses (54%) being suitable for analysis. One hundred and twenty-eight respondents (44%) provided obstetric anaesthesia in Private Practice, 112 (39%) as Staff Specialists and 50 (17%) as Visiting Medical Officers (VMOs). Two hundred and twenty respondents (76%) had more than five years experience as a specialist anaesthetist. Two hundred and sixty-one respondents (90%) indicated their preferred technique for labour analgesia was 'epidural'. One indicated 'Other' but did not provide details, while the remaining 24 respondents indicated 'combined spinal epidural (CSE)'.

The main results are presented in Figures 1-4 and Tables 1-3. The risks reported in the 'other' fields by respondents included: side-effects; shivering; pruritus; paraplegia/paralysis; pain with insertion; pain with injection; technical difficulty; partial/patchy/imperfect block; sedation; spinal; vascular injection; repeat procedure; paraesthesia; neurological damage; prolonged labour; financial consent; unable to perform procedure; catheter migration; blood patch; general statement of risk; serious complications; intracranial haemorrhage; incidental injury (e.g. falls); pressure injury; difficulty breathing and confinement to bed.

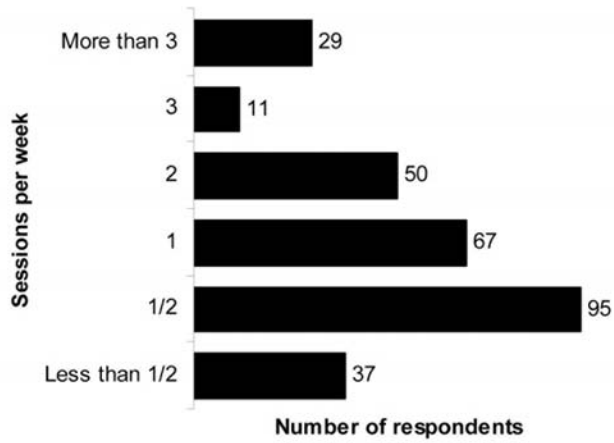

FIGURE 1: Respondents categorized by the 'average number of sessions per week' worked in the field of obstetric anaesthesia.

DISCUSSION

This is the first national survey in which OAs have been asked to identify and prioritize the risks they discuss with women regarding labour regional analgesia in both the acute and antenatal settings. The majority of OAs reported making a considerable effort to inform their patients of the risks of regional analgesia for labour. The most commonly discussed risks are: post dural puncture headache (PDPH), block failure, permanent neurological injury, temporary leg weakness, hypotension, temporary neurological injury, infection and haematoma. This is true for both the acute and antenatal settings. With the exception of haematoma, all these risks were identi-

