

Philadelphia College of Osteopathic Medicine

DigitalCommons@PCOM

PCOM Physician Assistant Studies Student
Scholarship

Student Dissertations, Theses and Papers

2023

Are medical clowns effective in reducing pain in pediatric patients undergoing procedures in the ED?

Olivia N. Goncerz

Philadelphia College of Osteopathic Medicine

Follow this and additional works at: https://digitalcommons.pcom.edu/pa_systematic_reviews



Part of the [Medicine and Health Sciences Commons](#)

Recommended Citation

Goncerz, Olivia N., "Are medical clowns effective in reducing pain in pediatric patients undergoing procedures in the ED?" (2023). *PCOM Physician Assistant Studies Student Scholarship*. 658.
https://digitalcommons.pcom.edu/pa_systematic_reviews/658

This Selective Evidence-Based Medicine Review is brought to you for free and open access by the Student Dissertations, Theses and Papers at DigitalCommons@PCOM. It has been accepted for inclusion in PCOM Physician Assistant Studies Student Scholarship by an authorized administrator of DigitalCommons@PCOM. For more information, please contact jaclynwe@pcom.edu.

**Are medical clowns effective in reducing pain in pediatric patients
undergoing procedures in the ED?**

Olivia N. Goncerz, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

December 16, 2022

ABSTRACT

Objective: The objective of this selective EBM review is to determine, “Are medical clowns effective in reducing pain in pediatric patients undergoing procedures in the ED?”

Study Design: A systematic review of two randomized controlled trials (RCT) and one Quasi RCT published between 2015 and 2016.

Data Sources: All three RCTs were discovered using PubMed, published in English, peer-reviewed journals, and selected based on their applicability to the clinical question.

Outcome Measured: The outcome measured in all articles was pain. Young patients utilized pain scales with facial images, such as the Wong-Backer Scale or Faces Pain Scale – revised, whereas older patients utilized a Numerical Rating Scale. Meiri et al. used the Visual Analog Scale, a blend of the two forms, catering to both young patients and their parents. Each ranked pain from zero, being “No pain”, to ten, being “The worst pain imaginable”.

Results: The RCT by Felluga et al. found no significant pain reduction with medical clowns compared to the control. The clown group experienced 0.25 mean change from baseline; the control had no change from baseline. P-value during triage was 0.334 and during procedural intervention was 0.183. Meiri et al. also found no significant pain reduction with medical clown distraction. The clown group had a mean change from baseline of 4.1, while that of the control group was 5.3. P-value was >0.05 . Therefore, both studies had small, not statistically significant treatment effects. In the RCT by Rimon et al. medical clowns reduced pain levels, reporting mean change from baseline of 2.2, whereas the control group was 7.5. P-value was <0.001 and treatment effect was large.

Conclusions: Only 1 of the 3 studies in this review exhibited statistically significant procedural pain reduction with medical clown intervention. The results of the other 2 studies were not statistically significant, rendering the results of this review inconclusive. The true extent to which medical clowns reduce pain in pediatric patients is undetermined. Future studies should incorporate larger sample sizes, blinded raters, homogenous painful procedures, and uniform pain scales.

Key Words: Medical clown, Procedure, Pain

INTRODUCTION

Procedural pain is short-term pain inflicted by a medically necessary diagnostic or therapeutic procedure.¹ Pediatric patients are particularly prone to intense anxiety and fear of medical procedures as they strongly associate them with prior painful experiences. Most emergency department (ED) visits require some procedural intervention, such as venipuncture, IV placement, or splinting. On a national level, approximately 133.8 million ED visits are recorded annually, 24% of which are pediatric patients (32 million).² For instance, in 2021, Children's Hospital of Philadelphia documented 57,291 ED visits.³ And, in 2019, infants under 1 year old visited the ED more frequently than any other age group (123 visits per 100 people).⁴

Children, like adults, feel pain. Anticipated pain can skew exam findings and make the completion of procedures more difficult, if not impossible.⁵ Furthermore, these early experiences of procedural pain shape a child's perception of medical care and influence future pain tolerance.⁵ Inadequate pain relief during procedures can create long-term apprehension of, and hesitancy towards, seeking necessary medical interventions in the future.⁶ Providing a distraction may reduce the perceived pain by diverting the child's attention to pleasant stimuli, such as a medical clown, thus improving efficiency of diagnostic and therapeutic measures.

