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Effects of preoperative at-home preparation on children's behavioral outcomes in Japan

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ABSTRACT

Introduction: The objective of the study is to determine the effects of at-home psychological preparation mainly on adjustment in the aspect of children's behavior in a randomized controlled trial as an exploratory and pragmatic clinical trial.

Methods: The eligible patients were randomly assigned to either of two groups that both watched a preparation video once as outpatients in a group of other patients prior to hospitalization ("standard care"); the control group later underwent surgery without any further preparation; the experimental group watched the same video repeatedly in reference to an auxiliary booklet at home with their caregivers prior to hospitalization.

Results: No beneficial impact of at-home preparation program was determined on the children's behavioral outcomes. However, children in the experimental group showed no higher upset in OR and no more negative behavioral changes after discharge than the controls. Over 90% of the caregivers in the experimental group expressed satisfaction with at-home preparation.

Discussion: These results suggested that at-home preparation program has no impact on the patients but resulted in high satisfaction from the caregivers in the experimental group.

Conclusion: At-home preparation program using video and booklet had no beneficial impact on the behavioral outcomes of children undergoing minor surgery. However, it can be highly a desired program to prepare small children and their caregivers for surgical hospitalization.

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1. Introduction

A preponderance of the literature also views surgery accompanied by hospitalization as a stressful, anxiety-producing experience that can lead to either transient or long-term psychological disturbance in a majority of children [1–10], and indicates the need for psychological support for all children receiving medical care [11–14].

Studies of hospitalized children have revealed that "preschool" children are relatively upset by a crucial event such as "surgery" or "hospitalization," and that very young children under 3 years of age would not benefit psychologically from the psychoeducational interventions [1,8,15–17]. The preschool years comprise the period from 3 to 5 years of age, a time considered critical for emotional, language, and psychological development [18].

It has been considered essential that preparing preschool children for upcoming procedures decreases their anxiety, promotes their cooperation, supports their coping skills and may teach them new ones, and facilitates a feeling of mastery in experiencing a poten-

tially stressful event at hospital [14,19–23]. To reduce their anxiety, audio-visual information materials are most effective for younger patients who are beginning to communicate verbally [22]. Thus, many studies have emphasized the importance of preparing preschool children for surgery and hospitalization. Vernon and Thompson also revealed the benefits of preoperative experimental interventions on children's behavior after hospitalization in their review and synthesis [24].

Our previous study of children ages 4–7 years undergoing elective herniorrhaphy in hospital revealed that 1) young patients were already distressed on admission and maintained distress during hospitalization; 2) 54.2% of children showed negative behavior changes after leaving the hospital, "separation anxiety" being particularly high at 45.8%, and behaviors such as "crying at night (33.3%)," "temper tantrums (20.8%)," and "needing help to do things (20.8%);" and 3) relief of anxiety including children's distress and psychological upset is associated with the "child's understanding their experiences associated with surgery and hospitalization," and indicated the need for psychological support for young Japanese children undergoing surgery [25,26].

Considering the style of preparation program appropriate in Japan, the main caregiver was considered the best qualified person to prepare children for routines, items, procedures, and all events of

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illness, surgery, and hospitalization. The main caregivers can elicit and accept the child's feelings while understanding their child's insufficient communications skills and providing more spiritual support to children than anyone else. Furthermore, children can undergo a preparation program more calmly at home than at hospital. Thus, this preparation style where caregivers provide their children with at-home preparation under the direction of medical staffs having expertise in pediatric surgery and medical knowledge was considered to be the most appropriate and natural for Japanese preschool children and caregivers.

The purpose of the present study is to examine the effects of an at-home preparation program using audio-visual materials on the adjustment to surgery and hospitalization of Japanese preschool children who were scheduled to undergo elective herniorrhaphy and of their caregivers in a randomized controlled trial.