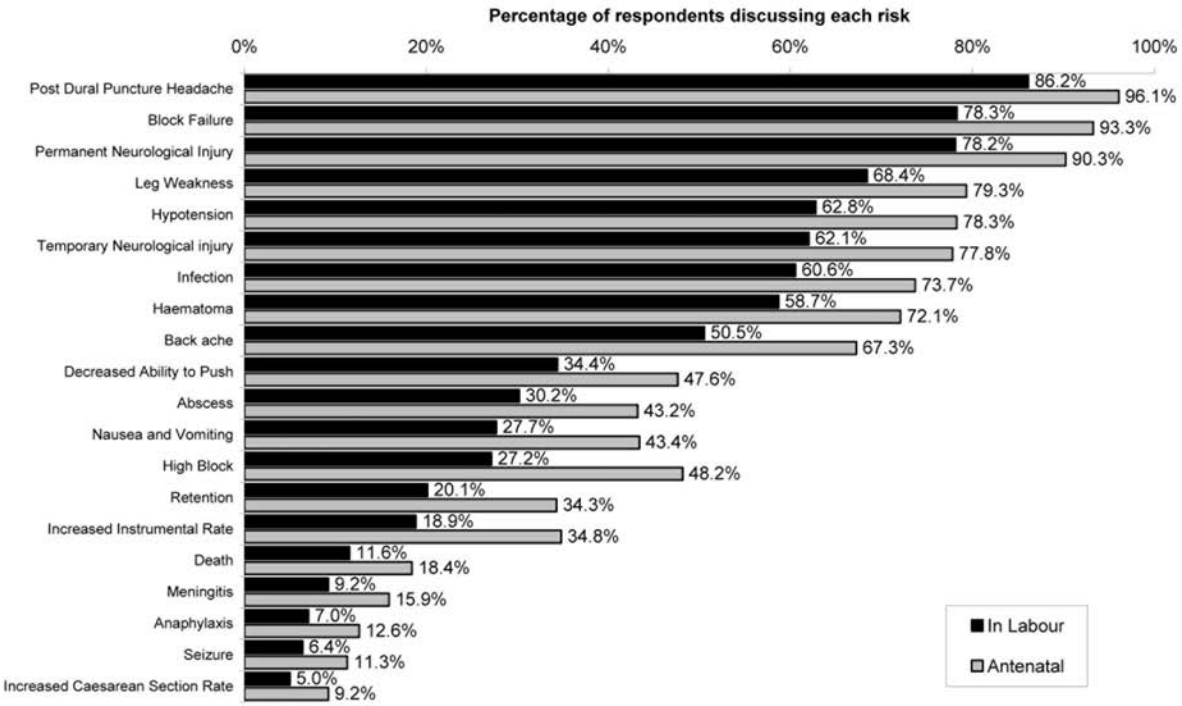

FIGURE 2: The percentage of respondents who report discussing the presented risks, prior to provision of regional analgesia in the settings of labour (Scenario L) and at an antenatal clinic (Scenario A).

TABLE 1

A summary of the range of incidences quoted by obstetric anaesthetists when discussing risks for regional analgesia in labour

Risk	Rates quoted by respondents	Published rates
Post dural puncture headache	1/1000-3/100; Mode=1% (n=57) 0.5% (n=37); 'Very rare'-'Sometimes'	0.5-1.0%[18,19]
Failure of block	1/5000-1/5; Complete: 'Rare'; Partial or unsatisfied: 'Common'; 1/10	0.9%-4.7%[18]
Permanent neurological deficit	1/1000-1 in a million; 'Exceedingly rare'-'Rare'	Mono-neuropathy: 1:11 000[18] Cord/root: 1:80,000-100,000[18]
Temporary leg weakness	1/10,000-100%; 'Due to obstetric causes'; 'Very rare'	
Hypotension	1 in 200 to 100%; 'Common' (2/5ths of respondents); 'Occasional'; some explanation of LA strengths and hypotension	'Infrequent if avoiding high doses and supine posture'[18]
Temporary neurological deficit	1/100 000-1%; 'Very rare'; 'Occasional'	1:2200 Usually due to obstetric or surgical causes[19]
Infection	1/100,000; 'Unbelievably rare'; 'Rare'	Unknown[20]
Haematoma	'Unbelievably/extremely/very rare'-'Uncommon'; 1/500,000-1/5000	
Back ache	'Common but not increased by EDB'; 'rarely chronic'; 'temporary'	
Decreased ability to push	'Not a problem'; 'depends on dose/management'; 'common'	
Abscess	1/100,000-1/5000; 'Exceedingly rare'-'Rare'	
Nausea and Vomiting	1/100-70%; 'Common'; 'Uncommon'; 'Rare'; Related to other factors	
High block	'Extremely rare'-10% (LSCS comment)	1:1400[18]
Urinary retention	1/100; 'Common'; 'Institutional practice'; 'Rare'	Persistent 3-6 months: if not catheterised-1:12,500[19]
Increased instrumental delivery rate	'8-50% increase [in rate]'; 'Not due to epidural'; 'Multi-factorial'; 'Debatable'	
Death	'Remote'; 'Unbelievably rare'; Routine [to mention] as part of GA discussion	None in the U.K. Confidential Enquiry 2000-2002[21]
Meningitis	1/100,000-1/5000; 'Exceedingly rare'	<1:50,000[19,20]
Anaphylaxis	'Extremely rare'	?1:100,000[19]
Seizure	1/100-1/20,000; 'Rare'; 'Usually not [due to] epidural'; Careless IV injection'	<1:11,000[18] diminishing as a result of modern techniques
Increased caesarean section rate	Not due to epidural (n=4); common (n=1); sometimes (n=2); no comment (n=18)	Not a risk[22]