A 2020 study reported that medical clowns save hospitals money not only because hiring clowns costs less than anesthetics do, but children who interact with medical clowns feel less of a need for pharmacological pain management.⁷ The average cost of a medical clown is not documented, however it is lower than the out-of-pocket cost of anesthesia, which ranges from \$500 for local anesthetics to as much as \$3,500 for regional/general anesthetics.⁸

What we do not know is if clowns provide a sufficient amount of distraction to decrease pain to the same degree as typical methods, that being the comfort provided by parents, hospital

supplied toys, or anesthetics. Using humor as a method of pain reduction may be preferred over pharmacological measures, which are more invasive, fear provoking, and costly. Additionally, it assists anxious parents/guardians in providing comfort during a situation that can be equally nerve-wracking for them. By providing a positive stimuli as a distraction, pediatric patients are more likely to endure the procedure to its completion with less perceived pain.⁹ This paper evaluates 3 randomized controlled trials (RCT), assessing the efficacy of medical clown therapy on reducing pain experienced by pediatric patients undergoing procedures in the ED, as compared to other forms of distraction or anesthesia.

OBJECTIVE

The objective of this selective EBM review is to determine, “Are medical clowns effective in reducing pain in pediatric patients undergoing procedures in the ED?”

METHODS

The population of interest for this selective EBM review was pediatric patients undergoing a medical procedure in the ED. Details regarding the demographics and characteristics of the selected studies can be found in Table 1. Medical clowns were the intervention observed in all of the studies, however, the comparisons varied. Felluga et al. compared medical clowns to distractions (bubbles, video games, television, books, etc.) provided by ED nurses.⁵ Rimon et al. used parental distraction and comfort as a comparison.¹⁰ And, Meiri et al. compared to neither clown nor EMLA anesthetic.⁹ Pain was the outcome measured in this selective EBM review composed of 2 RCT and 1 Quasi RCT.

The studies selected for review were chosen via PubMed based on their relevance to the proposed clinical question and their consideration of patient-oriented outcomes (POEMs). Key words utilized to locate the studies included: “medical clowns”, “procedure”, and “pain”. All

selected articles were published in English, in peer-reviewed journals, between 2015 and 2016. Inclusion criteria consisted of RCTs published between 2011 and the present, with children as the population of interest. Studies were excluded if they were secondary studies, published in 2010 or older, and/or targeted adults. Statistical analysis was based on the reported mean changes from baseline and p-values.

OUTCOMES MEASURED

The outcome measured in this review is subjective pain level as measured by pre-determined pain scales ranging from zero to ten, zero being “No pain” and ten being “The worst pain imaginable”.^{9,10} Pain levels were assessed during or immediately following the procedural intervention. Felluga et al. and Rimon et al. employed two different pain scales that catered to different age groups. For instance, Felluga et al. utilized the Wong-Backer Scale for children 4 to 7 years old, which displayed six faces expressing increasing degrees of pain each representing a numerical value increasing by increments of 2.⁵ Whereas children 8 to 11 years old used the Numerical Rating Scale (NRS) ranging from 0 being “No pain” to 10 being “The worst pain”.⁵ Rimon et al. followed suit,¹⁰ however, Meiri et al. chose to provide all age groups with the Visual Analog Scale (VAS), a 10-cm line allowing for more sensitive data collection as one can mark perceived pain anywhere on the number line between 0 and 10 and/or point to 1 of 10 corresponding faces to indicate their pain level.⁹

RESULTS

Felluga et al. conducted a quasi RCT to evaluate the efficacy of medical clowns in reducing the pain level of pediatric patients undergoing procedures performed in an Italian ED.⁵ Forty children between the ages 4 and 11 who required venous blood sampling, intravenous cannulation, burn or wound dressing, limb immobilization or wound suturing, were randomly

