

A quasi randomized-controlled trial to evaluate the effectiveness of clowntherapy on children's anxiety and pain levels in emergency department

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Abstract The aim of the study is to investigate if the presence of medical clowns during painful procedures in the emergency department (ED) affects children's anxiety and pain. Forty children (4–11 years) admitted to the ED with the need of painful procedures were prospectively enrolled. They were randomly assigned to the clown group, where children interacted with clowns or to the control group in which they were entertained by parents and ED nurses. The children's anxiety was assessed by the Children's Anxiety and Pain Scales; pain was evaluated with the Numerical Rating Scale and Wong-Backer Scale, according to the children's age. Staff and clown's opinions were evaluated by means of dedicated questionnaires. Children's anxiety levels in the clown group were significantly lower than those compared with the control group, while children's pain levels did not change between the two groups.

Conclusion: The presence of clowns in the ED before and during painful procedures was effective in reducing children's anxiety.

What is Known:

- Anxiety and fear caused by medical procedures exacerbate children's pain and may interfere with the procedure.
- To reduce anxiety, fear, and pain and to facilitate patient's evaluation, different non-pharmacological approaches have been proposed and positive effects of laughter and humor have been reported.

What is New:

- The presence of clowns in the waiting room and in the ED during medical evaluation and painful procedures helps to reduce children's anxiety.
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Keywords Clown therapy · Procedural pain · Anxiety · Emergency department

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Abbreviations

CAPS	Children anxiety and pain scales
ED	Emergency department
NRS	Numerical rate scale

Introduction

Fear, anxiety, and pain are frequent in children admitted to the emergency department (ED) [5] being related to medical evaluation, painful procedures, and undercurrent illnesses. Uncontrolled fear and pain may significantly interfere with the patient's physical evaluation and may cause long-term negative emotional and psychological sequelae [1]. In order to reduce anxiety, fear, and pain and to facilitate patient's evaluation, different nonpharmacological approaches have been proposed [5, 18], including various cognitive psychological techniques and distraction techniques (bubbles, books, video games, or cartoon videos) [16]. Both emotional context and attentional state influence pain perception. Expectation of pain increases anxiety and pain perception while distraction may reduce pain intensity, diverting children's attention from pain towards a pleasant stimulus in order to reduce both pain perception and psychological distress [14]. Laughter and humor, by releasing endorphins and decreasing stress hormones, may reduce pain and increase stress tolerance during medical evaluation and painful procedures [9, 18]. Clowns' presence, by inducing both distraction and laughter, may be applied to reduce patients' pain and anxiety.

In one study, the presence of clowns during the induction of anesthesia significantly reduced the level of anxiety of children and parents as compared to a control group [18].

To the best of our knowledge, only one study described the presence of clowns during painful procedures in the ED settings [22], showing that their presence is effective in reducing stress with a statistically nonsignificant reduction in pain. We conducted a randomized controlled trial to investigate if the presence of medical clowns is effective in reducing children's anxiety and pain during painful procedures in the ED.

Materials and methods

This is a prospective, randomized, controlled study, carried out at the ED of a third level children hospital in Italy (Institute for Maternal and Child Health, Trieste). Children were considered eligible for the study if they needed one of the following procedures: venous blood sampling, intravenous cannulation, burn or wound dressing, immobilization of injured limbs, or wound suture.

Inclusion criteria were a minimum age of 4 and maximum age of 11 years and the need to undergo painful procedures.

This age range was chosen to facilitate a homogeneous measurement of pain and anxiety.

Premedication with any drug was considered an exclusion criterion. The study was approved by the local ethical committee and written informed consent for study participation was obtained from the parents.

Study participants were randomly assigned to an intervention or control group by an allocation concealment scheme. Patient group assignment was determined at the time of patient enrollment by accessing consecutive sealed envelopes maintained in a dedicated location in the ED.

In the intervention group, children and their parents interacted simultaneously with two clowns, both in the waiting room for a fixed 20-min period and in the ED, for the time needed to complete the medical examination and the painful procedure. Clowns used various methods for entertaining the children, according to their age: pantomime techniques, prestidigitation, juggling, and improvisation (puppets, music, etc.). The clown doctor is a figure with a specific practical and theoretical background: each clown doctor goes through a specific training, focused on the practical work situations within the social-sanitary context. These training sessions provide the trainee with theatrical and artistic/clown competences in addition to social, psychological, and pedagogical skills. The training envisages 200 h of theoretical learning and 39 traineeship hours in different settings, with at least one in-service training every year.

