Afternoon symposium

Informed consent in pregnancy: what's the status in Switzerland?

14h-14h30: The midwives' perspective

Sue Brailey (Bern)

14h30-15h: The obstetricians' perspective

Patrick Hohlfeld (Lausanne)

15h-15h30: The anesthesiologists' perspective

Christian Kern (Geneva)

Markus Schneider (Basel)

Informed consent in pregnancy: what's the status in Switzerland? the anesthesiologists' perspective

Medicolegal issues of informed consent
given during labor
(Christian Kern)

Competency and decision-making capacity
of laboring women
(Markus Schneider)

Two principles in medical ethics

Beneficence obligates to act in a way that is reliably expected to result in the greater balance of clinical benefits over harms for the patient – as judged from a rigorous, evidence-based clinical perspective.

Respect for autonomy obligates to acknowledge the integrity of a patient's values and beliefs, to elicit her preferences, and to carry out that preferences unless there are ethically compelling reasons for not doing so (paternalism for beneficence-based reasons).

McCullough LB et al, Clin Perinatol 2007

Background of informed consent (IC): ethics & law

In ethical terms, IC is a process

- communication between patient and care provider (MD)
- adequate disclosure of material information of
  - risks, benefits, alternative treatment options
  - recommendations (evidence-based reasoning)
- informed decision-making and autonomous authorization
  - adequate understanding and comprehension
  - right of informed decision to refuse an intervention

In legal terms, IC is a strict requirement

- Elective medical procedure without IC: assault/battery

Wissler RN, SOAP Newsletter 1998

Controversy of informed consent (IC) in labor

Key questions referring to the validity of IC:

- Can a woman in the agony of labor distress really give informed consent to epidural pain relief?
  - 'To form a theoretical opinion as to whether or not to have an epidural for labour pain … when rational and pain free, is **not** in any way an informed consent.'
- Can a woman who has never experienced labor pain give consent to epidural pain relief?
  - 'There is clearly a case for saying that the **only** time when consent to an epidural to relieve pain is truly informed is in labour itself.'

Scott WE (editorial), Anaesthesia 1996

What can we learn from jurisdiction?

3 cases in the LexisNexis® database

- Hall *vs* United States (1955)
- Dunlap *vs* Marine (1966)
- Patterson *vs* Van Weil (1977)

3 decisions in favor of the defending anesthesiologist

- Adequacy of IC obtained during the stress of labor
  - reasonable information given to the patients
    - explanation of procedure, risks, benefits
    - opportunity to ask questions
  - lack of objection by the patient
  - cooperation during performance of the procedure

Knapp RM, Anesthesiology 1990

The format of informed consent

Informed consent in obstetrics (OAA)

- no difference in the principle of obtaining consent for obstetric anesthesia or any other medical treatment
- several documentation options Int J Obstet Anesth 1995
  - implied or expressed, oral or written (note in chart)
    - preprinted consent forms should not detract from the verbal consent process
    - checklist of specific anesthesia risks are useful

'Informed consent can never be reduced to a signature on a consent form.' Hoehner PJ, J Clin Anesth 2003


The onus of proof lies with the physician … (OR 41)
Ott WE, SÄZ 2004

Decision-making capacity after receiving opioids

Process of informed consent (IC) assessed by

- distant recall as endpoint:
  - may be an indicator of the adequacy of a patient's information if present
  - says little about the patient's understanding at the time of consent if absent

Distant recall as endpoint:

- is not necessarily equivalent to adequate understanding and comprehension at the time of the IC process

Hoehner PJ, Clin J Anesth 2002

Epidural analgesia for labor and delivery: IC issues

Retrospective Canadian study, epidural analgesia (n = 60)

