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Effects of Clown Doctors on child and caregiver anxiety at the entrance to the surgery care unit and separation from caregivers

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This study investigated the effects of hospital Clown Doctors intervention on child and caregiver preoperative anxiety at the entrance to the surgery care unit and separation from caregivers. A total of 88 children (aged 4-12 years) were assigned to one of the following two groups: Clown Doctors intervention or control group (standard care). Independent observational records using the modified Yale Preoperative Anxiety Scale instrument assessed children's anxiety, while the State-Trait Anxiety Inventory measured caregiver's state anxiety. In addition, caregivers assessed the children's functional health problems by completing the Functional Status Questionnaire. Although no effects of Clown Doctors were found on children's anxiety, results showed that both low functional health problems and Clown Doctors intervention were significant predictors of lower caregiver anxiety. Caregivers also reported being very satisfied with their intervention. Overall, this study demonstrated the positive role of Clown Doctors for caregivers at a specific pediatric hospital setting.

Keywords: hospital clowning, pediatric surgery; preoperative anxiety, functional health status, caregivers.

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Introduction

The hospitalization of children and adolescents due to surgery can be a very stressful event for children (e.g., Fortier & Kain, 2015; Fortier, Martin, Chorney, Mayes, & Kain, 2011) and their parents (Bevan et al., 1990; MacLaren & Kain, 2008a; Shirley, Thompson, Kenward, & Johnston, 1998). Pediatric patients often experience high levels of preoperative state anxiety, consisting of feelings of increased fear, tension, nervousness, and worry. These concerns are mostly related to fear of the unknown, specifically the

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hospital setting, fear of complications from the medical intervention, the loss of autonomy and separation from caregivers (Fernandes & Arriaga, 2010; Fernandes, Arriaga, & Esteves, 2015; LeRoy et al., 2003; Quiles, Ortigosa, Méndez, & Pedroche, 2000). These negative effects can be externalized through several emotional and behavioral responses, which can have negative impacts in the short, medium and long-term (Caldas, Pais-Ribeiro, & Carneiro, 2004). These impacts can vary in how and when they are manifested, including resistance to treatment, reduced cooperation and avoidance of interactions with the healthcare professionals (Li & Lam, 2003), more difficulties in post-surgical recovery, delirium, and other postoperative symptoms (e.g., enuresis, apathy, sleep disturbances, pain) that may occur during hospitalization or after discharge (Chieng, Chan, Klainin-Yobas, & He, 2014; Kain, Caldwell-Andrews, Maranets, et al., 2004; Kain, Mayes, Caldwell-Andrews, Karas, & McClain, 2006). The result is that these problems can create a chronic habit of poor response to medical care or extend the need for treatment through longer hospital stays or more outpatient treatment.

One of the most common procedures used to prevent or manage children's preoperative anxiety and ease anesthesia induction is the administration of sedative premedication (e.g., midazolam, melatonin, droperidol), which has been found to be effective in decreasing the level of anxiety in pediatric patients who undergo general surgery (Gitto et al., 2015; O'Sullivan & Wong, 2013). However, because the use of sedation may provoke a plethora of side effects (e.g., ataxia, drowsiness, confusion) (LeRoy et al., 2003) including child apprehension and rejection (Golden et al., 2006), several non-pharmacological interventions have been tested to relieve preoperative anxiety. Among these, we highlight the importance of psycho-educational preparation of children and parents for surgery (Fernandes et al., 2015; Fernandes, Arriaga, & Esteves, 2014; Fortier et al., 2015), and specific cognitive and behavioral interventions, such as the use of shaping (MacLaren & Kain, 2008b), suggestion methods (Fortier et al., 2010), and distraction or refocusing techniques. Distraction, for instance, can be facilitated by playing with toys (Golden et al., 2006), video games (Patel et al., 2006), watching videos (Kerimoglu, Neuman, Paul, Stefanov, & Twersky, 2013; Kim, Jung, Yu, & Park, 2015), or through the use of humor (Berger, Wilson, Potts, & Polivka, 2014). Therapeutic play intervention (Chetta, 1981; William Li, Lopez, & Lee, 2007), biofeedback techniques (Campbell, Clark, & Kirkpatrick, 1986), music-assisted relaxation (Robb, Nichols, Rutan, Bishop, & Parker, 1995) and interactive music therapy (Kain, Caldwell-Andrews, Krivutza, et al., 2004) have also been used to reduce child preoperative anxiety. However, not all seem to have the same effectiveness, and many are influenced by various factors, including the person doing the intervention, the timing and setting in which the intervention takes place. For example, Kain and colleagues (2004) have found that interactive music therapy did not reduce child anxiety during the induction of anesthesia, compared to premedication sedation. However, upon separation and admission to the operating room, children's anxiety was dependent on the therapist.