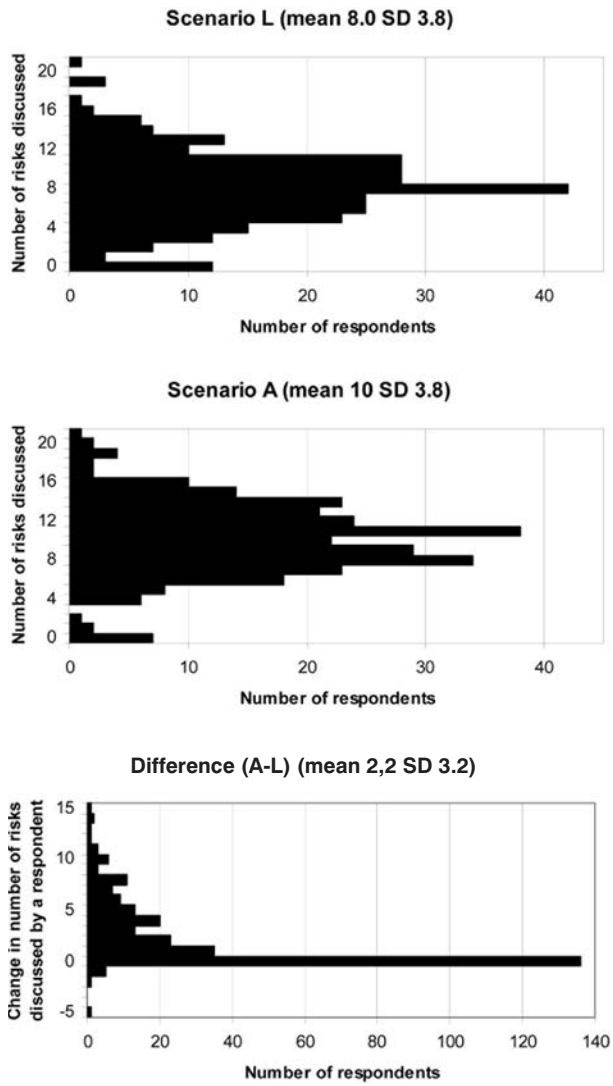

FIGURE 3 Respondents categorized by the number of risks they discuss for regional analgesia in the settings of labour (Scenario L) and an antenatal clinic (Scenario A); and the difference (A-L) in the number of risks they discuss in each setting.

fied by a majority of women surveyed by Kelly et al as information they would like to know prior to regional analgesia[6]. Less than half the OA respondents discuss urinary retention and nausea and vomiting, which was desired information by over 80% of Kelly et al's respondents[6]. Although 96% of OAs reported discussing PDPH, nearly 20% did not place it among their 'top 5 most important risks' for discussion. PDPH is the only risk relating to regional analgesia that has been identified, by the Australian courts, as a 'material risk'[10]. In Jackson et al's survey, women identified four risks (of 11 presented) that were more likely to change their minds about having regional analgesia. These were: 'any effects on the baby', 'death or paralysis', 'seizure', and 'infection'[5].Only two of these risks, 'paralysis' and 'infection', are ranked by our respondents within the six most important; and less than 20% of OAs report discussing seizures or death. A doctor's duty of care is to disclose all 'material risks' to their patients. A risk is material if a 'reasonable person' might attach 'significance' to it, but it does not need to be significant enough to change the patient's mind[10]. Information about what might constitute 'material risk' includes that which could be termed 'consumer information' as well as that which is important to the decision making process. The studies by Jackson et al[5] and Kelly et al[6] together with ours, suggest that some anaesthetists may need to reconsider discussing common side effects and rare complications (e.g. seizures). The onus remains with the doctor to elicit the extent of information each patient wishes to know, prior to consent[1].