2. Methods

2.1. Participants

The subjects were selected from pediatric surgery outpatients who had been scheduled to undergo elective herniorrhaphy for inguinal hernia and hydrocele testis and their main caregivers at the surgery department in a large metropolitan children's hospital in Japan. The eligibility criteria were the following: preschool children between the ages of 3 and 6, who were identified and informed of being scheduled to undergo elective herniorrhaphy for inguinal hernia and hydrocele testis and their caregivers. Patients were excluded from participation if they or their caregivers had 1) chronic pain or suffering, 2) problems with any of the five senses (touch, taste, hearing, eyesight, and smell), 3) mental disorders or other disease that requires special treatments, 4) problems with communication or reading and writing in the Japanese language, or 5) stressful life event in the family in the past month.

2.2. Sample size

In the present study, the total target sample size was estimated to be 156 cases, which was based on the following anticipation: the type I error was $\alpha = 0.05$ (two-sided), the power was $1 - \beta = 0.80$, the mean weighted effect size + 0.44 which indicates that the children in the experimental group changed less in a negative direction or more in a positive direction than the control group in the review most recently published as a meta-analysis, which had synthesized all known research that evaluated psychological interventions through the use of the PHBQ, by far the most commonly used method of examining post-hospital behavior [24].

2.3. Procedures

For inguinal hernia and hydrocele testis, patients underwent pre-operative examination at the hospital a week before surgery. The contents of the study were then explained to the eligible subjects by the researcher. The researcher asked whether each subject agreed to participate in the present study and also asked the caregivers whether they or their child corresponded to any of the exclusion criteria. Caregivers then completed consent forms, based on the child's oral assent.

Subsequently, subjects who met the eligibility criteria were randomly assigned to either an experimental group or a control group by the results of each child's drawing of lots. All the medical staffs were blinded to assignment until the end of the study. And all the participants were given no information about complete contents of the two groups, the Hawthorne effect could be ruled out.

2.4. Study design

In the present study, the subjects were confined to preschool children between the ages of 3 and 6 undergoing elective herniorrhaphy for inguinal hernia and hydrocele testis because the preparation tools of video and booklet were designed to meet disease-specific and age-related psychological preparation.

Our hypothesis was that children who watch the video together with the help of the booklet as frequently as they want at home in a relaxed atmosphere (at-home preparation) would be better informed and prepared, and therefore exhibit less distress regarding surgery and hospitalization than those who watch the same video once at the outpatient clinic a week before surgery (outpatient preparation).

2.5. Measures

To demonstrate the effectiveness of at-home preparation using the video and booklet, the children's attitude toward surgery and the children's behavioral changes were each assessed. The demographic characteristics of the children and caregivers were also examined (Table 1).

The children's psychological distress at anesthesia induction was assessed by several medical staffs from the operating department who had no connection with the study using a behavioral assessment scale that consisted of 3 items of children's attitude: upset and cooperation items from Wolfer's Upset & Cooperation scale [27] and "emotional attitude" as an additional item. Emotional attitude was rated on a score of 1–4, ranging from "not crying or resisting at all" to "tearfully resisting so much that we had to restrain the child." Manifest upset attitude was rated on a score of 1–3, ranging from "not upset at all" to "extremely upset although the nurse tried to pacify." The cooperation attitudes were rated on a score of 1–3, ranging from "cooperative" to "extremely uncooperative and rejective." There was no difference in the way the anesthesiologists put the children under anesthesia between the two groups.

The children's post-hospital behavioral changes were assessed by the Post-hospital Behavior Questionnaire (PHBQ), by far the most commonly used method of examining posthospital behavior, designed to evaluate maladaptive behavioral responses and developmental regression in children following hospitalization or surgery [28]. The original version of this questionnaire consisted of 27 items dealing with behaviors identified as being characteristic of children after hospitalization or surgery e.g., temper tantrums, fear of the dark, and being upset when left alone. Caregivers were requested to consider each behavioral item, comparing their child's post-hospital behavior with that manifested before hospitalization. The five-point response scale ranged from the behavior occurring "much less than before" (scored 1) to "much more than before" (scored 5). The validity and reliability of the total score has been found to be satisfactory ($\alpha \geq .76$, $P < .001$). The PHBQ has been translated into Japanese and used in a research but has not yet been standardized [29]. Therefore the PHBQ was retranslated into proper Japanese and used in the present study after obtaining written approval from Vernon for the Japanese usage of the PHBQ. The reliability of the total score of the Japanese version of the PHBQ has been confirmed in this study ($\alpha = .76$). In the present study, data were collected after hospitalization from two groups at 1 week after surgery and 1 month after surgery.