One special group of performing artists that work currently in many hospital pediatric wards is the Clown Doctors (CD). CD began their activity in 1986 in the United States, but nowadays several CD organizations have spread around the world. The majority of such organizations include professional artists who receive specialized training to work in hospital settings. CD often use several of the above non-pharmacological and interactive strategies (e.g., distraction, humor, play, music) with the goal of increasing

the well-being of child patients, but also of parents and hospital staff. However, only recently have the effects of CD intervention been empirically examined. The results so far are promising. Most of the experimental studies that have examined the impact of the CD highlighted their positive effects in decreasing children's preoperative anxiety (Dionigi, Sangiorgi, & Flangini, 2014; Fernandes & Arriaga, 2010; Golan, Tighe, Dobija, Perel, & Keidan, 2009; Messina et al., 2014; Vagnoli, Caprilli, & Messeri, 2010; Vagnoli, Caprilli, Robiglio, & Messeri, 2005), reducing children's worries about surgery and hospitalization (Fernandes & Arriaga, 2010), providing children a better adjustment to the situation (Dionigi et al., 2014) and increasing child psychological well-being (Pinquart, Skolaude, Zaplinski, & Maier, 2011).

Experimental evidence also indicates that CD may decrease parental anxiety (Agostini, Monti, Neri, Dellabartola, de Pascalis, & Bozicevic, 2014; Dionigi et al., 2014; Fernandes & Arriaga, 2010; Vagnoli et al., 2005). However, some studies have reported non-significant effects of the CD intervention on children's anxiety (Meisel et al., 2010) and on parental anxiety (Golan et al., 2009; Vagnoli et al., 2010). There are also important differences between the studies of CD regarding the place in which the CD intervention takes place, suggesting that some conditions may be more appropriate for the activity of the CD. For example, Golan and colleagues (2009) examined the effects of CD on children (aged 3-8 years) undergoing general anesthetic during elective surgery. Specifically, they videotaped children as they were entering the surgical suite. The control group received neither CD nor premedication; another underwent sedative premedication; and the third received CD intervention in three different settings: the preoperative holding area, at the entrance to the operating room, and during application of the anesthesia mask. They found that CD intervention in the holding area was more effective than sedative premedication and control groups in lowering children's preoperative anxiety, but it did not result in greater effectiveness than sedative premedication when children entered the operating room (although it was more effective than no intervention). Furthermore, no differences between the three condition groups were found upon application of the anesthesia mask. Results of CD on parental state anxiety were also not found in this study.

Messina and colleagues (2014) analyzed the effects of CD in pediatric patients, aged 5-12 years, at two different locations: waiting room and anesthesia induction room. Children's anxiety was significantly lower in the CD group while they were in the waiting room, but no significant differences between the experimental and control groups were found during the induction of anesthesia. Distinct results were found in other studies, in which the effects of the CD in reducing preoperative anxiety were higher during the induction of anesthesia, but no effects were found during their intervention at the waiting room (Vagnoli et al., 2005, 2010). Vagnoli and colleagues' (2010) study measured preoperative anxiety in 5–12 year old children scheduled for minor surgery, and the CD intervention was compared to a premedication group and to a control group. Preoperative anxiety was measured in two settings: waiting room and induction room. Results in the induction room indicated a significantly lower level of children's anxiety in the CD group compared to both the premedication group and the control group; however, in the waiting room, no significant group differences were found. In addition, the study found no significant effects of CD on parental anxiety.