The quoted incidence of a risk plays an important part in a patient's assessment of the significance of the risk to them self. One of the most striking findings of our survey was the range of incidences quoted by anaesthetists when discussing some risks. The majority of OAs reported giving an incidence for PDPH between 0.5 and 1%, which is consistent with the published literature on this topic[11]. Our respondents also consistently reported informing women that long-term backache was not associated with regional analgesia, and this is also supported by good evidence[12]. We were surprised, however, to find that more than 60% of OAs discuss hypotension and ranked it fourth most 'important risk to discuss'. Furthermore, many consider hypotension a 'common' event, some suggesting that it is inevitable. One can only presume these respondents either use traditional epidural techniques using high-concentration local anaesthetic or were erroneously reporting the risk associated with caesarean-related blocks.

In Kubli et al's randomized controlled trial of fluid pre-loading before low dose epidural analgesia for labour, none of 168 participants required vasoactive drugs for hypotension[9]. In the absence of venacaval compression, one might question whether hypotension is a material risk when low-dose epidural analgesia or CSE is offered. Regional analgesia is also not associated with increased caesarean section rates[13-15], yet 18 respondents (6%) reported informing patients that this is a risk. Respondents reported a wide range of incidences for various other risks, such as nausea and vomiting, temporary leg weakness, reduced ability to push, high block and instrumental delivery. Most of these risks are multifactorial, being influenced by factors such as the combination or dose of neuraxial medication or obstetric factors. Inaccurate information, conflict-