Children in the control group were exposed to the distraction techniques that ED nurses usually provide in our setting with the involvement of parents (soap bubbles, video games or television, books, according to patient's age).

The primary outcome of the study was the influence of clowns on children's procedural pain.

Secondary outcome was the influence on children's anxiety.

Pain perception was evaluated by the medical staff, by means of the Numerical Rating Scale (NRS) [20] for children older than 8 years or to the Wong-Backer Scale [23] for the younger ones. Children's anxiety level was assessed both in the waiting room before medical evaluation and after medical procedure, by a psychologist using the Children Anxiety and Pain Scales (CAPS-Anxiety). This is a self-report measure for assessment of anxiety/fear and pain in children from 4 to 10 years of age [8, 11], where the child is asked to select the face that represents how scared he feels. The CAPS-Anxiety scale allows children to self-report their level of anxiety distinguishing anxiety from pain by mean of two sets of 5 different faces, one reporting pain and the other reporting fear/anxiety.

Staff and clowns opinions were also evaluated by means of dedicated questionnaires. The questionnaire for health professionals was developed by Vagnoli et al. [18], to obtain the health professionals' opinion about the presence of clowns

Table 1 Assessment report on the efficacy of the interaction of the clowns (from ref [18])

The child...	For nothing	A little	Enough	A lot	Very much
Looked interested	1	2	3	4	5
Participated	1	2	3	4	5
Reacted positively	1	2	3	4	5
Smiled	1	2	3	4	5

during the medical procedures and to determine if they are useful in reducing anxiety.

The clowns filled out a Clown Effectiveness Self-Evaluation Form to evaluate their interaction with the children in the waiting room and in ED; this form was developed by Vagnoli et al. [18] and contains 4 items indicating participation of the children, scoring on a scale of 5 (Table 1).

Statistical analysis The number of 40 patients (20 per group) was established on the base of the expected difference of 50 % in the child anxiety between the two groups, considering and alpha level of 0.05 and a power of 90 %.

Data were analyzed with the use of R Project 3.1.0 for Windows (The R Foundation for Statistical Computing, Wirtschaftsuniversität, Wien). $P < .05$ was considered significant.

The demographic characteristics were analyzed with descriptive statistics. Data are presented as median and interquartile range (IQR) for continuous variables and as numbers and percentages for categorical ones.

The differences between pain levels measured during the Triage and pain levels measured during medical procedures for both groups were calculated. Mann-Whitney test was used to analyze differences between the two groups in continuous variables. Fisher's exact test was used to access differences in proportion.

Results

From December 2013 to May 2014, study enrollment was proposed to 49 eligible patients, 9 of which refused to be included. No child was lost to the evaluation.

Table 2 Demographics data of the study sample (median–IQR)

Variable	Clown group ($N=20$)	Control group ($N=20$)	P value
Age of the child, years, median (IQ range)	8 (6–9.5)	10 (7–10.5)	0.108
Gender, male, N (%)	13 (65 %)	14 (70 %)	1.000
Age of the parent, years, median (IQ range)	42 (38–46)	43 (39–46,5)	0.833
Parent, mother, N (%)	14 (70 %)	15 (75 %)	1.000

Demographic characteristics, child's anxiety values, and pain scores when arriving at the ED of both groups are reported in Table 2.

Pain levels did not change between the two groups while anxiety levels were significant lower in the clown group (Table 3). The results of the Health Professionals' Questionnaire are shown in Table 4. Clowns self-evaluated the efficacy of their intervention by means of the Clown self-Evaluation scale as 4.79 (+0.71) on a 0 to 5 scale.

Discussion

This study shows that the presence of clowns in the waiting room and in the ED during medical evaluation and painful procedures might be useful in reducing anxiety. No benefit was observed on pain levels.

In the last decade, there has been a rapid growth in the presence of clowns in hospitals, particularly in pediatric settings.

