Brief Report: Evaluation of an Interactive Intervention Designed to Reduce Pediatric Distress During Radiation Therapy Procedures

James L. Klosky,1,6 PhD, Vida L. Tyc,1,5 PhD, Deo Kumar Srivastava,4,5 PhD, Xin Tong,4 MPH, Mindy Kronenberg,1,6 MS, Zorana J. Booker,1 MS, Alberto J. de Armendi,3,5 MD, and Thomas E. Merchant, DO,2,5 PhD

1Division of Behavioral Medicine, 2Department of Radiation Oncology, 3Department of Anesthesiology, 4Department of Biostatistics, St. Jude Children’s Research Hospital, 5Department of Pediatrics, University of Tennessee College of Medicine, and 6Department of Psychology, University of Memphis, Tennessee

Objective To evaluate the efficacy of an interactive intervention in reducing distress related to radiation therapy (RT) among pediatric cancer participants as measured by occurrence of sedation, observed behavioral distress (OBD), and heart rate (HR).

Methods Seventy-nine children receiving RT simulation were assigned randomly to a STARBRIGHT Hospital Pals group (i.e., interactive intervention group; IG) or modified control group (MCG). The interactive intervention included filmed modeling, exposure to an interactive Barney character, and passive auditory distraction.

Results Children in the IG experienced significantly lower HR when compared with MCG participants. No differences were found in terms of sedation or OBD.

Conclusions The interactive intervention was effective at reducing RT-related distress (as measured by HR) and would be a useful tool in pediatric radiation oncology settings.

Key words pediatric distress; interventions; noninvasive medical procedures; radiation therapy.

Radiation therapy (RT) is a curative form of therapy used to treat a variety of pediatric and adult malignancies. It can be used alone or with surgery and chemotherapy to eradicate malignant disease and preserve normal tissue structure and function (Merchant, 2000). Before treatment, a 30–90-min planning session, or simulation, takes place to construct customized immobilization devices, radiographically localize the region to be treated, position the patient for treatment, and perform measurements to simulate the geometry of the treatment machine (i.e., linear accelerator).

Although RT is noninvasive and painless, distress reactions may occur as a result of unfamiliarity with the procedure and medical staff, painful experiences with previous medical procedures, separation from caregivers, or from the sights and sounds of the RT equipment (Slifer, 1996; Slifer, Bucholtz, & Cataldo, 1994). For optimal RT treatment delivery to take place, participants must be immobilized for extended periods. Daily reproducibility of patient positioning allows for more precise irradiation of the tumor site with subsequent reductions in healthy tissue irradiation and acute and chronic adverse side effects (Zhu et al., 2000). When children are unable to maintain a fixed and reproducible position required for treatment, the success of RT is compromised, and sedation or anesthesia is typically required. Completion of RT procedures without pharmacological intervention is preferred, as repeated sedation, high dosages of sedatives, multiple drug use, and general anesthesia all increase the risk of medical complication among children (Lew, 1992). It is therefore preferable to implement alternative behavioral approaches with RT whenever possible.

Psychological intervention has proven useful in the reduction of pediatric distress related to invasive medical
procedures (Schiff, Holtz, Peterson, & Rakusan, 2001; Zelikovsky, Rodrique, Gidycz, & Davis, 2000). For example, Jay, Elliott, Katz, and Siegel (1987) found that a cognitive–behavioral therapy (CBT) package consisting of filmed modeling, breathing exercises, imagery/distraction, positive incentives, and behavioral rehearsal significantly reduced observed behavioral distress (OBD), heart rate (HR), and pain ratings among children experiencing bone marrow aspiration. Schiff and colleagues (2001) used a cognitive–behavioral package to reduce OBD and child-reported pain among those undergoing routine venipuncture. Although the value of using CBT techniques in the reduction of invasive procedural distress has been established, much less is known about their role in reducing distress related to noninvasive medical procedures.

