

**A critical appraisal of “The lowering of bilirubin levels in patients
with neonatal jaundice using massage therapy: A randomized,
double-blind clinical trial”**

By

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Abstract

As an assignment for the Angelo State University Doctor of Physical Therapy Program, this is a critical appraisal of a randomized, double-blind clinical trial looking at the effects of massage therapy on jaundiced infants. This appraisal is to be used as guide to better decide if the research article discussed is unbiased, trustworthy, and should be used in evidence-based practice. Being able to decipher the strong and weak points within a research article is imperative for a healthcare provider to be able to deliver the highest quality of care to patients. The results of the study indicate that infant massage, when combined with phototherapy, will increase the defecation frequency and lead to lower serum bilirubin levels in jaundiced infants sooner than phototherapy used alone. These findings could be misleading due to the fact that there is a big percentage of withdrawal within the experimental and control group. Within the methods and results, there is vague information on the concealment of the study, how the control group was monitored, the accuracy of the outcomes measured, and if the results found are clinically significant enough to be used in the clinic. The introduction and discussion are written with good information and a variety of literature sources used to complement and contrast the findings. Overall, the research paper is not recommended to be used without further investigation into other high-quality studies using massage therapy as a way to lower bilirubin levels.

Key words

Appraisal, infant, massage, jaundice

Introduction

As a first-year student in the Doctor of Physical Therapy Program at Angelo State University we are required to take the course “Evidence Based Practice in PT”. Throughout this course we are learning to appraise research articles to determine their credibility and whether they should be referenced during evidence-based clinical practice. The purpose of this critical appraisal is to assist the reader through “The lowering of bilirubin levels in patients with neonatal jaundice using massage therapy: A randomized, double-blind clinical trial” and portray the strengths and weaknesses found throughout the article. This is important to ensure the reader understands what is being said as well as how reliable the information and results may be. We, as students, began this process by creating our own question: “Does infant massage therapy decrease bilirubin levels in neonates with jaundice?” With the use of proper search engines, key words, inclusions, and exclusions I was able to narrow down my options to this article. After reading this critical appraisal, the reader will have a better understanding on whether or not the use of this article and intervention is appropriate for implementation in the clinic.

Methods

The database used to find this article was the Angelo State University library – U-search interlibrary loan. The keywords were infant, massage, bilirubin levels, and jaundice. The limits placed on the search were full text, in order to have results with the full article attached, and scholarly/peer reviewed to increase the chances of finding a higher quality article, although peer reviewed does not always guarantee high quality information. The inclusions were infants with hyperbilirubinemia or jaundice and the exclusions were healthy infants without hyperbilirubinemia or jaundice. The reasoning behind these inclusion/exclusions were to not find

articles using infant massage on healthy infants. There were 35 total articles listed before beginning the search that lead to the discovery of this article.

This article was published in the *Infant Behavior and Development* Journal in July of 2017. The authors are professors at Hamadan University of Medical Sciences in Hamadan, Iran. Fatemeh Eghbalian and Hanneyeh Rafienezhad work in the Department of Pediatrics and Javad Farmal is from the Department of Biostatistics and Epidemiology. This study was conducted in 2015 within the Besat Hospital in Hamadan, Iran. I chose this article, among the others, for critical appraisal because after reading the abstract, before requesting access, it seemed matched best with what I was looking for. Upon retrieval, I realized this article would be appropriate to learn the appraisal process with as it has good things as well as areas of improvement within it.

Results

Summary of the study

Within this randomized double-blind clinical trial, the researchers measured bilirubin levels and defecation rates in infants with hyperbilirubinemia, commonly known as jaundice. They describe jaundice has having more than five mg/dl bilirubin above the normal level, this is a common occurrence in newborn infants. There were 67 subjects within each of the two groups at the start of the study. These two groups were randomly divided into an experimental group that received massage therapy and phototherapy, while the control only received phototherapy. There was no significant difference between the experimental and control group regarding gender, age, type of delivery, birth weight, and Apgar score (a score indicating the infant is in good health). All infants within the experimental group received the same type of massage therapy under the same conditions two times a day. It only specifically states the experimental

group received phototherapy two times a day, although the control group is also receiving some amount of phototherapy. Within the first two days of the trial, there were no significant differences between bilirubin levels and frequency of defecation between the two groups. There was found to be a significant relationship between bilirubin levels and defecation rate during the third and fourth days within the massage group, but this was not apparent for the control group for anytime of the study. From the results of this four-day study, it shows that infant massage when combined with phototherapy reduces the serum bilirubin levels in newborns with jaundice.

Appraisal of the study introduction

The introduction is relatively nicely written and begins by giving background information and the definition of hyperbilirubinemia. The authors also give insight into alternative methods that have been researched on their effects on bilirubin levels and mentions how well they may or may not have worked. Then massage therapy is introduced along with some of the positive effects it has on the infant as well as the mother. This information is an efficient way to engage and inform the readers before declaring that the reason for this study is because of previous studies and their conflicting results from similar trials.