Table 1. Demographics & Characteristics of Included Studies

Study	Type	# Patients	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Felluga 2016 (1)	Quasi RCT	40	4-11 years of age	A minimum age of 4 and maximum age of 11 years, the need to undergo a painful procedure	<4 or >11 years of age, Premedication with any drug	0	Clowns distracted children and their parents in the waiting room/during the medical procedure vs. ED nurses provided distraction techniques with parental involvement
Meiri 2015 (2)	RCT	100	2-10 years of age	Children aged 2-10 years, who required blood sampling/line insertion for clinical reasons	<2 or >10 years of age; Children in this age group who were acutely ill and unstable or potentially so	Not reported	Blood exam performed with medical clown distraction vs. Blood exam performed with neither clown nor ELMA anesthesia (control group)
Rimon 2016 (3)	RCT	55	2-15 years of age	Children 2-15 years old who's treatment plan included blood tests of IV cannulation; accompanied by at least 1 parent	Need urgent IV, developmental disability; critically ill or need IV for the treatment of a severe infection, or received glucocorticoids w/i 6 weeks	2	Children interacted with medical clown for 15 min. prior to blood collection/during procedure vs. Children underwent blood collection with distraction/comfort from parents

divided into an interventional or control group via an allocation concealment scheme of sealed envelopes.⁵ Children in the intervention group interacted with clowns for 20 minutes in the waiting room and throughout the duration of their medical procedure.⁵ Clowns underwent special training and used various methods to entertain the children, such as pantomime, juggling and music.⁵ Children in the control group were provided with the hospital's typical distraction techniques, such as television or books.⁵

Pain perception was assessed by medical staff during triage and again during the medical intervention using the Wong-Backer Scale in children 4-7 years old and the Numerical Rating Scale in children 8-11 years old.⁵ Statistical data was presented as median values, interquartile ranges and p-values. The difference between median values calculated at triage and during intervention were taken and then compared to evaluate the mean change from baseline of both groups. The intervention group which interacted with clowns experienced a 0.25 mean change from baseline, starting at a median pain level of 5.75 out of 10 and ending with a median pain level of 5 out of 10.⁵ Comparatively, the control group did not have a change from baseline, as perceived pain was reported to be 5 at triage and during intervention.⁵ The calculated difference between mean pain values of the medical clown group and the control group was 0.75 during triage and 0.5 during medical care. The calculated p-value for the assessment of pain level during triage was 0.334 and that during procedural intervention was 0.183, indicating that the estimates of treatment effect were not significant in this study and medical clowns were not effective at significantly reducing pain levels.⁵ Table 2, displayed below, summarizes the results.

Table 2. Pain Level Before and During Medical Intervention (*Median - IQR*)⁵

	Medical Clown Group	Control Group	Mean pain difference (calculated)	P-Value

Pain During Triage	5.75 (5-7)	5 (3-6.5)	0.75	0.334
Pain During Medical Care	5.5 (5-6)	5 (3-6.5)	0.5	0.183

Similarly, Meiri et al. conducted a RCT that compared the use of medical clowns to no intervention (neither clowns nor anesthetics) in reducing perceived pain of pediatric patients that required medical interventions in an ED in Israel.⁹ One hundred children in the ED between the ages of 2 and 10 that required venous blood sampling or intravenous cannulation were recruited to participate.⁹ The study randomly allocated participants to one of three groups to measure the effect of medical clowns, EMLA local anesthetic, or no intervention, however for the purpose of this selective EBM review only participants in the medical clown intervention group and the control group that did not experience an intervention, were analyzed.⁹ Children apart of the intervention group were entertained by a clown starting 10 minutes prior to their procedure, up until the child left the room following the conclusion of the procedure.⁹ The medical clown underwent special training and utilized various distraction techniques, such as music, magic and stories.⁹ The control group received standard care in which parents held and talked to their child while lying on the bed during the procedural intervention.⁹