Despite the absence of pain inherent to noninvasive medical procedures, young children frequently experience procedural distress that can adversely affect diagnostic and treatment outcomes (Bradford, 1990). As a result, an emerging literature has developed examining the effects of psychological intervention in reducing pediatric procedural distress during noninvasive medical procedures (Stevenson et al., 1990). Slifer et al. (1994) reported on a behavioral intervention package designed to increase motion control among children undergoing RT-related procedures. Despite receiving up to 3 hr of psychologist-delivered behavioral training, 60% of participants required sedation to complete the RT simulation procedure, with all children under the age of 5 years requiring sedation. However, when an in-treatment video component was added to the intervention, Slifer (1996) reported that 82% of participants voluntarily complied with RT simulation, a group that included children as young as 2.5 years of age. Despite small sample sizes and uncontrolled experimental designs, Slifer’s results suggest that the inclusion of in-treatment multisensory distractions in cognitive–behavioral intervention packages may increase voluntary compliance and decrease the need for sedation among preschool and school-age children experiencing RT simulation.

To date, no studies have examined the usefulness of psychological interventions that incorporate well-established CBT strategies delivered via automated interactive technology in the reduction of distress among children undergoing noninvasive medical procedures such as RT simulation. The primary purpose of this study was to evaluate the efficacy of an interactive–educational intervention in reducing RT-related distress as measured by sedation, HR, and OBD. We hypothesized that children who received the intervention would be less likely to require sedation for the RT simulation procedure and they would experience smaller increases in OBD and HR relative to baseline when compared to the control group. This study is unique in that the automated interactive intervention was delivered by health care professionals while behavioral, psychological, and sedation outcomes were simultaneously assessed.

Method
Participants
Seventy-nine parents and participants receiving RT at St. Jude Children’s Research Hospital (SJCRH) were consecutively enrolled on the study, which was reviewed and approved by the institutional review board. Eligible participants were those who were 2 to 7 years old (M = 4.2, SD = 1.6), used English as their primary language, had a primary diagnosis of malignancy, had no experience with external beam irradiation, and were functioning at a level at which they could tolerate RT intervention—that is, an Eastern Cooperative Oncology Group (ECOG) score of zero to 3. No families approached for the study refused participation.

Measures
Sedation. A child was considered sedated for the RT simulation if any type of pharmacotherapy intervention was delivered at the time of simulation initiation for the purpose of ensuring procedural compliance. Examples of sedation include general anesthesia, intravenous (conscious) sedation, par oral sedation, or any combination of these three.

OBD. Based on Jay, Ozolins, Elliott, and Caldwell’s (1983) Observation Scale of Behavioral Distress (OSBD), a checklist modified for use within the RT setting was used to code behavioral distress experienced during the RT simulation. This modified checklist comprised 12 operationally defined behaviors, which included verbal (e.g., “I’m scared,” “No, wait”), vocal (e.g., crying, moaning, whining), and nonverbal (e.g., physical resistance) behaviors. This checklist is similar in content to other behavioral observation scales and methodologies for rating and scoring children’s behavioral distress during invasive medical procedures (Elliott, Jay, & Woody, 1987). Observed distress behaviors have previously been reliably coded using a modified form of the OSBD during noninvasive pediatric procedures (Tyc, Leigh, Mulhern, Srivastava, & Bruce, 1997). Trained clinical observers independently rated participants’ distress behavior and recorded the frequency of these behaviors during 5-min intervals over a 10-min baseline period and simulation.
procedure. A Pearson product–moment correlation analysis yielding an $r$ of .95 ($p < .01$) across raters. The sum of these behaviors was used as the OBD dependent measure, and mean OBD per minute scores were used in the study analyses.

