Cross-Cultural Perspectives

Authoritative Knowledge and Childbirth

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North American Midwifery Practice: Keeping our Ally from Becoming a Foe? Randonized Controlled Trials as Thirteenth...
A welcome movement away from belief and tradition-based "current medical opinion" toward evidence-based care and intervention is occurring in obstetrics. Central to this development have been the increased use of and respect for the randomized controlled trial (RCT) as a research method and the use of meta-analysis as a tool for systematic quantitative summarization of existing RCT research. While RCTs in many instances have provided strong support for the midwifery model of woman-centered care, there are important limitations on their ability to assess certain aspects of midwifery care. This chapter discusses the strengths and limitations of the RCT as a tool for evaluating alternative birth practices and presents an example of an observational epidemiologic study of midwifery care that can address issues not amenable to RCT evaluation.

In 1989 a watershed in the development of evidence-based care in obstetrics was reached with the publication of Effective Care in Pregnancy and Childbirth (Chalmers, Enkin, and Keirse 1989), which presented systematic, scientific summaries (meta-analyses) focusing on the available RCT-based epidemiologic research concerning almost three hundred care issues in obstetrics. This scientific approach to evaluating care has proven strongly supportive of many aspects of the woman-centered, low-intervention type of midwifery care that has developed in North America over the last quarter century. Highly interventional approaches to the care of high-risk pregnant women and infants have a place. Intensive care of low birth weight infants, in particular, has contributed to substantial reductions in neonatal mortality (deaths in live-born infants in the first twenty-eight days of life) over the last few decades (Paneth 1999). However, it is less clear that this high-intervention approach is optimal for pregnant women without special medical risks or for infants in the normal birth weight range.

Although the RCT-based research has proven generally supportive of midwifery care, there is a danger in depending almost exclusively on RCT-based evidence. The limitations of RCTs need to be understood: there can be scientific, clinical, ethical, and political problems that make it difficult, if not impossible, to use RCTs to evaluate some important components of midwifery practice, particularly practices that are outside the pharmacologic interventionist medical paradigm. Other epidemiologic methods, in particular prospective observational studies, have different strengths than the RCT. They have played and will continue to play an important role in understanding what constitutes effective care.

In this chapter I first describe the important work that has been done using RCTs and meta-analysis to study perinatal management. Then I address various limitations of the RCT for evaluating effective birthing practice. Finally, a Midwives' Alliance of North America (MANA) research project that involves collecting detailed information on midwife-attended births is discussed as an example of a non-RCT epidemiologic study. The research is anticipated to be a valuable complement to the RCT work, particularly for addressing issues beyond the RCT's scope.

THE OXFORD ACCOMPLISHMENT: STRENGTHS OF THE RCT

Effective Care in Pregnancy and Childbirth was a landmark in the development of an authoritative knowledge of birthing practice. The 1,500-page two-volume tome was the culmination of a vision and a decade of work by three obstetricians, Marc Keirse from the Netherlands, Iain Chalmers from England, and Canadian Murray Enkin, in collaboration with a large number of dedicated colleagues. For the first time in any field of medicine, a thorough, systematic review of available research evidence on the effects of care was assembled. The medical literature was systematically and exhaustively searched from 1950 onward, and more than forty thousand obstetricians and pediatricians worldwide were contacted to locate unpublished research. More than one hundred epidemiologists, obstetricians, midwives, and other birth researchers were recruited to evaluate the more than 275 birthing practice issues for which research, in particular, RCTs, had been undertaken.

The overall results of the analyses were the identification of 99 currently used forms of care that reduce negative outcomes of pregnancy; 38 forms of care that appear promising but require further evaluation; 88 forms of care with unknown effects that require further evaluation; and 61 forms of care that should be abandoned in light of available evidence. An inexpensive paperback presenting only the main conclusions of the analyses was also published to allow access to the information by pregnant women, midwives, physicians, and other clinicians (Enkin, Keirse, and Chalmers
LIMITATIONS OF THE RCT

Specific technical limitations existed that prevented an opportunity for adequate replication in a well-controlled, randomized, controlled experiment. There were significant differences in baseline characteristics between the intervention and control groups. In addition, the intervention group received additional training in the use of the intervention tool. The control group did not receive this training. The intervention tool was designed to be used in conjunction with the intervention, but the control group did not use the tool.

The study was conducted over a 6-month period, with data collected at baseline and 3-month intervals. The primary outcome measure was the change in knowledge and attitudes. Secondary outcomes included changes in behavior and adherence to the intervention tool.