The outcome measured was pain level assessed by the patient using the Visual Analog Scale, in which the child self-reported their pain after the procedure by pointing to 1 of 10 faces associated with a numerical value, ranging from smiling (0 = no pain) to crying (10 = terrible pain).⁹ Statistical data was presented as means, standard deviations and p-values. The intervention group reported a mean pain level of 4.1 out of 10 with a standard deviation of ± 3.5 .⁹ Comparatively, the control group saw a mean pain level of 5.3 out of 10 with a standard deviation of ± 3.8 .⁹ Mean change from baseline was interpreted with the assumption that at baseline, prior to the procedure, the child's perceived procedural pain is 0. Therefore, the

intervention group had a mean change from baseline of 4.1, while the control group had a mean change from baseline of 5.3. The calculated difference between mean pain values of the medical clown group and the control group was 1.2. This indicates that children who were distracted by clowns experienced less pain than those who only had the comfort of their parents. However, the p-value for pain assessed by children in the clown intervention versus no aid was >0.05 , meaning the treatment effect was small and not statistically significant.⁹ Resultant data is displayed in Table 3 below.

Table 3. Pain level assessed by the child after medical intervention⁹

	Mean \pm STD	Mean pain difference (calculated)	P-Value
Medical Clown Group	4.1 \pm 3.5	1.2	>0.05
Control Group	5.3 \pm 3.8		

Rimon et al. conducted a RCT to investigate whether distraction provided by medical clowns reduces procedural pain of children in an Israeli ED.¹⁰ Fifty-three children between 2 and 15 years old were randomly assigned to the intervention or control group at the time of patient enrollment via an allocation scheme with a stratified block design using concealed envelopes.¹⁰ The intervention group interacted with the medical clown for 15 minutes prior to, and during, their medical procedure.¹⁰ Clowns used imagery, magic and jokes to distract children.¹⁰ Whereas the control group underwent the same medical procedure with only the comfort provided by their parents.¹⁰

The outcome measured was the child's self-reported pain assessed immediately (1 minute) after the procedure.¹⁰ The method of data collection varied based on age-appropriateness. Children under 7 years old used the Faces Pain Scale - revised (FPS-R) to point to 1 of 6 pictures of faces in varying degrees of distress to best indicate how they were feeling.¹⁰

Children 7 years and older reported their pain with the VAS, a 100 mm number line on which patients marked their degree of pain ranging from 0 being “no pain” to 10 being “worst possible pain”.¹⁰ Statistical data of this study was reported as mean values, standard deviations and p-values. The medical clown intervention reported a mean pain level of 2.2 out of 10 with a standard deviation of ± 2.5 .¹⁰ Comparatively, the control group saw a mean pain level of 7.5 out of 10 with a standard deviation of ± 2.9 .¹⁰ Again, pain at baseline, prior to medical intervention, was assumed to be 0. Therefore, the mean change from baseline for the medical clown group was 2.2, which is significantly lower than that of the control group, which was 7.5. The calculated difference between mean pain values of the medical clown group and the control group was 5.3. The p-value for pain level following the medical procedure was <0.001 , meaning the large treatment effect was precise and statistically significant.¹⁰ Results of the study are summarized in Table 4 below.

Table 4. Self-reported pain level of child following medical procedure¹⁰

	Mean \pm STD	Mean pain difference (calculated)	P-Value
Medical Clown Group	2.2 \pm 2.5	5.3	<0.001
Control Group	7.5 \pm 2.9		

DISCUSSION

Of the three studies, only that by Rimon et al. found statistically significant reduction in perceived pain when medical clowns intervened.¹⁰ Whereas, Felluga et al. and Meiri et al. reported that medical clowns did not notably alter patient pain levels as both studies calculated p-values greater than 0.05, indicating that the results are not statistically significant.^{5,9} Rimon et al. had a calculated mean pain difference of 5.3, compared to 1.2 in Meiri et al. and 0.5 in Felluga et

al, both of which had a small treatment effect.^{5,9,10} Interestingly, Meiri et al. discovered a significant reduction in anxiety and duration of crying when medical clowns were present for the procedure.⁹