**HR.** Physiological arousal has been typically included as a measure of distress and anxiety in studies examining pediatric invasive and noninvasive medical procedures, although no consensus exists regarding whether HR is a valid, reliable, and sensitive measure of distress (Jay et al., 1987; Peterson & Shigetomi, 1981). In this study, a Nellcor pulse oximeter recorded the HR of participants every 30 sec via an oxisensor attached at the patient’s finger. Mean HR-per-minute scores were used in our analyses.

**State-Trait Anxiety Inventory (STAI).** The children’s parents rated their own state anxiety via completion of the STAI (Spielberger et al., 1983). The STAI, a standardized inventory with well-documented clinical validity, is designed to measure state and trait anxiety in adults. The test–retest correlations ranges from .16 to .62, with a median alpha coefficient of .90, reflecting the transitory nature of state anxiety (Spielberger et al., 1983).

**Procedure**

Parents of eligible children were approached and presented with the details of the study as they arrived for their children’s RT simulation. At this time, informed consent was obtained according to institutional guidelines. Participants were then observed in an examination room via video monitor, and 10 min of baseline data (HR, OBD, and parental data) were collected just prior to the participants’ RT simulation. Participants were then randomly assigned to one of two groups: the intervention group (IG) or a modified control group (MCG).

**IG.** Children assigned to the IG received a cognitive–behavioral intervention package (STARBRIGHT Hospital Pals) that included exposure to an interactive animatronic plush Barney character, an educational video including filmed modeling, and passive auditory distraction via Barney-narrated stories delivered during the RT procedure.

**Educational filmed modeling.** For children randomized to the intervention condition, a 7-min educational video was shown once immediately after the collection of baseline data. The video demonstrated a young child successfully completing each stage of RT. The video, which is narrated by Barney and a young model patient, instructed children on three points: (a) the modalities and machines to be used, (b) the importance of remaining still during RT-related procedures, and (c) that Barney would accompany the child during each phase of RT treatment.

**Interactive ActiMates Barney.** This character was introduced to children in the IG just before viewing the educational video. The 13-in. (15.24-cm) automated plush Barney character interacted with the video while reinforcing key teaching points through movement and commentary. Once the intervention video was completed, the ActiMates Barney continued to interact with the child by playing age-appropriate games and singing songs to and with the child. During this phase, children interacted with Barney by manipulating the sensors on the character’s hands, feet, and eyes.

**Passive auditory distraction.** Upon entering the simulation room, the intervention participants were met by a noninteractive Barney character. This Barney character was noninteractive to emphasize the importance of the child’s remaining motionless during the simulation procedure. The noninteractive Barney sat on the treatment table and acted as a companion to the child during simulation while narrating vivid stories designed to distract and calm the child.

**Comparison group.** Children assigned to the MCG received a similar intervention composed of exposure to an age-appropriate cartoon video, a noninteractive children’s control character, and stories delivered via cassette tape during simulation. These participants did not receive the filmed modeling, interactive character, or Barney-narrated stories as those in the intervention condition did. This group is referred to as the MCG as these participants received intervention components that are not typically delivered as standard treatment at SJCRH.

**Logistics of observations and measurements.** Data collection began the moment the child entered the simulation room. If the child was unable to comply with the RT procedure in 15 min, sedation was prescribed. Simulation HR and OBD data were collected until the sedation agent was administered or until the simulation procedure was successfully completed.

**Data organization and reduction.** Data were organized to reflect two phases of baseline and treatment simulation: initial phase (first 3 min of HR data and the first 5 min of OBD) and total treatment (cumulative HR and OBD data collected during entire baseline and simulation procedures). Distress data (initial and total phases) were reduced to OBD and HR per minute to control for differences in time observed in treatment.

**Data analyses.** Sedation rates for the experimental groups were compared using Fisher’s exact tests, and a one-sided $p$ value was used. Repeated measures analyses of variance (ANOVAs) were conducted to assess associations between demographic, medical, and parental psychological variables with OBD and HR outcomes.
These variables included treatment group, gender, race, diagnosis, performance status (ECOG scores), age at simulation, treatment position, and parent state anxiety. Two-sided p values were reported for all repeated measures analyses. No significant baseline differences existed between groups on the demographic, medical, or parental variables.