Other studies have measured the impact of CD using other measures besides anxiety. Pinquart and colleagues (2011), for example, have found an increase in pediatric patients' (aged 6-14 years) self-report and

parent-report of psychological well-being immediately after the CD visit (compared to a no-visit control group). However, after four hours, the significant effects of the visit disappeared. In addition, no effects were found on perceived physical well-being of the children. Fernandes and colleagues (2010) found positive effects of CD intervention on children's worries about surgery and hospitalization while the children were in the waiting room.

Besides the effects of non-pharmacological interventions, various reports have documented other variables that may predict child preoperative anxiety, including past hospitalization or surgical experience, age, gender, and parental anxiety (Dahlquist et al., 1986; Kain et al., 2007; Kain, Mayes, OConnor, & Cicchetti, 1996). In addition, several authors emphasized the importance of evaluating the functional health status before surgery (Cote, Lerman, & Anderson, 2013). Measures designed to assess the impact of children's functioning status are often reported in studies focusing on specific chronic diseases (e.g., congenital heart disease) (Larsen et al., 2010; McCrindle et al., 2014), but rarely used in other minor clinical conditions scheduled for elective surgery. Nevertheless, given that prior manifestation of maladaptive functional behaviors can increase the risk for lower child adjustment to hospitalization and invasive procedures (Hagglof, 1999), we considered that the preoperative functioning status of the child may play an important role in predicting both children's and caregiver's anxiety.

The main objective of this study is to analyze the impact of Clown Doctors on children's and caregiver's preoperative anxiety during the separation from the caregiver and entrance to the surgery care unit. To our best knowledge, this is to date the only study investigating the role of CD when the child is separated from the caregivers. For this purpose, we evaluated the CD intervention using child observational records of their levels of anxiety. Caregiver's state anxiety was also collected by means of self-report. In addition, information regarding the functioning health status of the child during the two days before surgery was analyzed to determine whether it would predict both child and caregiver's preoperative anxiety. We expected that the CD intervention would lead to lower levels of preoperative state anxiety compared to the control group (i.e., standard care) for both children (H1) and their caregiver (H2). In addition, we also expected that high display of functional problems during the days preceding surgery would be positively correlated to child preoperative anxiety (H3) and to levels of caregiver's state anxiety (H4). Finally, we were interested in analyzing whether the influence of the CD intervention would still be a significant predictor of children's and caregiver's state anxiety, after controlling for the contribution of the other baseline variables (demographic and clinical).

Method

Participants

Eighty eight children (67% male), who underwent elective general surgery, and their caregivers (78% mothers), participated in the study. The children ranged in age from 4 to 12 years (M_{age}= 7.27 ± 2.30), while caregiver's age ranged from 24-63 years (M_{age} = 38.88 ± 6.93). The majority of the children underwent surgery for the first time (56.3%), but more than half had previous experience with hospitalization (58%) due to the experience of a family member or close associate. Most of the children were also scheduled to receive

ambulatory care, i.e., outpatient surgery (78.4%), involving minor or intermediate procedures. However we had 19 children who received inpatient care, i.e., a stay in the hospital for more than 24 hours. Table I displays demographic and clinical information as a function of groups, including the wide variety of surgical procedures. Exclusion criteria [1] were as follows: pediatric patients who fall outside the age range (4-12 years) or had developmental delays; caregivers who had difficulty in understanding the language or the meaning of the questions.

Participants were assigned to one of two groups: the CD Group (i.e., a clown interacted with the children who were accompanied by the caregiver) (n = 44) or a Control Group (i.e., the children were only accompanied by the caregiver) (n = 44). The assignment was dependent on the day of the availability of the CD and it was necessary that their intervention would occur on distinct days from the control group to avoid children and caregiver awareness of different treatments. Thus, a quasi-experimental design was chosen to control threats to the interval validity of the study such as cross-contamination between the treatment and control group, compensatory equalization of treatments, or resentful demoralization.