The studies contained limitations which may have skewed the validity of outcomes. Given the nature of the study and the outcome measured, none of the studies were able to appropriately blind all participants nor the rater, potentially inducing bias in the scoring of pain levels. Additionally, no study followed up with an intention-to-treat analysis. Felluga et al. and Rimon et al. were limited by their small sample size, negatively influencing the reliability of the results.^{5,10} Felluga et al. used non-homogenous painful procedures, which affects the study's generalizability.⁵ Most controversially, Meiri et al. did not utilize a randomization allocation concealment while enrolling participants and did not report the number of subjects lost, nor whether a worst case analysis was performed.⁹ Lastly, a patient's culture and prior experience with medical care influences their perception of pain and willingness to provide honest responses. The studies all failed to document these characteristics and they were performed in different countries, where cultural expectations can vary based on age or gender.

CONCLUSION

The evidence presented in this systematic review is inconclusive and unable to confidently infer whether or not medical clowns significantly reduce pain in pediatric patients undergoing procedures in the ED. Only one of the three RCTs reported a large treatment effect with statistically significant procedural pain reduction when compared to a control group. The calculated p-values of the remaining two studies fell out of range for statistical significance rendering them insignificant.

Further investigation of the role medical clowns play in the ED would be beneficial in determining their true capacity in optimizing care of pediatric patients. Additional trials should include larger sample sizes, homogenous painful procedures, blinding of raters, and the use of a uniform pain scale for all subjects. Greater benefit may be found if future studies limit research to one country so that variability in cultural expectations does not interfere with honest evaluation of pain. While the purpose of this selective EBM was to determine the effect medical clowns have on subjective pain experienced by pediatric patients, it may be fruitful to also examine their influence on anxiety levels of patients and their parents, as apprehension towards medical care is often a result of elevated anxiety rather than true pain.

REFERENCES

1. Wilson-Smith EM. Procedural pain management in neonates, infants and children. *Rev. Pain.* 2011;5(3):4-12. doi:10.1177/204946371100500303
2. Cabalatangan SN, Thode HC, Singer AJ. Emergency medicine physicians infrequently perform pediatric critical procedures: A national perspective. *Clin Exp Emerg Med.* 2020;7(1):52-60. doi:10.15441/ceem.19.004
3. The hospital and CHOP care network statistics. Children's Hospital of Philadelphia. Chop.edu. Published December 17, 2018. Accessed October 5, 2022. <https://www.chop.edu/about-us/annual-report-of-our-financials/hospital-statistics>
4. *Products Data Briefs - Number 434 - March 2022.* Centers for Disease Control and Prevention. <https://www.cdc.gov/nchs/products/databriefs/db434.htm>. Published March 17, 2022. Accessed October 5, 2022.
5. Felluga M, Rabach I, Minute M, et al. A quasi randomized-controlled trial to evaluate the effectiveness of clowntherapy on children's anxiety and pain levels in emergency department. *Eur J Pediatr.* 2016;175(5):645-650. doi:10.1007/s00431-015-2688-0.
6. Young KD. Pediatric procedural pain. *Ann Emerg Med.* 2005;45(2):160-171. doi:10.1016/j.annemergmed.2004.09.019
7. Gomberg J, Raviv A, Fenig E, Meiri N. Saving costs for hospitals through medical clowning: A study of hospital staff perspectives on the impact of the medical clown. *Clin Med Insights Pediatr.* 2020;14:117955652090937. doi:10.1177/1179556520909376
8. How much does anesthesia cost? CostHelper. Published 2022. Accessed October 5, 2022. <https://health.costhelper.com/anesthesia.html>
9. Meiri N, Ankri A, Hamad-Saied M, Konopnicki M, Pillar G. The effect of medical clowning on reducing pain, crying, and anxiety in children aged 2–10 years old undergoing venous blood drawing—a randomized controlled study. *Eur J Pediatr.* 2015;175(3):373-379. doi:10.1007/s00431-015-2652-z.
10. Rimon A, Shalom S, Wolyniez I, Gruber A, Schachter-Davidov A, Glatstein M. Medical clowns and cortisol levels in children undergoing venipuncture in the emergency department: A pilot study. *Isr Med Assoc J.* 2016;18(11):680-683.