

Medical Clowns and Cortisol levels in Children Undergoing Venipuncture in the Emergency Department: A Pilot Study

Ayelet Rimon MD^{1*}, Shelly Shalom MD^{1*}, Ido Wolyniez MD¹, Alejandro Gruber³, Anita Schachter-Davidov MD² and Miguel Glatstein MD¹

¹Pediatric Emergency Medicine and ²Pediatric Endocrinology Service, Dana-Dwek Children's Hospital, Tel Aviv Sourasky Medical Center, affiliated with Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel

³The Dream Doctors Project, Philnor Foundation, Israel

ABSTRACT: **Background:** Medical clowns are increasingly used for diminishing pain and anxiety during painful procedures being performed on children in the hospital setting. Cortisol levels rise as a response to emotional distress.

Objectives: To investigate whether medical clown-assisted interventions to reduce child's distress during venipuncture have an effect on cortisol levels.

Methods: During a 1 year period, children requiring blood work or intravenous access in the pediatric emergency department were prospectively randomized to either the presence or absence of a medical clown during the procedure. The child's distress was evaluated using the Faces Pain Scale - revised (FPS-R) for the 4–7 year age group and the visual analog scales (VAS) for those aged 8–15 years. Serum cortisol levels were measured in blood samples obtained by venipuncture.

Results: Fifty-three children aged 2–15 years were randomly assigned to the study group (with medical clown, n=29) or to the control group (without medical clown, n=24). Combined pain scores of the study group and control group were 2.2 and 7.5 respectively ($P < 0.001$). No difference in mean cortisol levels was found between the study group and the control group at all ages (16.4 µg/dl vs. 18.3 µg/dl, $P = 0.65$).

Conclusions: In this pilot study, medical clowns reduced the distress from venipuncture in children. No effect on cortisol levels was observed.

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attending the ED and can be very disturbing for children and their families, with real long-term negative emotional and psychological sequelae [2]. The anxiety, fear and behavioral distress caused by medical procedures, particularly those involving needles, exacerbate children's pain and may interfere with the procedure [3]. Cognitive psychological techniques, including distraction, can increase pain tolerance [4] and physicians should be aware of and utilize this modality [5]. Examples of distraction techniques used in children for venous blood sampling include: blowing bubbles, reading stories to children [6], using a hand-held kaleidoscope [7], watching television, using virtual reality by audiovisual eyeglasses, and listening to music [8]. In recent years there have been claims that humor and laughter possess unique characteristics that help coping with pain and stress [9], and medical clowns and humor have been shown to have a positive effect on patients [10,11]. In the last decade there has been a rapid growth in the presence of medical clowns in hospitals, particularly in pediatric settings [12].

Cortisol is secreted in response to stress and can be used to assess responses to stressful stimuli or to determine the effectiveness of a stress-reducing intervention [13]. Cortisol and ACTH are released episodically in pulses every 30–120 minutes throughout the day, but plasma concentrations of ACTH and cortisol tend to peak at 8 a.m. and to be low in the evening. Diurnal rhythms of ACTH and cortisol secretion begin to be established at 6–12 months. Levels also vary according to individual patterns, activity, sleeping, eating, and certain medications and illnesses. Although physical stress such as major injury or severe trauma can increase the secretion of ACTH and cortisol, minor surgery or minor illness have been shown to have little effect on ACTH and cortisol secretion [14].

The aim of the present study was to investigate the association between medical clown-assisted distractions for reducing children's pain and distress during standard blood collection as well as serum cortisol levels (as a proxy for physiological stress response).

The relief of pain and suffering is one of the most common reasons for seeking care at an emergency department (ED) [1]. Painful procedures are commonly indicated in children

*The first two authors contributed equally to this work

PATIENTS AND METHODS

This pilot study employed a prospective, randomized design. Children aged 2–15 years whose treatment plan included blood tests or intravenous (IV) cannulation in the pediatric ED were enrolled consecutively during a 1 year period ending September 2015. Children were enrolled in the study only if they were accompanied by at least one of their parents. Children were excluded if they needed urgent IV cannulation, had developmental disabilities, were critically ill or needed IV cannulation for the treatment of a severe bacterial infection, or if they had received glucocorticoids during the preceding 6 weeks. Following parental consent, study participants were randomly assigned to a control group or a study group by a patient allocation scheme implementing a stratified block design. Block size varied randomly from four to eight. Patient group assignment was determined at the time of patient enrollment by accessing consecutive sealed envelopes maintained in a dedicated location in the ED. Recruitment only occurred during the days when the medical clown was present in the ED. Prior to this study, the medical clown had not been part of routine care in the ED. Our control group consisted of children undergoing the same procedure with the regular distraction and comfort techniques that parents provide. The group randomized to the medical clown spent 15 minutes with the medical clown before the procedure, followed by blood collection in the presence of the medical clown. A single medical clown was involved in the study in order to reduce variation in technique. To minimize the effect of other behavioral factors, parents were not given any instructions regarding how to aid their child, nor did ED nurses utilize any guided imagery or distraction techniques, even though many were knowledgeable about distraction techniques. For the same reason, topical anesthetic was not used, although it is a well-established treatment in reducing pain. The cognitive behavioral techniques used by the medical clown for this project included:

- Distraction via humor before and during the procedure: this included various methods for entertaining the child (e.g., magic tricks, using puppets and telling jokes)
- Imagery: a technique to encourage the child to cope with the pain and distress of the procedure by asking them to imagine a pleasant object.