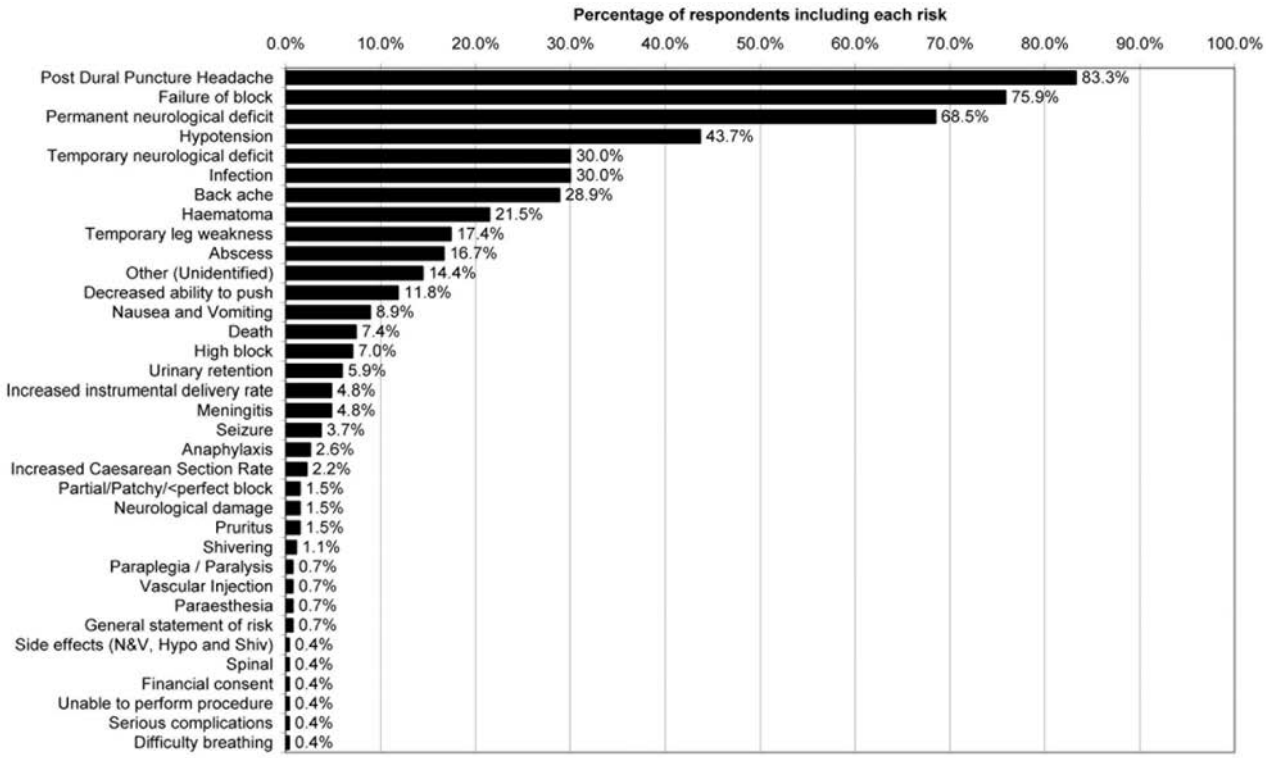

FIGURE 4: The percentage of respondents ranking each risk in their five 'most important risks' to discuss.

TABLE 2

Summary of obstetric anaesthetists' responses to the question 'Do you believe it is possible to get fully informed consent' from a 23 yr old woman, in three separate scenarios. (n=285)

Scenario L	A	AM*	n	%	Possible interpretation of response:
Yes	Yes	-	48	(17%)	Ability to consent not affected by active labour or lack of prior experience
No	Yes	-	176	(63%)	Ability to consent affected by active labour but NOT lack of prior experience
Yes	No	Yes	2	(<1%)	To give consent patient must have experienced labour. Active labour—no effect
Yes	No	No	1	(<1%)	Must be IN active labour in order to give consent
No	No	Yes	20	(7%)	Ability to consent affected by active labour AND lack of prior experience
No	No	No	38	(12%)	Never possible. ?reason

L=In Labour for the first time.A =Antenatal, nulliparous. AM=Antenatal, multiparous. *Only asked if response to scenario 'A' was 'no'.

TABLE 3

How obstetric anaesthetists gain consent for regional analgesia in labour, and whether they document the process (n=291)

Type of consent	Verbal	239 (82%)	Written	47 (16%)	Missed/Excluded	5 (2%)
Document discussion	Yes	217 (75%)	No	71 (24%)	Missed/Excluded	3 (1%)

ing advice and differing practices amongst OAs may cause patient confusion and mistrust. Knowledge of the evidence base supporting risk information, as well as local and personal audit, help provide accurate information so that patients can attach an appropriate level of significance to the risk.

Consent beliefs

The majority (70%) of OAs reported that they believe active labour inhibits a woman's ability to give consent. Brooks and Sullivan state that although pain, distress and drugs may inhibit a woman's capacity (legal competence to give consent), the available evidence suggests if a woman had capacity before labour, she usually maintains it in labour[3]. Nevertheless patients should be informed about labour analgesic techniques in the antenatal period where possible[3-5]. The urgency of the labour situation

may alter the amount of information given, but the extent of this should be determined by the patient and documentation should reflect this[10].

Approximately 20% of OAs indicated that they believe a 'primip' is incapable of giving antenatal consent. These respondents apparently believe that the unknown (in this case the actual experience of labour pain) prevents a woman from being fully informed. We disagree with this point of view. One can inform a nulliparous woman that she 'may experience pain beyond that which she can imagine possible', and if she chooses to disbelieve it, she is still informed to the degree possible in the given circumstances. Consequently, her consent or refusal is valid. A woman who refuses an epidural antenatally is merely expressing, at that time, a wish not to have one. Whether set out as a refusal 'no matter what I say' (the Ulysses directive) or simply as a negative desire in a birth plan, it amounts to the same thing[3].

Consent and refusal are decisions that can be changed at any time while a patient maintains capacity[3,7]. In the U.K., an anticipatory directive is only valid if the circumstances in which it is intended to apply and those arising are the same[1]. So when the circumstances change, such as a woman experiencing pain more severe than she had imagined, it is reasonable to perform regional analgesia if requested. Brooks and Sullivan state that there are opposing arguments, and that there is a legal risk[3]. Good communication and an understanding of the ethical and legal considerations are the best means of optimizing patient care while respecting patients' autonomy.