Results

**Sedation.** Our sample size yielded 80% power to detect differences between the intervention and control groups of approximately 0.5 SD at α = .05 on the sedation outcome. At simulation, 61.0% (25/41) of the interactive IG and 63.2% (24/38) of the MCG participants required sedation to complete the procedure. There were no significant differences between groups for sedation, Fisher exact test, p < .50. Among participants aged 4 years and older, 25% (4/16) of the interactive IG and 48% (10/21) of the MCG participants were sedated, yet no significant differences were identified, Cochran-Mantel-Haenszel statistic = 1.70, p < .16.

**OBD.** Means and standard deviations of OBD scores for the experimental groups are provided in Table I. Repeated-measures ANOVA was used to determine the effect of selected covariates on the initial and total phase of OBD from baseline to simulation, and none was significant.

**HR.** Means and standard deviations of HR scores for the experimental groups are provided in Table I. Repeated-measure analyses of variance (ANOVA) showed that intervention (interaction between treatment group and time), gender, and age at simulation were associated with HR. Participants in the interactive IG had lower mean heart rates from baseline to simulation during the initial phase, F(1, 56) = 3.81, p < .06, and during total treatment F(1, 56) = 4.11, p < .05, when compared with those in the MCG. Regardless of treatment group, male participants experienced significantly lower HR than female participants, initial F(1, 55) = 5.57, p < .05, and total F(1, 56) = 4.10, p < .05; and as age increased, HR decreased, initial F(1, 55) = 9.04, p < .01, and total F(1, 56) = 8.56, p < .01.

Discussion

The results of this investigation provide preliminary support for the effectiveness of the interactive intervention (STARBRIGHIT Hospital Pals) in decreasing HR but not rates of sedation or OBD associated with RT simulation among children treated for cancer with radiation therapy. Differences between the experimental groups may not have been as salient because of the modified nature of the comparison group experience. Specifically, MCG participants received a moderate intervention that was not typically provided as routine care. Another explanation for our limited findings may be that participants only received a single exposure to the preparatory portion of the intervention before simulation. Perhaps one-time interventions may be inadequate to produce the dramatic changes in children who have experienced repeated exposures to aversive medical procedures. Future studies should examine the interactive intervention experience longitudinally and in comparison to a true standard-care control condition to better determine the efficacy and dosage needed for a more meaningful intervention during the typical RT simulation experience.

Although statistically significant sedation differences were not identified between treatment groups, the difference in sedation rates between treatment conditions warrants further discussion. Among children 4 to 7 years old, 75% of the participants in the IG were able to complete the simulation procedure without sedation, whereas only 52% of the MCG participants successfully complied with the procedure without sedation. Because the effects of the intervention were in the hypothesized direction for all distress outcomes, future studies examining this intervention would benefit from larger sample sizes, which would increase the probability of detecting statistically significant treatment effects, particularly in the case of sedation and OBD.

Regarding clinical significance, MCG participants experienced increases in HR of 3 to 5 beats per minute (relative to baseline) at RT simulation, whereas interactive intervention participants experienced decreases of up to 6 beats per minute over procedures which lasted up to 60 min. Although heart rate has been questioned