Data on the demographic and clinical characteristics of the child (age, gender, order of birth, past medical history, history of present illness, experience of hospitalization, experience of surgery, diagnosis, resilience) and the caregiver's characteristics (relationship to the child, age) were obtained from the caregivers using a self-reported questionnaire.

Table 1
Demographic and clinical characteristics.

	Experimental group n = 77 (100%)	Control group n = 81 (100%)	P
Child			
Months of age (mean (SD))	59.8 (15.8)	61.1 (16.9)	0.48
Age (years)			0.57
Three-year-old	21 (27.3)	20 (24.7)	
Four-year-old	18 (23.4)	20 (23.5)	
Five-year-old	19 (24.7)	21 (25.9)	
Six-year-old	19 (24.7)	21 (25.9)	
Gender			0.64
Boy	49 (63.6)	50 (59.2)	
Girl	28 (36.4)	31 (40.8)	
Order of birth			0.77
1(-)	18 (23.4)	17 (21.0)	
1(+)	29 (37.7)	31 (38.3)	
2-	30 (39.0)	33 (40.7)	
Past medical history			0.89
No	66 (85.7)	71 (87.7)	
Yes	11 (14.3)	10 (12.3)	
History of present illness			0.68
No	70 (90.9)	75 (92.6)	
Yes	7 (9.1)	6 (7.4)	
Previous experience of hospitalization			0.55
No	53 (71.6)	55 (72.4)	
Yes	21 (28.4)	21 (27.6)	
Previous experience of surgery			0.55
No	68 (88.3)	68 (84.0)	
Yes	9 (11.7)	13 (16.0)	
Diagnosis			0.23
Left inguinal hernia	21 (27.3)	26 (32.1)	
Right inguinal hernia	35 (45.5)	37 (45.7)	
Bilateral inguinal hernia	6 (7.8)	5 (6.2)	
Left hydrocele testis	3 (3.9)	3 (3.7)	
Right hydrocele testis	12 (15.6)	10 (12.3)	
Caregiver			
Relationship to the child			0.85
Father	3 (3.9)	6 (7.4)	
Mother	73 (94.8)	74 (91.4)	
Grandmother	1 (1.3)	1 (1.2)	
Age			0.82
20s	10 (13.0)	9 (11.1)	
30s	53 (68.8)	68 (88.3)	
40s	11 (14.3)	13 (16.0)	
Others	1 (1.3)	1 (1.2)	
No answer	2 (2.6)	2 (2.5)	
Trait anxiety scores of STAI (mean (SD))	41.0 (8.9)	41.6 (8.7)	0.68

Values are mean \pm standard deviation or n (%).

All these data were collected from the two groups in the same period. In addition, the caregivers in the experimental group were asked to report the implementation of the at-home preparation (regarding the frequency of video viewing and how they watched the video), assess the degree of satisfaction with such intervention using a 4-point scale, and give their impressions of such at-home preparation, 1 week after surgery.

2.6. Statistical analyses

Demographic and clinical characteristics data were tested by the Student *t*-test, chi-square test, or Mann–Whitney *U* test to assess comparability between the groups.

Intention-to-treat analysis was performed to assess the effects of intervention on post-hospital behavior measured by PHBQ. First, repeated measures analysis of covariance (ANCOVA) adjusted for the baseline scores was used to test whether there was a difference between the experimental group and the control group over the study period, which comprised interaction between 'group' and

'time' (group-by-time interaction) and the main effects of 'group.' Second, ANCOVA adjusted for the baseline data was used for the comparison of the two groups at each measurement time with every outcome when there were significant effects at the first stage.

All data analyses were conducted using SPSS for Windows 12.0J, a statistical package for the social sciences (SPSS Japan Inc). A *P*-value of less than 0.05 was set as a significant level.

2.7. Ethical consideration

The study protocol was reviewed and approved by the Institutional Review Board of the study hospital and the Ethics Committee of the Faculty of Medicine, the University of Tokyo, Japan.