Type of consent and documentation

The majority of OAs (75%) reported documenting the risk discussion, and most considered that verbal consent is more appropriate for labouring women. Some respondents use locally designed forms for consent and documentation, while others use the Australian Society of Anaesthetists brochure[16]. The majority reported making some form of documentation in the medical record. Of the 71 OAs (25%) who do not document the discussion, 57 (20%) obtain verbal consent only, indicating that no written record of consent is kept. Medical defence organizations (MDOs) recommend that documentation is essential. The courts have favoured a patient's recollection of events over that of a doctor's—even when it was the doctor's 'usual practice'[10]. A number of OAs reported that they document the presence of partners, midwives and other witnesses during the consent discussion. MDOs and ANZCA provide recommendations for how to document consent. It might be useful to provide a form that recognises local risk rates and on which the name and signature of at least one independent witness (midwife, and possibly the birth partner) can be recorded.

Limitations

Although we attempted to contact all OAs associated with ANZCA, 139 of the 681 members of the OASIG did not have a current email address registered. In addition, some OAs may not be members of the OASIG. Our response rate was a little disappointing and could have reflected some reports of difficulty with our web questionnaire and downloading the paper version. The majority of respondents were, however, experienced anaesthetists with regular obstetric exposure.

This is a survey of reported practice, rather than observed practice. As such, the responses may not reflect practice accurately. The survey emphasised that the regional analgesia in question was for labour and not caesarean section, however a few respondents answered questions in a manner that suggested they were discussing consent for surgery. For example, it is unlikely that a neuraxial block for labour analgesia would cause a high block in 10% of cases; nor is conversion to general anaesthesia relevant to this setting.

In the survey scenarios, we used the common descriptor term 'primip' because in our institution this is used freely, by both obstetricians and anaesthetists, to describe a gravid, nulliparous woman. Alongside the term 'multip' this wording appears to have been interpreted as intended and only one respondent commented on this ambiguity ('primip' and primipara do not have the same meaning[17]) but confirmed they had assumed we meant nulliparous.

The questions identifying beliefs regarding consent were posed in the context of the scenarios, because we felt it was better to maintain the focus of the survey on them. However, less interpretation may have been required had we asked direct questions such as: "Does active labour prevent a woman giving fully informed consent?"

CONCLUSION

The majority of respondents to our survey believe that they cannot get fully informed consent from a nulliparous woman in labour. However, the majority also reported that they discuss more than seven risks with their patients prior to the provision of regional analgesia and that they document the discussion. A fifth of the respondents reported that they have no record of consent or the risk discussion. A few discuss risks that, according to available evidence, are not

associated with regional analgesia in labour. Verbal consent may be appropriate for labouring women; possibly using standardized forms that can serve as both a reminder of the risks and a record of the discussion. Consensus is required as to what are the levels of risk from regional analgesia in labour.

ACKNOWLEDGEMENTS

We thank those anaesthetists who submitted a response and Juliette Mullumby at ANZCA for organizing the anonymous distribution of our survey. We also thank Craig Hirte and Peter Baghurst for statistical advice, and Geoffrey Black (Wallmans Lawyers) for advice on legal aspects discussed in the manuscript.