<p>| Table I. Means and Standard Deviations of Heart Rate (HR) and Observed Behavioral Distress (OBD) per Minute for the Intervention Group (IG; n = 41) and Modified Control Group (MCG; n = 38) |
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<th>Baseline</th>
<th>Simulation</th>
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<tr>
<td><strong>Initial HR mean</strong></td>
<td></td>
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<tr>
<td>IG</td>
<td>111.5 ± 3.0</td>
<td>108.6 ± 2.9</td>
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<tr>
<td>MCG</td>
<td>104.7 ± 2.2</td>
<td>109.7 ± 2.6</td>
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<tr>
<td><strong>Total HR mean</strong></td>
<td></td>
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<tr>
<td>IG</td>
<td>112.3 ± 3.0</td>
<td>106.2 ± 3.2</td>
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<tr>
<td>MCG</td>
<td>105.1 ± 2.3</td>
<td>108.4 ± 2.8</td>
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<tr>
<td><strong>Initial OBD mean</strong></td>
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</tr>
<tr>
<td>IG</td>
<td>0.7 ± 0.2</td>
<td>0.9 ± 0.2</td>
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<tr>
<td>MCG</td>
<td>0.7 ± 0.2</td>
<td>1.5 ± 0.3</td>
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<tr>
<td><strong>Total OBD mean</strong></td>
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</tr>
<tr>
<td>IG</td>
<td>0.6 ± 0.1</td>
<td>1.2 ± 0.3</td>
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<tr>
<td>MCG</td>
<td>0.5 ± 0.2</td>
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as a reliable indicator of distress, reductions in HR are significant since the intervention was successful at reducing HR to levels below baseline during a distressful medical procedure. Because of the baseline differences between groups, the HR interpretations are based on HR change scores. Since an inverse relationship naturally exists between HR and age, baseline HR differences between groups may be attributed to age differences (Watchie, 1995). Specifically, the mean age for the IG was 3.98 years (SD = 1.48) and for MCG participants 4.44 years (SD = 1.62; nonsignificant difference). As an inverse association has been demonstrated between chronological age and pediatric procedural distress, one might conclude that the experimental group with the greater mean age would experience less procedural distress (Blount, Sturges, & Powers, 1990; Voepel-Lewis, Tait, & Malviya, 2000). However in our study, the intervention significantly reduced HR for those in the IG, despite their age disadvantage of nearly 6 months (on average).

The HR reductions attributed to the experimental intervention are similar to those of other CBT pediatric interventions that have been shown to be as effective as orally administered diazepam (Valium) in reducing HR and associated distress during pediatric medical procedures (Jay et al., 1987). The advantages of the intervention, when compared with traditional CBT and pharmacological interventions, lie in its free cost to hospitals, ease of delivery, and avoidance of medical risk.

Distress reductions during initial experiences with repeated medical procedures are an important part of establishing a positive reinforcement history that may in turn maximize the likelihood of future successful procedures. This habituation is particularly important in the case of RT simulation as it is the first of lengthy daily treatments that may last up to 7 weeks. Although data are not available, observations made by our clinical staff have suggested that children who are less distressed during RT simulation have successful RT treatment experiences and are commonly “weaned” off sedation during the RT treatment process. Furthermore, Voepel-Lewis, Malviya, Prochaska, and Tait (2000) found that among children aged 3 to 7 years, those who were more distressed in adapting to MRI procedures were more likely to experience sedation failure than those children who were less distressed. The findings presented by Voepel-Lewis and colleagues suggest that reduction of procedural distress is important for all children receiving RT, regardless of sedation status.

The results of our study represent a positive step toward reducing children’s RT-related distress, although the findings should be interpreted in the context of its limitations. First, the participants’ sedation and medical procedures histories were not assessed. Second, there is potential for observer bias with regard to the behavioral coding because observers, as well as the RT staff, were not blind to the children’s assigned treatment conditions. Although the coders of OBD and RT personnel were not informed of the hypotheses of the study, procedural logistics made it difficult to ensure absolute objectivity. Third, consistent with other studies that have successfully implemented CBT packages to reduce procedural-related distress, one cannot identify components of the current treatment package that are responsible for the effects obtained. Despite the promising HR findings of the experimental intervention, our results were disappointing regarding sedation and OBD. Therefore, it will be important for future research to examine individual child or parent–child differences that moderate treatment effectiveness. Modified interventions may then be developed in the future to meet the needs of children, particularly preschool-age children, who may not respond optimally to this type of intervention.

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