The primary outcome measurement was the child's rating of pain, using an age-appropriate scale, immediately (1 minute) after the procedure. Children 4 to 7 years old used the Faces Pain Scale - revised (FPS-R) [15] which utilizes a picture scale with faces in different levels of pain-distress. The FPS-R is a simplified six-face adaptation of Bieri's validated faces pain scale. Patients indicate the level of their pain by identifying the face picture of the pain they experienced. It does not contain smiling faces or tears, thus avoiding the confounding of affect and pain

intensity. A clinically significant change in pain in children is represented by a decrease in one face score, although a change of two faces indicates a more significant reduction [16]. For children 7 years and older, a visual analog scale (VAS) 100 mm in length, anchored by the terms "no pain" to "worst possible pain" was used. The children were asked to mark the point on the line that they felt represented their pain during the procedure. The minimum clinically significant change in measured patient pain severity is considered to be 13 mm [17,18].

Serum cortisol plasma levels were determined in blood samples collected during the IV cannulation to study the hypothalamic-pituitary-adrenal changes induced by this procedure, in an attempt to objectively measure stress response. The blood was collected at limited hours during the day (i.e., evening shift) to minimize the diurnal rhythm variation of cortisol secretion. Samples were centrifuged and plasma samples were stored at 4°C. Total plasma cortisol levels were determined with a commercially available chemiluminescent immunoassay kit within 2 hours of removal from storage. Information obtained from the medical record included the child's age and gender, history of previous immunizations or other painful procedures, and any use of medications.

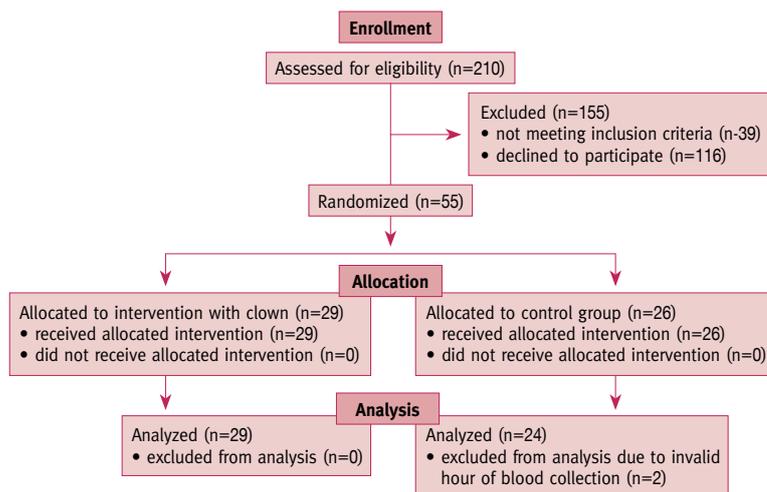
Details of the procedure, including overall success, number of attempts and procedure duration were documented. The calculation of the duration of the procedure did not include the time spent with the medical clown before the procedure since it did not consume any time or effort of the ED personnel.

Statistical analysis was performed by SAS for Windows, version 9.4. The *t*-test was used for continuous variables with normal distribution and the Wilcoxon test for non-normally distributed data as appropriate. Categorical data were analyzed using Fisher's exact test. A *P* value of 0.05 was considered significant. The study was approved by the Institutional Ethics Committee.

RESULTS

A total of 55 children were enrolled in the study. Eleven patients were 2–3 years old, 7 patients were 3–4 years old, 16 were 4–7 years old, and 21 were older than 8 years of age. Twenty-six patients were randomly assigned to receive standard care (control) and 29 were assigned to have a medical clown present during the procedure [Figure 1]. Two participants who were randomized to the control group were removed from analysis because eventually the blood test was performed outside of the defined hours of the day (not during the evening shift).