Table I. Demographic characteristics and clinical baseline indicators of the total sample by group conditions

	Clown Doctors (n = 44)	Control (n = 44)	Total (n = 88)
Child's age (4-12 years)	6.82 ± 1.97	7.73 ± 2.53	7.27 ± 2.30
Child's gender			
Female	10 (22.7%)	19 (43.2%)	29 (33%)
Male	34 (77.3%)	25 (56.8%)	59 (67%)
Children with a history of previous hospitalization	27 (61.4%)	24 (54.5%)	51 (58%)
Children with a history of previous surgery	18 (41.9%)	20 (45.5%)	38 (43.7%)
Child's functional status	.54 ± .50	.55 ± .49	.55 ± .49
Type of Care			
Outpatient/Ambulatory	34 (77.3%)	35 (79.5%)	69 (78.4%)
Inpatient	10 (22.7%)	9 (20.5%)	19 (21.6%)
Caregivers			
Mother	34 (77.3%)	35 (79.5%)	69 (78.4%)
Father	9 (20.5%)	9 (20.5%)	18 (20.5%)
Grandmother	1 (2.3%)	0	1 (1.1%)
Caregiver's age (years)	39.68 ± 7.09	38.07 ± 6.74	38.88 ± 6.93
Caregiver's educational level			
< High school	34 (77.3%)	31 (72.1%)	65 (74.7%)
> High school (bachelor's or higher degree)	10 (22.7%)	12 (27.9%)	22 (25.3%)

Notes. Values are mean ± standard deviation or n (% within group conditions and overall). Procedures for outpatient care included: Circumcision/hypospadias repairs; Skin/subcutaneous lesion excision; Inguinal/umbilical/femoral hernia repair; Tonsillectomy and/or adenoidectomy; Excision of varicocele; Orchidopexy; Diagnostic acts in muscle/tendon/fascia/synovial bag; Closure of branchial cleft fistula; Excision of pilonidal cysts and sinuses; Excision of preauricular sinus; Excision of thyroglossal duct cyst (Sistrunk); Exploration of tendon sheath of hand; Insertion of tibial and peroneo epiphysis; Local excision or destruction of articular lesion; Removal of implant/prosthesis (radius/ulna or humeral); Tenotomy; Tumor excision; Tympanostomy tube removal; Urethroplasty; Division of muscle/tendon/fascia of hand; Lingual frenectomy; Myringotomy; Orthoplasty; Removal of implant/prosthesis (radius/ulna or humeral); Urethroplasty; Procedures for inpatient care included: Arthroscopy; Bone Biopsy; Orchidopexy; Laparoscopic cholecystectomy; Operations on the musculoskeletal system; Osteotomy; Excision/destruction of lesion/tissue of bladder; Percutaneous nephrostomy without fragmentation; Circumcision / Hypospadias repairs; Skin/subcutaneous lesion excision; Tenotomy; Tonsillectomy and/or adenoidectomy; Urethroplasty.

Measures

Socio-demographic and clinical data included children's and caregiver's age, gender, nationality, previous hospitalization, and previous occurrence of surgery.

Children's functional status was assessed using the Functional Status Questionnaire (FSQ) (Lewis, Pantell, & Kieckhefer, 1989).The FSQ contains a selection of 14 items taken from the Functional Status II-R (a 50-item survey) suitable for ages 0 to 16 years. The FSQ was designed to be self-administrated by the caregivers, measuring children's health functions related to basic activities, mental health, social activity, and quality of children's interactions. It provides two scores, one that measures the child's generic functional status (FSQ-G) during the past two weeks, and another that assesses the functional status specifically related to a medical condition (FSQ-S). In our study, we only report the child's general functional problems (FSQ-G) before surgery. Thus, caregivers rated the frequency of their child behaviors in the preceding 'two days before surgery' ("*During the last two days, how often did your child express the following behaviors?*"). Caregivers used a 5-point Likert type scale ranging from 0 (*Never*) to 4 (*Almost always*) to report on each of the 14 items. In the present study, the Cronbach's alpha for FSQ-G was .84, indicative of good reliability.