REFERENCES

1. White S, Baldwin T. Consent for anaesthesia. Anaesthesia 2003; 58:760-774.
2. Danbury C. General principles of consent. Anaesthesia 2003; 58:281.
3. Brooks H, Sullivan W. The importance of patient autonomy at birth. Int J Obstet Anesth 2002; 11:196-203.
4. Pattee C, Ballantyne M, Milne B. Epidural analgesia for labour and delivery: informed consent issues. Can J Anaesth 1997; 44:918-923.
5. Jackson A, Henry R, Avery N, VanDenKerkhof E, Milne B. Informed consent for labour epidurals: what labouring women want to know. Can J Anesth 2000; 47:1068-1073.
6. Kelly G, Blunt C, Moore P, Lewis M. Consent for regional anaesthesia in the United Kingdom: what is material risk? Int J Obstet Anaesth 2004; 13:71-74.
7. Meek T. Consent issues in obstetric anaesthesia [letter]. Anaesthesia 2003; 58:404-406.
8. Skene L, Smallwood R. Informed consent: lessons from Australia. BMJ 2002; 324:39-41.
9. Kubli M, Shennan AH, Seed PT, O'Sullivan G. A randomised controlled trial of fluid pre-loading before low dose epidural analgesia for labour. Int J Obstet Anesth 2003; 12:256-260.
10. Lawrence v NT of Australia & Others [2001] NTSC 37. Available from: http://www.nt.gov.au/ntsc/doc/judgements/2001/0/NS000570.htm
11. Weeks S. Postpartum Headache. In: Chestnut DH, editor. Obstetric anaesthesia. St. Louis: Mosby; 1999, 621-638.
12. Howell CJ, Kidd C, Roberts W, et al. A randomised controlled trial of epidural compared with non-epidural analgesia in labour. BJOG Obstet Gynaecol 2001; 108:27-33.
13. Howell C. Epidural versus non-epidural analgesia for pain relief in labour (Cochrane Review). The Cochrane Library 2004; Chichester, UK: John Wiley & Sons, Ltd.
14. Decca L, Daldoss C, Fratelli N et al. Labor course and delivery in epidural analgesia: a case-control study. J Matern Fetal Neonatal Med 2004; 16:115-118.
15. Gaiser R. Labor epidurals and outcome. Best Pract Res Clin Anaesthesiol 2005; 19:1-16.
16. Harris A. Epidural—Anaesthesia and You: Australian Society of Anaesthetists. Available from: http://www.asa.org.au
17. Stedman TL. Medical Dictionary. 25th-Illustrated Ed. Hensyl WR ed. Baltimore: Williams & Wilkins; 1990, p. 1131.
18. Paech MJ, Godkin R, Webster S. Complications of obstetric epidural analgesia and anaesthesia: a prospective analysis of 10 995 cases. Int J Obstet Anesth 1998; 7:5-11.
19. Scott DB, Tunstall ME. Serious complications associated with epidural/spinal blockade in obstetrics: a two year prospective study. Int J Obstet Anesth 1995; 4:133-139.
20. Reynolds F. Infection as a complication of neuraxial blockade. Int J Obstet Anesth 2005; 14:183-188.
21. Confidential Enquiry into Maternal and Child Health. Why Mothers Die 2000–2002: The Sixth Report of the Confidential Enquiry into Maternal Death in the United Kingdom. London: RCOG Press, 2004.
22. Cammu H,Martens G,Van Maele G. Epidural analgesia for low risk labour determines the rate of instrumental deliveries but not that of caesarean sections. J Obstet Gynaecol 1998; 18:25-29.

APPENDIX

Below are the scenarios used in the survey and a list of the risks presented. The original survey is available at the following website for an indefinite period from the time of printing: http://au.geocities.com/sandjblack/survey

Scenario 1 (renamed L for Labour)

23 year old woman, primip, in established labour. Her cervix is 4 cm dilated; she is in moderate distress and is requesting a regional block (CSE/Epidural). She has no past medical history of note.

Scenario 2 (renamed A for Antenatal)

23 year old woman, primip, presents to clinic 1 week before term and wishes to discuss regional analgesia (CSE/Epidural) for labour. She has no past medical history of note.

Scenario AM (Antenatal Multip)

23 year old woman, multigravida, presents to clinic 1 week before term and wishes to discuss regional analgesia (CSE/Epidural) for labour. She has no past medical history of note.

Risks

Hypotension; Nausea and Vomiting; Urinary retention; Failure of block; Post Dural Puncture; Headache; Haematoma; Temporary leg weakness; Temporary neurological injury; Permanent neurological injury; High block; Decreased ability to push; Increased instrumental delivery rate; Increased Caesarean Section Rate; Back ache; Infection (general statement); Meningitis (specifically); Abscess (specifically); Anaphylaxis; Seizure; Death; Other (1); Other (2).