Fifty-three children (24 in the control and 29 in the study group) were included in the analyses. There were no significant differences in demographics or previous clinical experience of patients assigned to either group [Table 1]. Most children had a previous painful experience in the form of immunization, but only two had undergone IV cannulation prior to the cur-

Figure 1. Diagram of participant enrollment and study progress**Table 1.** Demographic and clinical data of the study groups

	Study group (n=29)	Control group (n=24)	P value
Male, n (%)	18 (62%)	13 (54%)	0.56
Age, yrs, mean ± SD	5.6 ± 2.8	6.9 ± 3.4	0.14
Previous intravenous cannulation, n (%)	2 (7%)	0 (0%)	0.49*
Previous immunization, n (%)	29 (100%)	23 (95%)	0.45*
Triage pain score, mean ± SD	2.0 ± 2.8	1.4 ± 2.5	0.41
Procedure duration in minutes, median (Q1, Q3)	1.5 (1.0, 2.5)	1.0 (1.0, 5.0)	0.64
Pain score, median (Q1, Q3)	2.0 (0, 4.0)	8.0 (6.0, 10.0)	< 0.001
Pain score, mean ± SD	2.2 ± 2.5	7.5 ± 2.9	< 0.001
Cortisol level, µ/dl, median (Q1, Q3)	14.5 (2.9, 23.0)	18.0 (7.0, 28.0)	0.25
Cortisol level, µ/dl, mean ± SD	16.4 ± 16.2	18.3 ± 12.5	0.65

*Fisher's exact test

rent ED visit. There was no significant difference in duration of the procedure between the two groups. The mean pain score in the intervention group was 2.2/10, which was significantly lower in comparison to a mean of 7.5/10 in the control group ($P < 0.001$). Mean serum cortisol levels were unchanged by the presence of the medical clown.

DISCUSSION

We found that pain scores were significantly lower in children who were accompanied by a medical clown during IV cannulation, but that the serum levels of cortisol were not changed by this intervention. This indicates that although the presence of a medical clown was able to reduce the subjective appreciation of pain and distress, it did not reduce an objective measure of stress. Vagnoli et al. [4] obtained results similar to ours when

they showed that the presence of a therapeutic dog reduced pain and distress in children during venipuncture, but that although blood cortisol levels were reduced the difference was not statistically significant. Due to the small number of children in the different age groups, we combined the results of two pain assessments (VAS and FPS-R). This is based on the good agreement found between the VAS and the faces scale in a previous pain evaluation study in an intensive care unit [19].

It is possible that the measurement and timing of the cortisol sampling could not reflect changes that may in fact have occurred, or that the medical clown's effect may have been nullified by the fact that drawing blood in younger children is often difficult and prolonged. A larger sample may also have revealed different results. The effect of the presence of a medical clown, employing humor in addition to traditional distraction techniques, during urgent medical procedures in children has only rarely been studied.

Hansen and colleagues [20] studied the effect of the presence of a hospital clown on 60 children treated with botulinum toxin in an outpatient setting, and Tener et al. [21] looked at the effect that medical clowns had on anxiety expressed by children undergoing evaluations after allegations of sexual abuse. The present study is a first pilot study to compare pain scores with cortisol levels, representing an objective measure of physiological stress. We attempted to assess the medical clown's influence on cortisol levels during a stressful situation in a relatively homogenous group of patients, and it seems that venipuncture, similar to minor surgery or minor illness, has little effect on the secretion of cortisol.

LIMITATIONS

There are several limitations to our study. Being a pilot study, our sample size was small and included children younger than 4 years of age, which only gave data of cortisol levels and no pain scoring. Secondly, we were unable to blind the subjects and parents to the intervention, due to the nature of the intervention which may have introduced significant bias into the results. Thirdly, the medical indication for the procedure was not controlled for in the design. In order to minimize this factor on the levels of cortisol we excluded patients with a severe illness (reflected by urgent blood tests or a diagnosis of a severe bacterial infection). Fourthly, our data are limited to IV cannulation attempts and may not be generalizable to other painful procedures performed in the ED. Finally, the pain scores we employed may not measure aspects of pain perception that are relevant to patients, and they may miss other valuable information.

CONCLUSIONS

Many techniques have been suggested for reducing pain and anxiety in the ED, and some have been successfully implemented. Distraction by humor has proven to be more economical than the use of certain analgesics and it is easier to make a

child laugh than an adult [7]. The use of medical clowns has already been well implemented on pediatric wards [22,23] and we believe they should be part of routine care for children in the ED.

Medical clowns have special training in acting and clowning and, combined with medical knowledge and an understanding of patient behavior, have become a very useful addition to ED personnel. This study demonstrated no difference in physiological stress response between the two groups, as represented by serum cortisol levels, but rather showed that a medical clown was able to reduce pain and distress subjectively in children undergoing a painful procedure in the ED. Research on the reproducibility of the instruments used in our study, and testing on larger numbers of children, would further elucidate the actual effect of the medical clown in the pediatric ED. We also suggest that future studies attempt to compare the medical clown intervention to proven pharmacological pain-reducing alternatives.

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Correspondence

Dr. A. Rimon

Pediatric Emergency Medicine, Dana-Dwek Children's Hospital, Tel Aviv Sourasky Medical Center, Tel Aviv 64239, Israel

Phone: (972-3) 697-4500

Fax: (972-3) 692-5700

email: ayeletr@tlvmc.gov.il

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