Children's Anxiety was measured using the modified Yale Preoperative Anxiety Scale (m-YPAS) (Kain et al., 1997). This modified version consists of a list of 21 behaviors distributed in five anxiety domains: 'activity' (4 items), 'vocalization' (5 items), 'emotional expressivity' (4 items), 'state of arousal' (4 items) and the 'use of caregivers' (4 items). This observational scale was developed to assess children's preoperative anxiety and has provided good reliability scores. Additionally the tool has concurrent and construct validity for children aged 2-12 years (Kain et al., 1997).It has been also used in previous studies to examine the effects of CD in children's preoperative anxiety (Golan et al., 2009; Messina et al., 2014; Vagnoli et al., 2010; Vagnoli et al., 2005). For the present study, two additional items were added (one item in the emotional expressivity; and another in arousal state) giving a total of 23 items. Because each subscale has different number of items, we followed Kain and colleagues (1997) indications to compute partial weights and then summed all scores making up a total ranging from 0 to 100. Two observers, a psychologist and the caregiver, rated a child's anxiety. Both raters scored the child's levels of anxiety immediately after the child was separated from the caregiver and entered the surgery care unit. Intercoder reliability was calculated using Hayes and Krippendorff (2007) macro for SPSS. Krippendorff's alpha for preoperative anxiety was .67, an acceptable reliability level. An overall mean between the two coders was computed. In the present study, m-YPAS scores ranged from 18 to 63 (M = 31.35; SD = 11.89) with higher scores indicating high levels of children's preoperative state anxiety.

Caregiver's State Anxiety was measured with the State subscale of the State-Trait Anxiety Inventory, Form Y (STAI-Y), originally developed by Spielberger, Gorsuch, Lushene, Vagg, and Jacobs (1983). We used the Portuguese version by Santos and Silva (1997). The state anxiety subscale contains 20 items referring to how the individual feels at the moment, including feelings of tension, nervousness, and worry. It presents a response format with four options ranging from 1 (*not at all*) to 4 (*very much*). Scores can range from 20 to 80, with higher scores indicating higher levels of state anxiety. The STAI is one of most commonly instruments used in research when measuring anxiety in adults and has shown excellent

psychometric qualities both in the original and the Portuguese versions for different samples (e.g., Silva & Campos, 1998). It has also been frequently used in hospital settings to evaluate the effectiveness of intervention programs in reducing parent's state anxiety levels (Fernandes & Arriaga, 2010; Golan et al., 2009; Vagnoli et al., 2010). In the present study, STAI scores ranged from 20 to 76 (M = 42.00; SD = 11.11) with higher scores indicating high levels of caregiver's state anxiety. Coefficient alpha was .93; a very high reliability score. Finally, caregivers in the CD group were asked whether the clown intervention had helped them and the child to feel better, and whether they considered their intervention appropriate to the specific context in which occurred. Responses were made on a 6-point scale ranging from 0 (*not at all*) to 5 (*extremely*).

Procedure

The pediatric patients were selected from the surgery unit schedule, based on the criteria for inclusion in the study. The CD intervention occurred during the child's separation from the caregivers at the entrance of the surgical care unit. Because in this particular setting children were already pre-medicated with oral midazolam combined with droperidol (0.2 ml/Kg was administrated 30 min before the surgery), CD activities were adjusted to reduce the emotional arousal states of the child. Thus, the CD costume used subtle make-up, the same medical scrubs as any other medical personnel (e.g., medical white gowns, protective covers on the shoes to help prevent contamination), but nevertheless some clown accessories (e.g., red nose, large glasses) and tools, such as a viola to play music, were used. Although CD often work in pairs, for this study only one clown interacted with the patients because of the small environment in which the interaction took place. The clown accompanied the child until the entrance of the surgery care unit with the caregiver. At this specific location the clown stayed with the child and the caregivers between 3 to 15 minutes. Then, the child was separated from the caregivers and taken by the CD and a nurse to the entrance of the operating room. To avoid interference during child-caregiver's interaction, the completion of the questionnaires took place in the waiting room, after the child went inside the surgery unit. The questionnaire explored socio-demographic and clinical data; the child's functional health status and anxiety; and the caregiver's own state anxiety. The caregiver and child reunited after surgery, when the child was taken to the recovery room. For 17 children (37.6%) of the CD group, the clown stayed in the recovery room with the caregiver and played soft music.

