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CRITICAL APPRAISAL OF A STUDY EVALUATING RUBUS IDAEUS IN PREGNANCY, LABOUR, BIRTH, AND THE NEONATE

BY LISA KELLY

Introduction

This paper will critically appraise a case control study involving 108 women conducted at Westmead Hospital (Sydney) in 1998. The study did not outline a specific question or hypothesis as such but its purpose was to evaluate the safety and efficacy of raspberry leaf products in regards to pregnancy, labour, birth, and the neonate. These multiple dependent variables were assessed by a combination of qualitative (survey) and quantitative (hospital database) means (1). It will be shown that this study has poor validity due to issues of control regarding the independent variable, lack of operationalization, erroneous conclusions and an unsuitable study design to address the aim. All these aspects will be analysed & discussed. The format for this assessment is loosely based on a combination of that recommended by Vickers (2) and Polgar (3).

Design and methodology critique of the study

Identification of the Aim and Question

The study did not have a hypothesis because it was partly qualitative in nature and because the data was collected for the purpose of assessment of safety and efficacy not to prove or disprove anything. This aim was addressed by various data collection measurements during pregnancy, labour, and birth, as well as neonate assessment and need for extra care.

Literature review

The literature review addressed both traditional and scientific sources of information regarding the herb which would have represented contemporary knowledge at the time of the study (1998). The review does include negative findings from clinical trials such as a rise in blood pressure in one study and premature labour or miscarriage in another however these findings tend to be dismissed more readily than positive findings. The positive research findings are based on an animal study and a study using RL on women postpartum, neither of which are relevant to the current question involving the effects on the human mothers up to and including birth but not post-partum. Overall there is a bias in the literature review in favour of raspberry leaf.

Research Design

Case control is a suitable design for assessing safety (4) but not particularly effective for assessing efficacy. Efficacy is better assessed by experimental or perhaps a quasi-experimental design when randomisation is inappropriate (3). The sampling method used in the study was convenience sampling involving women in their postpartum hospital stay. This means that even though this is a case control study it fails assess the risk for miscarriage or death by sampling only those women who successfully gave birth at the hospital. This puts into question the validity of the study in regards to answering the question of safety.

The inclusion of a survey was beneficial to assess the occurrence of adverse reactions such as Braxton Hicks; as well as revealing who recommended the use of RL (predominately midwives followed closely by obstetricians and friends). It is unclear as to whether this survey data was obtained as a written survey or an interview. The way it was obtained could affect the outcome (3) e.g. Illiteracy could have elicited an untrue response when recruiting participants; if it was obtained as an interview then bias involving the interviewer(s) may be involved. However the questionnaire was not part of the article and not obtainable by the author of this paper using Medline or the SCU journal library. The actual survey would need to be obtained to replicate this study.

Due to the retrospective nature of the research extraneous variables were not controlled for and therefore there may be confounding factors influencing the results. It also predisposes the research to recall bias. This is particularly important to consider given that all the information regarding the use of the herb came from the survey.

Internal Validity

Participants:

Participants were a convenience sample all sourced from the same population and were comparable in terms of important factors that may affect birth

outcome e.g. age, parity, ethnicity, public and private patients. There were no exclusion criteria so there is possibility of confounding factors such as coexisting health conditions. Co-interventions such as the use of other herbs or medicines were not assessed for either group which could interfere with the results. The sampling process only involved recruiting women in their post-partum hospital stay and therefore could not assess women who miscarried early in pregnancy or who died. These aspects suggest that even though subjects appeared comparable there may have been differences between groups and within groups that could influence the outcome.

Operationalization:
Testing and measuring procedures were equal between groups, however plant identification and dosage was not possible to accurately assess due to the study being retrospective. The survey revealed a variety of forms of raspberry leaf (tea/tablets/tincture) none of which could be verified as actually being raspberry leaf (Rubus idaeus), nor could quality and potency be assessed. This calls into question the whole purpose of the study which is to assess Rubus idaeus safety and efficacy. Conclusive identification and some range of standard practise in regards to dose are essential to answer these questions.

The survey was not included in the article nor was there information as to how it was conducted (as previously mentioned) or by how many people if it was conducted as an interview. The choice of words, leading questions, inference of judgements, questions of confidentiality, limitations of options, length and order of questions could all have a bearing on subject response (3).

Database outcome variables and results:

ï‚ Maternal blood pressure â€" data for 11participants was not available but the breakdown from which group (RL or control) was not stated. Of the remainder of the sample (97) 4 of the 6 who had a raised BP were in the RL group. Even though this was not statistically significant (p=0.47) the unavailable 11 results could have changed this significantly. This is an important point to consider as the literature review cited changes in BP in previous clinical trials; however this point was not elaborated on anywhere else in the article.

ï‚ Gestation length â€" the standard deviation was smaller in RL group when compared to the control suggesting less variation in gestation length but the p value of this comparison was not significant and therefore not at a level to consider clinical significance. However this was mentioned in the summary as being important in a clinical context.

ï‚ Maternal blood loss at birth â€" excluding caesareans showed no significant difference.

ï‚ Labour duration â€“ despite some difference between groups in stage 1 of labour (RL stage 1 labour was shorter) there was no significant difference in overall labour duration between groups. However the conclusion tended to mislead the reader by claiming that labour was shortened.

ï‚ Need for medical intervention during labour and birth â€“ no significant difference between groups. However the slight and statistically insignificant differences between groups in regards to birth were used in the summary to claim that raspberry leaf may decrease the likelihood of needing medical intervention.

ï‚ Neonate need for special care â€“ no significant difference between groups.