Within the introduction, it could be beneficial to the reader for more additional information on jaundice, the occurrence rates in infants, and overall explanation of some of the medical terms used. This would better explain the importance of the study as the reader would have a better understanding on the possible severity of jaundice and its complications. There is one reference cited in the introduction that is published in the same journal as this article, *Infant Behavior and Development*. This could be interpreted as the journal trying to increase their impact factor. The other literatures cited are current and from other credible journals.

Appraisal of the study methods

The research design for this study is a randomized control trial, double blinded which, when implemented correctly, is considered to be an experimental design with low bias probability and a high-quality study. The type of massage therapy used for the infants is described thoroughly with the frequency of massage and the technique used. This is a strong point of the methods so that another researcher could duplicate the exact study parameters.

However, the authors did not explain the concealment of the study thoroughly. They only indicate that the infants were placed in the groups randomly. The infants are blinded because they cannot voluntarily influence their defecation rates or bilirubin levels. The mothers are not blinded from which group they are assigned to based on whether they learn the massage technique or not. There is no mention of if the clinician or outcome assessors are masked to the group assignments. There are also some inconsistencies throughout the methods and results sections with the number of subjects that participated throughout the study. The flow chart, not titled, at the end of this section describes the process of how they got to the end number of participants within the study. This chart may be a little difficult for some readers to follow or understand due to the amount of information given within a small area. Within this chart, the fourth day of the experimental group appears as if there are still 55 participants in the group, where it should say ($n_1=8$), as it does in the results section. Table 3 is difficult to compare results as it displays the frequency of bowel movements between the groups but only indicates the mean and standard deviation over the entire length of the study, not day-to-day results.

Appraisal of the study results

The results section is relatively brief, written clearly and straight to the point stating which data is or is not statistically significant. The results are presented with their corresponding p values and compared either within or between the two groups. The authors do report all of the subjects and outcome measures presented from the introduction and methods. This can be a strength if the reader is looking for quick answers and analysis of the numbers.

The results given do not directly address the research question as in, the authors do not specifically mention the question or hypothesis and agree or disagree, in this section. The study might show its greatest weakness in the amount of attrition or withdrawal that occurs throughout the study. Referring back to the flow chart in the methods and in Table 2 of the results, it shows that within the two groups the data starts with 67 subjects in each but by the fourth day, only eight participants remain in the experimental group and 21 in the control group. These are very high withdrawal rates which may impact the results significantly. The authors do not mention any concept concerning the minimal clinically important difference (MCID) or calculate the number needed to treat (NNT) before or after analyzing the data. With the amount of attrition and the other limitations that are stated throughout the study, I am skeptical that the results are clinically meaningful.

Appraisal of the study discussion

The authors repeat the results of the study but also indicate further meaning of the findings. Also, the study results are compared to other existing literatures, some have shown to have similar results and others do not support the results from this study. The contradicting studies may have these differences due to variable sample sizes, massage therapy methods, and

different severities of jaundice. The authors do conclude that, based on this study, massage therapy in addition to phototherapy is an effective way to induce the reduction of serum bilirubin levels within a four-day time period in infants with jaundice. Clinical significances are mentioned such as, with massage therapy decreasing bilirubin levels can lead to a faster discharge of the patient from hospital services.

The authors state that the short time period of four days, small sample size, and the single type of massage method used are recognized as limitations throughout this study. These limitations can lead to bias results ultimately decreasing the value of this study. Future studies are recommended for studies in this area be conducted for longer time periods, larger sample sizes, and explore the impact of different massage techniques.

Discussion

The clinical significance of this study to current physical therapy practice and the question of “Does infant massage therapy decrease bilirubin levels in neonate with jaundice?” is that infant massage therapy, when combined with phototherapy, can reduce bilirubin levels in neonates with jaundice faster than phototherapy alone. This could lead to a decreased length of hospital stay for affected infants. A decreased length of stay would greatly decrease stress on the infant and the family burden of hospital bills while increasing the family bonding and attachment period that is critical in infant development. Research conducted in this area is important due to the common occurrence of jaundice in infants and getting them recovered as soon as possible.

Although there is a high percentage of attrition and many limitations throughout this study, the potential risks are not high for implementing this intervention in the hospital. The technique could be performed by a therapist, nurse, or the mother as in this study and even if it

does not directly influence the bilirubin levels could lead to overall decreased stress for the infant and the mother. If this study would have been conducted using a larger sample size with less withdrawal and a longer time frame, the argument in favor for using the appraised intervention would be greatly increased.

I do not have enough confidence in the research validity of this specific paper to consider using this evidence with future patients because the data is too inconsistent and displayed poorly through the methods and results section. However, I do anticipate possibly implementing this intervention safely and appropriately in a clinical setting if I continue my education in this neonatal therapy field. I believe there has been other published research conducted using similar interventions that were studied properly and indicate the benefits of the use of massage therapy.

After careful analysis of each section of this paper, it is difficult to fully support the information and final decision of the use of massage therapy to decrease bilirubin levels in the clinic. In order to make an educated decision before implementing this intervention, I would advise the reader to investigate different studies conducted with different sample sizes and study lengths to ensure statistically significant results are consistent throughout the literature.