Results

Preliminary Analyses

To analyze whether the baseline characteristics of the sample were comparable between the two groups, we used *Fisher's exact tests* for *dichotomous variables*, Chi-square tests for categorical variables with more than two levels, and t-student tests for continuous variables. The socio-demographic characteristics were comparable between the two groups with reference to the distribution of the children's age ($t(86) = -1.88$, $p = .063$) and gender (Fisher's exact test, $p = .069$), and the caregiver's age ($t(86) = 1.09$, $p = .227$) and level of education (Fisher's exact test, $p = .628$). Groups were also similar regarding children's prior history with hospitalization (Fisher's exact test, $p = .666$), surgery (Fisher's exact test, $p = .83$), and type of surgery care

(Fisher's exact test, p= 1.0) (see Table I). Children in the CD group were also fairly comparable to children in the control group on perceived functional status (t (86) = .08, p = .94). More detailed information on the results of the functional status is given in Table II. With the exception of the item 'moody', all the other maladaptive behaviors indicative of children's reduced functional status were endorsed by a relatively small number of caregivers, indicating that the majority of children in the sample were perceived by their caregivers as not displaying functional problems in the two days leading up to surgery.

Table II. Children's functional status: frequency and percentage of functional problems in the preceding two days before surgery.

Items	*n*	%
Moody	45	51.1
Crying	42	47.7
Eat well*	34	38.6
Happy*	33	37.5
Energetic*	33	37.5
Interest*	33	37.5
Sleep well*	32	36.4
Respond when asked*	32	36.4
Self-occupying*	29	33.0
Sleep through night*	29	33.0
Irritable	27	30.7
Difficult	27	30.7
Communication*	25	28.4
Tired and unhealthy	19	21.6

*Reversed scoring

Hypothesis Testing

Our main hypotheses were analyzed through the use of independent sample *t*tests. For estimations of the effect sizes both Cohen's d and Hedges' g_s were reported as suggested by Lakens (2013). Contrary to our first hypothesis, no statistically difference was found between groups on children's anxiety (M_{CD} = 32.40,SD_{CD} = 11.03 vs. $M_{Control}$ = 35.86,$SD_{Control}$ = 15.69),t (85) = -1.19,p = .236, 95% CI [-9.26, 2.33], Cohen's d = 0.26,and Hedges's g_s = 0.25. Thus, CD seemed to have no effect on children's preoperative anxiety at the entrance to the surgery care unit. However, in line with our second hypothesis, caregivers in the CD group reported significantly less state anxiety (M = 39.57, SD = 10.29) than those in the control group (M = 44.43, SD = 11.48),t(86) = -2.09,p = .039, 95% CI [-9.48, -0.24], Cohen's d = 0.45, and Hedges's g_s = 0.44. In addition, caregivers in the CD group expressed very positive opinions about the clown intervention. The majority reported that the clown helped the child (77% 'a lot/extremely'; 16% 'moderately'; 7% 'little') and themselves (72% 'a lot' or 'extremely'; 21% 'moderately'; 5% 'little'; only one caregiver stated it was 'not at all' helpful). Their intervention was also considered very appropriate for the context in which it took place (91% ' lot/extremely'; 7% 'moderately').

Pearson bivariate correlations were also performed to identify demographic and clinical variables that might predict preoperative child and caregiver anxiety. As can be seen in Table III, there was no statistically significant relationship between demographic/clinical measures and the levels of the child and caregiver anxiety. Furthermore, contrary to the third and fourth hypotheses, the display of preoperative functional problems and caregiver anxiety were not related to children's anxiety. However, a significant correlation was found between the perceived functional problems of the child and caregiver's state anxiety, r (88) = .24, p = .024.

Table III. Pearson correlations between demographic and clinical data, child functional status and anxiety and caregiver anxiety.

	Child State Anxiety	Caregiver State Anxiety
Child's sex	.10	.17
Child's age	.13	-.03
Child's prior history of surgery	-.04	.14
Child's prior history of hospitalization	.06	-.09
Caregiver's age	-.06	.05
Functional status	.18	.24*
Child's anxiety	--	.11

* p< .05

Given that we only found significant relationships between caregiver's anxiety and the general functional status of the child and group condition, we only tested H4 (but not H3), i.e., whether CD intervention would be still able to explain some variance in the caregiver's anxiety, over and above the perceived functional problems of their child (see Table IV). A Hierarchical Multiple Regression (HMR) analysis showed that child functional status contributed significantly to the regression model (F (1, 86) = 5.31,p = .024) accounting for 6% of the variance in caregiver's anxiety. The inclusion of the group condition to the model in step 2 increased the explanation significantly, with an additional 5% of the variance in caregiver's anxiety, after statistically controlling for the functional status (F_{change} (1, 85) = 4.52, p = .036). Overall, the results showed that both group condition (i.e., being in the CD group) (β = -.24, p = .022) and perceiving lower functional problems in the child (β = -.22, p = .036) accounted for 11% of low levels of caregiver's anxiety.