Laughter and humor have been reported as effective in order to reduce pain and increase stress tolerance during medical evaluation and painful procedures [9]. Humor involves cognitive, emotional, behavioral, psycho-physiological, and social aspects [12], while laughing replaces negative feelings with positive ones [3] and modulates the release of endorphins. Laughing creates a connection between the children and clowns facilitating further interaction and distracts the patient from the procedure [13].

Some randomized trials studied the effect of hospital clowning during specific medical interventions [2], investigating the presence of clowns before, during, and/or after surgery or anesthesia induction, and showing a reduction of anxiety [6, 19] and pain [17, 21]. The same positive results were reported by other trials, dealing with a possible long-term effect in the context of an in-patient hospital stay [4, 15]. The clown doctor's intervention seems to have both a short-term and a long-lasting effect and is appreciated since it can be easily personalized according to children's needs [7].

Procedural pain is one of the most relevant causes of pain in the ED. Many factors may influence children's anxiety during medical procedures, such as anticipation of pain [10], fear of the unknown, the stressful environment of ED setting, and parental anxiety. For these reasons, an efficacious treatment aimed at reducing stress would be welcome in this setting.

Table 3 Anxiety and pain in the two groups, before and during procedure (median–IQR)

Variable	Clown group	Control group	<i>P</i> value Pr (>F)
Anxiety in the waiting room (CAPS)	2 (1–3)	2 (0–3)	0.759
Anxiety during the medical care (CAPS)	1 (0–2)	2 (0–3)	0.013
Pain during triage (Wong-Becker Scales/NRS)	5,75 (5–7)	5 (3–6,5)	0.334
Pain during the medical care (Wong-Becker Scale/NRS)	5.5 (5–6)	5 (3–6.5)	0.183

To the best of our knowledge, only one study described the effects of the presence of medical clowns during children's venipuncture in the ED [22] reporting a nonstatistically significant reduction of pain. In this study, parents' anxiety was reduced, while children's anxiety was not measured. Our study is the first in the literature reporting a reduction of anxiety levels in children in the ED.

The clown's presence was appreciated by children and parents. The staff attitude towards clown was positive as far as the clown remained in the waiting room.

In contrast, most of the staff considered the clowns interfering with their routine ED activities, as already reported in one study in the operating room setting [18]. These data are in contrast with the global satisfaction reported by health practitioners in a pediatric ward [2]. As a matter of fact, the ED is a place with high turnover of patients, with possible time and space restraints. Moreover, staff's awareness of the benefits of reducing anxiety in children in this setting may be insufficient. Further studies could address this issue.

Table 4 Results of the questionnaire for health professionals

Questions	Staff (<i>N</i> 20) %
1 Level of appreciation for the presence of clowns in ED %	
Very favorable	10
Favorable	65
Indifferent	20
Contrary	5
Very contrary	–
2 This activity is useful:	
For the child	
Yes	75
No	5
I don't know	20
For the parents	
Yes	75
No	10
I don't know	15
For the staff, <i>n</i>	
Yes	35
No	55
I don't know	10
3 Clowns are a disturbance	
Yes	35
No	35
Sometimes	40
4 I'm favorable with the activity continuing in the PS waiting room, %	
Yes	95
No	5
5 I'm favorable with the activity continuing in the PS medical room, %	
Yes	10
No	90

This study has some limitations such as the small sample size, the fact that non homogenous painful procedures were investigated and the use of a single measure of self-report of anxiety.

A strength of the study is the fact that clowns intervention was benchmarked against a well-established standard of care, consisting on routinely application of several distraction techniques such as soap bubbles and videogame playing. Another peculiarity of the study was the use of couples of clowns that allowed to involve both the child and the parent.

Conclusions

In this study, the presence of clown doctors in the ED before and during painful procedures was an effective intervention on children's anxiety, when compared to other distraction techniques, fostering an active involvement of the child and his parents. The presence of clown doctors was not effective in reducing pain.

Further studies on larger series of specific painful procedures are needed to confirm these results.

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Author's contribution MF, IR, MM, IL, RG, and EB were involved in the design of the study; MF, IR, MM, and RG collected and analyzed the reported data; and MM, IR, and EB drafted the initial manuscript and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Compliance with ethical standards

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Conflict of Interest The authors declare that they have no conflicts of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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