ï‚ Qualitative aspects â€“ the survey revealed that most women who took raspberry leaf thought it had reduced their labour and would use it again and would recommend it to a friend. Given the difficulty of actually being able to perceive a difference and filtering for so many possible variables (e.g. parity, age, changes made during pregnancy, etc) it appears there may be a placebo affect psychologically if not physically.

External validity
Participants:
Because the study was retrospective it is representative of how raspberry leaf is used by people in everyday life. Because of this retrospective design it was representative of standard care for the hospital. However, the sample size was too small to assess the treatment in terms of being representative of the general population and all the many variables associated with such large numbers. Participants are not necessarily representative of the target population as this was a convenience sample which may vary between hospitals and between states/territories.
This means it has external validity as far as it being applicable to the patient population of this hospital but larger subject numbers are needed for external validity applicable to the general population of pregnant women.

Operationalization:
The tests used were standard practise for this hospital - due to retrospective design nothing was changed as a result of the study. However no description of the tests was given nor was the protocol given for making the decision for further neonate care. How the practises of this hospital differ or don\'t differ from those of other hospitals is unknown due to lack of detailed information. This also reduces the ability to replicate the study. Because of these factors external validity is called into question.

Data and Statistics

Although measures of central tendency were shown (descriptive statistics) there were no confidence intervals for any of the findings (inference statistic) and results were not graphed. The power of the study was not given (true positive) and P values were mostly insignificant but misinterpreted or ignored in the analysis. This combination of lack of information, misrepresentation and lack of succinct graphical disclosure made assessment of this study confusing and time consuming. The fact that there were no significant differences between the raspberry leaf and control groups suggests safety but not efficacy but due to lack of sufficient detail and methodological rigour these results cannot be taken at face value.

Bias

Sponsorship or other interests were not declared so it remains unknown if there are any. According to this research article it is midwives who most frequently recommend the use of raspberry leaf to their patients. The interpretations of the findings as being in favour of RL were not logical because conclusions were based on statistically insignificant differences. This bias may be explained by the fact that all 3 researchers work within the field of midwifery and antenatal care and they were trying to find what they wanted or expected. A further possible researcher bias is that they were not blinded and therefore may have discounted or treated data differently when it was being processed into statistics.

Being a retrospective design this study was subject to recall bias of the participants in the survey section of the research and this may be enhanced by the high degree of physical, mental, and emotional stress that respondents had recently experienced or were still experiencing so soon after giving birth. Overall bias was shown in the analysis of the data and there were other areas of possible bias.

Plausibility of the concept

According to Friedland (5) an important thing to consider in assessing the validity of a study is plausibility. Plausibility in the context of previous literature and biological plausibility do exist for the use of raspberry leaf safety and efficacy during pregnancy, labour and birth. The former predominately come from traditional knowledge and the researchers involved use of good quality sources such as Mills and Hoffman as evidenced by the reference list. The biological plausibility comes from less reputable sources due to it being old or involving animal or in vitro research. This is not a poor reflection on the researchers as there is not a lot of relevant research or information on this herb and their recognition of the need for research is justified.

Quality of the Article

This article was of poor quality due to the poor validity of the study, erroneous conclusions, and poor presentation. It is difficult to find particular information as it is spread out and not always under appropriate headings (e. g. neonate apgar details are under the safety issues heading not under birth outcomes heading). According to Polgar (3) all important findings need to be presented in a summarised format such as tables and/or graphs. This study does not summarise the data into graphs often enough. Instead of being able to quickly refer to a graph for clear and concise information the reader has to reread through the text to get the information. As a result it required more time and effort to read and reread the data to put it all in perspective.

There was no succinct summary of information and the biased conclusions were harder to see because the data that was relevant to the point was hidden within the details of the outcomes. The summary included erroneous conclusions such as raspberry leaf shortening labour â€" the results showed a statistically insignificant difference in stage one of labour only not overall labour time; RL reducing the need for medical intervention during labour â€" this was also statistically insignificant; a smaller standard deviation in the RL group compared to the control was interpreted as reducing post and preterm births but the p value of this comparison was not significant.

Scope of the Study

Given that this is Australian research it would have been useful for practitioners in Australia if the study had greater validity. Australia has certain minimum standards of care and the majority of the population is Caucasian which means that the study could have had a certain degree of representativeness of the target population. However different hospitals and states would have various ratios of ethnicity which may alter outcomes. This study only incorporated Caucasian, Asian and south pacific islanders. Practitioner patient characteristics would need to be taken into account before applying any findings from this study.

Further breakdown within the study of the variables would have been interesting such as comparison of hospital and survey data between nulliparous and multiparous subjects, and public compared to private subjects. The scope of the research question is large i.e. determining the overall safety and efficacy of raspberry leaf. Many smaller variables would need to be assessed to be confident that effects on subgroups within the general population were taken into reasonable consideration. This would require not just further data collection from within subgroups but involve a much greater number of subjects with a standardized treatment protocol carried out at a variety of centres.

Conclusion

Subjects reported benefits inconsistent with quantitative results but both qualitative and quantitative methods revealed few side effects. Despite this

there needs to be further assessment of whether RL increases incidence of Braxton Hicks or has an effect on blood pressure of the mother. There were no differences in any of the important outcomes that were of clinical significance between the two groups. As definitive plant identification and issues of dosage were not addressed due to the retrospective design all outcomes must be regarded with caution.

Poor presentation lead to this study being difficult to read and interpret. The lack of operationalization means this study cannot be replicated therefore it is not falsifiable nor can it be verified. Lack of information such as confidence interval; bias; erroneous interpretation of results; and unsuitable study design for addressing the aim all conspire to make this a study with poor validity. In the final analysis, the research did not achieve its aim which was to assess the safety and efficacy of Rubus idaeus.

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