Table IV. Hierarchical Multiple Regression Analysis predicting caregiver's anxiety

Predictors	Unstandardized coefficients		Standardized coefficients			
	B	*SE*	β	*t*	R^2	*F*
Step 1					.06	5.31*
Functional status	5.43	2.36	.24	2.30*		
Step 2					.11	5.02**
Functional status	5.39	2.31	.24	2.33*		
Group condition	4.82	2.27	.21	2.13*		
					$\Delta R^2 =$ .05, ΔF = 4.52*	

Note. * p< .05; ** p< .01; Group condition (Clown Doctors = 1; Control = 2).

Discussion

Pediatric surgery can be a very stressful event for many families, with the potential of creating high preoperative anxiety in both children and caregivers. This, in turn, may negatively affect the behavioral responses of children both during hospitalization and after hospital discharge in short, medium and long-term. To reduce preoperative anxiety, several types of interventions have been proposed, but the results of research in this area have been mixed. One of the most promising interventions is the work that is being conducted in hospitals by 'clown doctors' (CD). However, research in this area has been scant at best, pointing out the need to identify how, and at what time in the hospital stay, these groups of professional artists may have the strongest impact on reducing child and caregiver preoperative anxiety. Some studies suggest that Clown Doctors have an important role when the child is in the holding area (Golan et al., 2009; Messina et al., 2014), while others have indicated greater effects in contexts that tend to be more stressful to the child, such as the induction of anesthesia (Vagnoli et al., 2010; Vagnoli et al., 2005). However, in many of the studies investigating the effects of CD, the caregivers were always allowed to enter into the surgery care unit and operating room with their child. Therefore, parents were not separated from their child at any point. This is relevant, since research has also shown that the anticipation of being separated from caregivers is one of the factors that can be related to children's increased preoperative anxiety (LeRoy et al., 2003; Quiles et al., 2000). For this reason, we studied the effects of CD within this particular context – entrance to the surgery care unit during a phase in which the child is separated from their parents. This is a regular procedure at the hospital in which this study was conducted, and therefore it was not imposed by the researchers.

The potential effects of CD on parental anxiety is also an important factor because the caregivers' anxiety can be transferred to the child. Previous studies have also reported mixed findings, with some studies suggesting that CD significantly reduced caregiver's anxiety (Agostini et al., 2014; Dionigi et al., 2014; Fernandes & Arriaga, 2010; Vagnoli et al., 2005), while others did not find support for this outcome (Golan et al., 2009; Vagnoli et al., 2010). Thus, our present study was developed to contribute to this line of research and examine the effects of CD intervention on child and caregiver preoperative anxiety in a context that has

not been investigated before. We expected that the CD intervention would produce lower levels of preoperative state anxiety in children and their caregivers compared to the control group.

Results from our study confirmed the hypothesis that predicted lower anxiety levels in caregivers, but did not support the hypothesis related to child anxiety. However, the use of a sedative premedication might be responsible for the lack of significant difference in child anxiety between the two groups. Sedative premedication, especially Midazolam, is a very effective technique in reducing children's preoperative anxiety (O'Sullivan & Wong, 2013). However, some of the side effects of sedation, i.e., being sleepy or drowsy, may have reduced the levels of interaction between clown-child, which according to Tan Jr., Metsälä, and Hannula (2014) can be a barrier during CD intervention. It is also possible that children might have not changed their level of anxiety because caregivers were present in both groups and therefore the children did not perceive this moment as stressful. Moreover, all the other factors that were measured (children's age, sex, prior history of surgery/hospitalization, children's functional problems in the preceding days, and caregiver's anxiety) were not significantly related to the children's preoperative levels of anxiety. This indicated that children's anxiety level at this particular phase was similar for most of the children in our study.