Response: Although the intervention group showed significant improvements in knowledge and attitudes, the control group did not. These findings suggest that the intervention tool was effective in improving knowledge and attitudes, but further research is needed to determine the long-term effects of the intervention.

Randomized, Controlled Trials

The randomized, controlled trials are necessary to see the bigger picture. The results of these trials provide evidence for the effectiveness of an intervention. However, the results of these trials should be interpreted with caution, as they may be influenced by various factors, including the design of the trial, the quality of the intervention, and the characteristics of the study population.

Conclusion: The randomized, controlled trials provide valuable information for the design and implementation of interventions. However, the results of these trials should be interpreted with caution, and further research is needed to determine the long-term effects of interventions on knowledge, attitudes, and behavior.
the patient know when a woman has been induced or a fetal monitor is being used.

Furthermore, just because a study employs randomization does not mean that the research is good. The question asked may be inappropriate or irrelevant. The study may be unethical (e.g., the use of placebo controls when an effective treatment is proven and available). The advantages of randomization may be undermined by unblinding of allocation or outcome assessment, cointervention(s), biased dropouts or losses to follow-up, or subjective responses. Although the RCT generally minimizes the chance of problems with bias, there are no guarantees—just as is the case in non-RCT research.

Clinical Judgment
When RCTs are used to evaluate birth practices, the criteria for judging outcomes or the need for intervention often depend on practitioners’ perception or judgment: Is there fetal distress? Is there a need for intervention in a long second stage of labor? Is there failure to progress? What is the amount of blood loss? What is the newborn infant’s physical status? When combined with a lack of blinding, it is possible that the systematic bias that the RCTs have labored to eliminate may creep in. If practitioners participating in the trial are overly optimistic about the new treatment or, conversely, disagree or are uncomfortable with it, it is possible that the observation of the outcome or the pressure to intervene may be skewed. For example, one of the first RCTs in Britain to evaluate active versus physiologic management of the third stage of labor instructed anesthetists to try to leave the cord attached to the baby until the placenta was delivered. They were unable to comply with this directive in 51 percent of cases, probably because they were unaccustomed to and thus uncomfortable with this procedure. In a recent trial of restricted use of episiotomy (Klein et al. 1992), physicians in the study, when told to do episiotomies only when “absolutely necessary,” still perceived a need for them in 25 to 90 percent of the births. In contrast, North American midwives find episiotomies necessary less than 5 percent of the time (Johnson, Davis, and the Midwives’ Alliance of North America Research and Statistics Group 1994).

Evaluating Emotional/Social Issues
The RCT is best suited to study very specific, technical issues with specific, easily measured outcomes (e.g., which type of suture material results in the lowest infection rate). The RCT is much more difficult to undertake for broader and less specific interventions and outcomes such as “satisfaction with care.” Ann Oakley (1989) describes in detail the trials, tribulations, and ethical dilemmas for researchers and care providers alike of undertak-
THE STRATEGY

THE SUCCESS OR FAIL OF RCT IN NEUROSCIENCE RESEARCH

RCT (Randomized Controlled Trials) are considered the gold standard in neurosciences research. This methodology is essential because it allows for the most rigorous testing of treatments or interventions. RCTs are designed to minimize bias in the results by random assignment of participants to different groups. This helps ensure that any observed effects can be attributed to the treatment being tested rather than other factors. RCTs are considered the gold standard in healthcare research because they provide the strongest evidence for the effectiveness of a treatment. However, RCTs are not always feasible or practical in all research settings.

The number of participants in a RCT is critical to ensure the validity of the results. Adequate sample size is necessary to detect meaningful differences between groups. Inadequate sample size can lead to insufficient power to detect true effects, resulting in false negatives. On the other hand, overly large samples can lead to diminishing returns in terms of additional information gained with each additional participant.

RCT results are considered the gold standard because they provide the strongest evidence for the effectiveness of a treatment. However, it’s important to note that RCTs may not capture all aspects of real-world practice, such as patient preferences and provider adherence. Therefore, once effective treatments are identified through RCTs, they may need to be tested further in real-world settings to ensure they are effective and safe in diverse populations.

The success or failure of RCTs can significantly impact the future direction of research in neuroscience. If a treatment is found to be effective in RCTs, it may lead to further research and development efforts, potentially changing clinical practice. Conversely, if a treatment fails to show effectiveness in RCTs, it may lead to reevaluation and repurposing of the intervention or the development of new treatments.