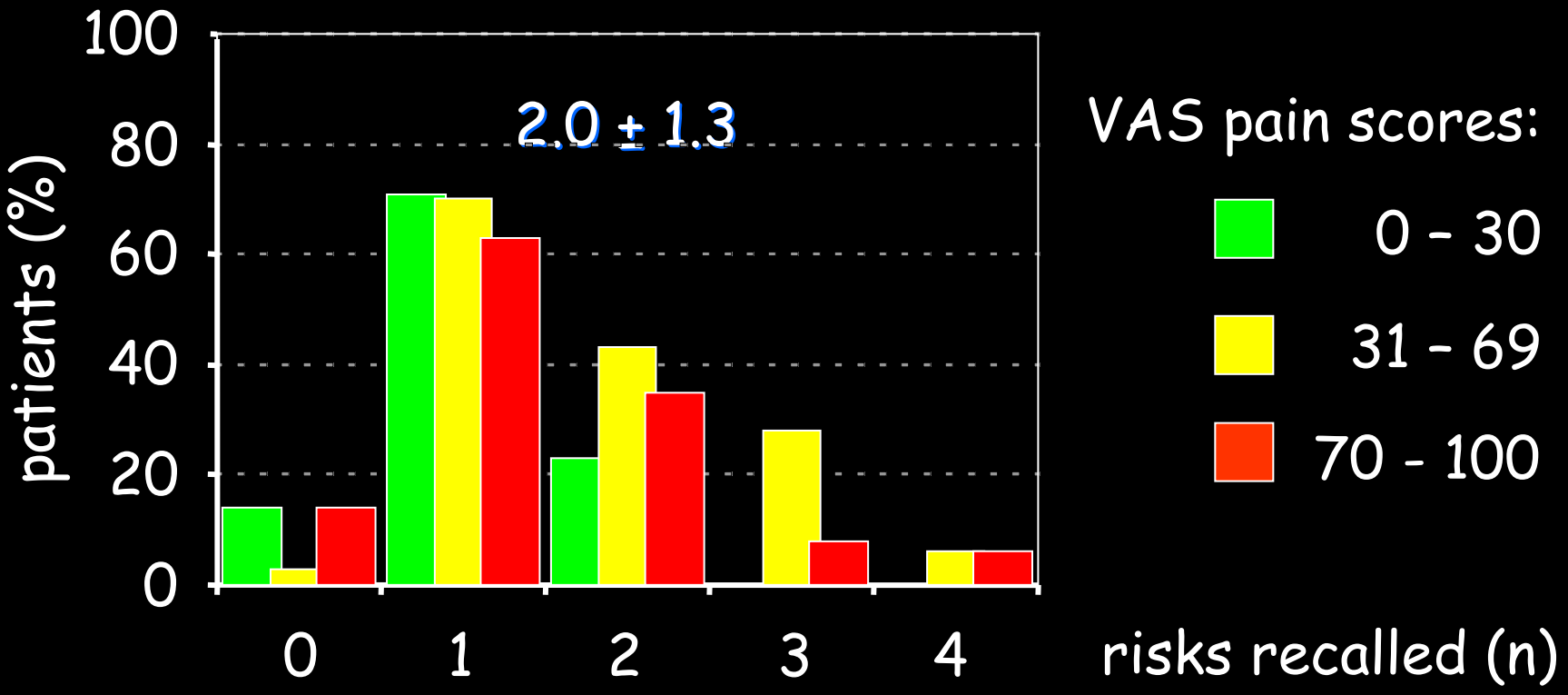
- Survey: in-hospital & ≤ 8 wks p. p. — VAS $_{0\text{-}10}$
  - Pain score before giving IC — ~ 9.2
  - Distress during labor — 8.8
  - Interference with comprehension of IC — 3.0
    - + opioid analgesia (n / n) — 37 / 60
  - IC by preference before labor — 9.4
  - Importance of risk disclosure during IC
    - death/paralysis or effects on baby — 9.4
    - convulsions — 9.3
    - …
    - inability to walk — 7.0

Pattee C et al, Can J Anaesth 1997

Recall of risks following labor epidural analgesia

Parturients in active labor, VAS $_{0- - 100}$ 78 ± 25 (n = 101)

- standardized oral risk information (13 true risks)
- 24-h recall test: printed list of 5 true & 3 false risks



Affleck PJ et al, J Clin Anesth 1998

Recall after verbal (V) *vs* verbal + written (V+W) IC

RCT: V *vs* V+W IC, 10 point checklist, parturients (n = 82)

- Telephone interview: + 5-7 mths, 10 questions
  - 5 true risks, 2 false risk, 3 situational questions

Results	IC_{verbal}	$IC_{verbal + written}$	
true risks $_{0-50}$	45 (30-50)	50 (50-50)	<0.001
false risks $_{0-20}$	15 (5-20)	15 (5-20)	NS
situational $_{0-30}$	25 (15-30)	30 (30-20)	0.001
correct answers (n)	7 (7-9)	9 (8-10)	<0.001
incorrect answers (n)	1 (0-2)	0 (0-1)	0.03
not sure answers (n)	1 (0-2)	0 (0-1)	0.01

Gerancher JC et al, Int J Obstet Anesth 2000

Informationen für Schwangere

Die Regionalanästhesie zur Schmerzlinderung bei der Geburt