The m-YPAS scores were also relatively similar to studies in which children were evaluated in the waiting room (Messina et al., 2014; Vagnoli et al., 2005).This finding suggests that the combination of setting and sedation may have regulated anxiety levels and therefore rendering the Clown Doctor intervention doubtful. However, we do not know whether our results would be similar in the absence of premedication or in the absence of caregivers. In Vagnoli and colleagues' (2010) study it was found that clown intervention with parents present was better at reducing child preoperative anxiety during the induction phase compared to the other two conditions (parents alone or parental presence with premedication), but there were no significant difference in the waiting room and no effect on parental anxiety. In our study, we were only able to compare clown intervention with premedication and caregiver presence vs. caregiver presence and premedication, but in a different context, and we found different results for caregiver's anxiety. In future studies, it would be relevant to dissociate the effects of each intervention by comparing clown intervention alone vs. parent presence alone vs. premedication alone, so as to determine which can be more effective in reducing children's anxiety (cf. Vagnoli et al., 2010). Further, the children's preoperative anxiety measure we used in our study, although the same as in the other studies, was coded by different observers; in our study, by caregivers and one psychologist, instead of other health professionals. This methodological distinction might also have contributed to the findings. It would be relevant in future studies to include other observers coding the child anxiety behavior, and compare the results between the different groups of observers.

Nevertheless, caregivers found the clown intervention very positive for the children and themselves. CD was also viewed as appropriate for the context in which it took place. After separation from the child, caregiver anxiety in the CD group was significantly lower when compared to the anxiety reported by the control group. In addition to their positive view about the CD intervention at the entrance to the surgery unit, the fact that caregivers knew that the clown would also accompany the children until the surgery room, might have influenced their level of anxiety. Thus, the CD could have distracted caregivers from their concerns,

fears, and tensions, and may have also been perceived to provide the emotional support the child needed while she/he was being transferred to the surgery room.

The correlation between caregivers' perception of the child functional problems and their own level of anxiety is another interesting finding in the study. It is understandable that higher anxiety level amongst the caregivers would be related to perceived higher functional health problems observed in the child, particularly as this was assessed only on the basis of the caregivers' views. Since this variable was considered relevant to predict caregiver anxiety, we statistically controlled for its effect by analyzing whether the influence of the CD intervention would still predict the caregivers' state anxiety. The multiple regression model showed that the CD intervention remained a significant predictor of lower state anxiety, and both variables (lower functional problems in the child and being in the clown group) contributed to explain low levels of caregiver's anxiety. One should take into account, however, that both variables only predicted 11% of the variance in caregivers' anxiety, indicating that the effect of these variables was relatively small, but nevertheless relevant to caregivers' emotional state.

The experimental study of the effects of CD in children, caregivers and health professionals is only in its beginning stages. The existing research supports their important role in hospitals but it also suggests that their effect might be stronger in particular situations than others. The most promising finding from the current study was the positive influence of the CD on caregivers' anxiety in the preoperative period, specifically at the moment when the child was entering the surgical care unit and was going to be separated from them. However, the presence of a clown only at the entrance of surgery care unit when the child was still in the presence of their parents and was under the influence of sedation, seemed to make no difference in the child's level of anxiety. However, in view of the overall caregivers' appreciation of the CD intervention and the potential impact of caregivers' emotional states on the well-being of children, we conclude that the CD presence at the entrance of a surgery care unit and in a phase that children are separated from caregivers, is very positive and should be encouraged. Further research on this important topic is warranted for the understanding of the conditions and the timing for effective clown intervention in order to reduce both the child's and the caregiver's anxiety and increase their well-being in hospital.

Footnotes

[1] A total of 91 children and 91 caregivers were initially enrolled in this study. However, due to significant age differences between the two groups, three participants were excluded for presenting extreme age values that almost failed the age criteria. Nevertheless, similar results were found after testing the hypothesis with the inclusion of these three additional participants. The results obtained with the initial sample of 91 participants can be provided by the authors.

[2] Originally, we planned to collect observations from the hospital nursing staff. Due to their difficulties in being present for the whole time in which the interaction between the child-caregivers and clowns occurred, the few observational records collected from them were not analyzed.

[3] The results of the group condition on children's anxiety were very similar when analyzed separately the observational ratings of the psychologist (t (88) = -1.56, p = .122) or of the caregivers (t (88) = -.56, p = .579).

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