3. Results

3.1. Study sample

Of the eligible 161 subjects, 158 consented (consent rate, 98.1%) to participate in the study. They were randomly assigned to either the experimental group (n = 77) or the control group (n = 81). The demographic and clinical variables did not differ significantly between the experimental and control groups (Table 1).

3.2. Effect of intervention on adjustment to anesthesia induction

Although there were no significant between-group differences in emotional attitude, manifest upset attitude, or cooperation attitude, the children in the experimental group had a more poised attitude ($Z = -1.781$, $P = 0.075$) and a more cooperative attitude ($Z = -1.66$, $P = 0.097$) than those in the control group (Table 2).

3.3. Effect of intervention on children's behavioral changes

At baseline, there were no significant between-group differences in the PHBQ score (Table 3).

The repeated measures ANCOVA, which controlled the baseline score, showed no group-by-time interaction ($F = 0.018$, $P = 0.89$) and no significant between-group difference over the post-hospital period in the PHBQ score ($F = 3.035$, $P = 0.084$). However, the PHBQ score in the experimental group was always lower than that in the control group over the post-hospital period, and the difference in score calculated by subtracting the control group from the experimental group was 1.61 ± 0.05 (mean \pm SD) on average.

3.4. Examination of quantity and quality of intervention

3.4.1. Practice of intervention

The subjects in the experimental group watched the video 3.2 ± 2.4 (mean \pm standard deviation [SD]) times (range: 1–15) at home. Though we required them to watch the video at least twice at home, some actually watched it only once.

With regard to how they watched the video, 61.1% children watched the video together with caregivers every time. It was also recognized that every child had watched the video at least twice with his/her caregiver at home.

3.4.2. Satisfaction with intervention

Of the caregivers in the experimental group, 91.7% expressed satisfaction, while 8.3% caregivers expressed no satisfaction with the at-home preparation.

From a written description of the caregivers in the experimental group, 2 caregivers made the following negative comments: they highly appreciated the contents of the videotape but described that her child become anxious about the coming surgery because of at-home repeated watching. However, as a result, these 2 subjects

Table 2
Children's psychological distress at anesthesia induction.

Outcome	Experimental group	Experimental group	Group effects	
	n = 74 (%)	n = 76 (%)	z*	P
Emotional attitude			-1.781	0.075
Not crying or resisting at all	60 (81.1)	52 (68.4)		
Frying or going to cry	7 (9.5)	8 (10.5)		
Overlong crying	4 (5.4)	7 (9.2)		
Tearfully resisting so much that we had to restrain the child	3 (4.1)	9 (11.8)		
Manifest upset attitude			-1.282	0.2
Not upset at all	47 (63.5)	41 (53.9)		
Upset initially or slightly but recover composure when pacified by the nurse	21 (28.4)	25 (32.9)		
Extremely upset although nurse tried to pacify	6 (8.1)	10 (13.2)		
Cooperation attitude			-1.659	0.097
Cooperative	56 (75.7)	50 (65.8)		
Uncooperative and rejective initially or slightly	13 (17.6)	15 (19.7)		
Extremely uncooperative and rejective	5 (6.8)	11 (14.5)		
Total (emotional, manifest upset, cooperation) attitude (mean (SD))	4.08 (1.83)	4.74 (2.39)	-1.49	0.136

* z statistic in Mann–Whitney U test.

Table 3
Results of repeated measures ANCOVA on children's post-hospital behavior changes.

Outcome (range)	Time ^a		Effects			
			Group		Group × time ^c	
	At 1 week after surgery ^b	At 1 month after surgery	F ^d	P	F ^d	P
	(Mean (SD))	(Mean (SD))				
PHBQ (27–135 ^e)						
Experimental	82.3 (3.48)	81.2 (8.00)	3.035	0.084	0.018	0.89
Control	83.9 (6.38)	82.6 (5.24)				

SD: standard deviation.

^a Analysis of covariance (ANCOVA) adjusted for the baseline.

^b None of the differences between groups was statistically significant by the Student *t* test.

^c Repeated measures ANCOVA adjusted for each baseline score for the group effect over the study period.

^d F statistic in repeated measures ANCOVA adjusted for each baseline score.