The success or failure of RCTs in neuroscience research can have significant implications for healthcare policy and practice. Effective treatments may lead to improved patient outcomes and reduced healthcare costs. On the other hand,无效 treatments may be discarded, allowing resources to be directed towards more promising avenues of research.
States and Canada. Second, MANA provides a neutral forum for data collection because it is an organization that has no disciplinary function. Midwives can feel safe about reporting the truth about their management of birth without fear of repercussions or disciplinary action. With a greater respect for and patience with variations in women’s laboring, an expanded view of what is normal during birth has developed. Thus this forum also provides an opportunity to document the range of what “normal birth” may actually be.

The care provided by these midwives is focused on being “with women.” It includes continuity of a caregiver or caregivers through pregnancy, labor, and the postpartum period, an emphasis on the development of a caring and trusting relationship between mother and midwife, patience during labor, and the use of modern low-tech intervention tools such as sterile gloves, uristsicks, and Pinard horns. Labor and delivery take place in an environment in which a woman feels safe and are attended by midwives who believe in a woman’s ability to deal with pain and successfully labor with little intervention. High-quality high-tech obstetrical backup care is available when required.

As an observational study, this research project provides an opportunity to efficiently investigate many different aspects of care and their effects on outcome. Whereas an RCT can be used only to study the practice that has been randomized, an observational study can be used to evaluate many aspects of care. Midwives practice independently and in a variety of ways (e.g., differing methods of perineal support, use of water during labor and birth, of management of second-stage labor, of dealing with delivery of the placenta, of use of herbs during pregnancy, labor, and postpartum, etc.). It should be possible to examine midwifery practices and their relation to pregnancy outcome for issues including the following: the overall approach of woman-centered midwifery care and perinatal mortality rates; not setting arbitrary time limits on the various stages of labor; differing approaches to delivery of the placenta and complications; differing approaches to perineal stretching during the third trimester and perineal tear rates; home versus hospital vaginal birth after cesarean; differing approaches to shoulder dystocia; and restricted use of episiotomy in relation to third- and fourth-degree perineal tear rates. With a database representing several thousand births, a variety of situations that occur rarely such as shoulder dystocia, long second-stage labor, and retained placenta, as well as practices that are not required often such as episiotomy, external cephalic version, and emergency transport can be evaluated in a systematic way not possible through individual or informal observation.

Because the subjects are not randomized to different forms of care, one can never be positive that results do not reflect a bias introduced by some unmeasured factor that is associated with both the choice of practice and the outcome. Cautious evaluation is required as biased information might result because the caregiver is also the observer. However, as with a formally randomized sample, characteristics of mothers (age, parity, prenatal problems, socioeconomic status, ethnicity, etc.) can be compared (and controlled for in analysis if necessary) to increase the likelihood of unbiased evaluation. Furthermore, the development of epidemiologic knowledge, theory, and tools over recent decades has provided a strong backdrop for careful evaluation, and it is likely that considerable useful information can be obtained from observation of the outcomes of different forms of care used by different midwives. As with any study, suitable caution in the interpretation of results will be exercised.

Although no one study is conclusive, this work should be helpful in describing the outcomes of variations of care based on an approach dominated by a belief in women’s ability to give birth with little or no intervention. The study analyses should provide a number of leads as to which forms of care may be effective, which may not be useful, and which may be detrimental. Some results may suggest areas in which RCTs would clarify or validate observational data. Because a number of states will be collecting data with the same form (reproduced at the end of this chapter), it should be possible to compare outcomes in different parts of North America, and in different settings, for consistency and reproducibility.

CONCLUSION

Epidemiology, in the form of both the RCT and the observational study, is an important ally for supporting and further developing low-intervention woman-centered midwifery care. The recent meta-analysis work done in the field of obstetrics is giving a new profile to evidence-based care, particularly that gained through RCTs, and is beginning to change obstetrics. The movement of authoritative knowledge away from “current medical opinion” toward evidence-based care has proven strongly supportive of many aspects of the woman-centered low-intervention type of midwifery that has developed in North America over the last quarter century. Armed with a balanced understanding of the strengths and limitations of RCTs and other types of epidemiological studies, we will be better able to assess the efficacy of alternative birth practices.

NOTES

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REFERENCES

see John [1958]

Multiple factors and the chance of misclassifying the diagnosis for a specific case, impacting the final outcome. The precision of these factors and their potential influence on the diagnosis are crucial.

Current methods of diagnosis and classification in clinical practice are limited in their accuracy and reliability. The accuracy of these methods is often dependent on the expertise of the healthcare provider and the availability of diagnostic tools. The development of new tools and techniques for improving the accuracy of diagnosis is an ongoing area of research.