^e Higher scores indicating greater maladaptive behavioral responses and developmental regression in children.

underwent surgery as usual without any problems and completed all assessments over the study.

4. Discussion

The present study was the first report on a randomized controlled trial of a psychological preparation program including psychoeducational intervention for Japanese preschool children, as an exploratory and pragmatic clinical trial.

All the participants were given no information about the complete contents of the two groups (experimental or control group) and the Hawthorne effect could be at least ruled out.

4.1. Adjustment to anesthesia induction

The present study revealed that the children in the experimental group had a relatively more poised and cooperative attitude than those in the control group, although there was no significant difference between groups. A cooperative attitude has been especially considered the most beneficial response for medical staffs among the different types of attitude of young patients [30–32]. Therefore, the findings suggest that at-home preparation using video and booklet might have had no adverse effect for young Japanese children and medical staffs at anesthesia induction.

4.2. Children's behavioral changes

Assessment of the effect on children's behavioral changes indicated a between-group difference over the post-hospital period in the score of the PHBQ. The result of this study revealed that the PHBQ score in the control group was slightly higher than that in the experimental group in both periods after surgery just as the anxiety

score of the caregivers in the control group was higher than that in the experimental group at the same periods. Kain et al. indicated that there was a moderate positive correlation between the caregivers' perioperative state anxiety and the incidence of the children's negative behavioral change [33]. Thus, children and caregivers could possibly interact psychologically with each other under stress-remained circumstance.

Thompson and Vernon demonstrated in their review and synthesis that subjects hospitalized for periods of 2–3 days exhibited more behavioral distress than did those hospitalized for either shorter or longer periods and that children's negative behavioral change disappeared by 2 weeks after discharge because the impact of illness, surgery, and hospitalization decreased with time [16]. In the present study, the subjects were hospitalized for 2 days, and so revealed that the PHBQ score in the control group at 1 month after surgery was higher than that of the experimental group at 1 week after surgery, which means that negative behavioral change in the control group had not disappeared at 1 month after surgery. The implications of these manifestations of negative behavioral changes in the control group are considered to be as follows: when faced with difficulties and realizing that their caregivers would not come to help, the children feel cheated, conspired against, and tricked by their caregivers and lose trust in them even after discharge, based on previous studies [17,19,34].

4.3. Examination of quantity and quality of intervention

No participants dropped out during the at-home intervention period in this study. All the children (100.0%) in the experimental group had watched the video at home with their caregivers. Although we anticipated that cultural difference would probably lead to the lower achievement rate of intervention and the lower satisfaction with intervention in this study, the complete adherence

rate was higher than those achieved in previous studies conducted in Western countries, which ranged from 32.6% to 66.1% [35–37]. Therefore, this intervention style was shown to be effective and can be applied to Japanese preschool children who are scheduled to undergo short-term surgical hospitalization.

The large majority (91.7%) of caregivers in the experimental group found the video as an at-home preparation tool to be helpful and made positive feedbacks concretely on the effect of intervention. However, 2 subjects in the experimental group made negative comments apparently on the intervention. These responses had been much anticipated because Kain et al.'s report [38] and some former studies suggest that specific preparation strategies might even have a negative 'sensitizing' effect on younger children or children who have previously been hospitalized [19,35,39,40]. In the present study, the result would imply that we have problems of psychological intervention like a negative 'sensitizing' effect on younger children that need further consideration in the future, although these 2 subjects underwent surgery as usual without any problems and completed all assessments over the study.

5. Conclusions

The present study suggested no beneficial impact of at-home preparation programs on the behavioral outcomes of preschool children undergoing elective herniorrhaphy in Japan. However, children in the experimental group showed no higher upset in OR and no more negative behavioral changes after discharge than the controls. Therefore at-home preparation programs had no negative effects for the children undergoing surgery and resulted in high satisfaction from the caregivers in the experimental group. Given the relatively easy administration and low production cost, it can be recommended as a popular, practical and cost-efficient program to prepare children and caregivers for surgical hospitalization.

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Author contribution

My contributions were all; study design, data collection, data analysis, manuscript writing and confirmation.

Conflict of interest statement

No potential conflict of interest relevant to this article was reported.

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