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Psycho-educational intervention for chemotherapy-associated nausea and vomiting in paediatric oncology patients: a pilot study

Key Messages

1. Descriptive data suggest that progressive muscle relaxation and education offer benefits by reducing vomiting, and promoting the use of anti-emetic as a preventive measure.
2. Both interventions were well accepted by patients and their parents.
3. The current pilot study supports the feasibility and appropriateness of the study design.

Introduction

Intensive chemotherapy (CT) regimens are widely used to treat childhood malignancies and are generally more emetogenic than those used in adults. A survey on chemotherapy-associated nausea and vomiting (CANV) in children reported a prevalence of 67 to 71% during CT and 77 to 82% after the CT cycle.[1]

As the severity of CANV may become cumulative over time,[2] preventive measures given to chemotherapy-naive patients are considered the most efficacious. The four pathways through which the vomiting centre can be stimulated are: the cerebral cortex and limbic system; the vestibular system; the chemoreceptor trigger zone; afferent vagal and visceral nerves (Fig).[3] Based on this theoretical framework of the neural pathways involved in transmission of emetic stimuli,[3] a multi-dimensional psycho-educational programme combining the use of relaxation techniques (progressive muscle relaxation [PMR]) and patient education has been developed by the authors (Fig). Relaxation techniques block the cerebral and limbic system cortical pathway. Patient education focusing on risk assessment, use of antiemetics, and meal preparation works by blocking the other three pathways. It appears logical to adopt a comprehensive programme able to block all emetic stimuli pathways, however, each major component of the programme needs to be examined separately in an exploratory trial. This pilot study aimed to assess the feasibility of using the two major components—relaxation and patient education—of a comprehensive programme.

Methods

This study was conducted from January 2005 to December 2006. An exploratory trial using a pre- and post-test control group design was used.

Intervention

Group 1: Six sessions of PMR and guided imagery (GI) training (day 0-5; 30 minutes/session) were administered as recommended by Baider et al,[4] then the skill was practised daily for a period of 2 months; PMR and GI audiotapes were provided. Group 2: Two patient/parent education sessions were given (day 0 and day 2; 30 minutes/session) focusing on risk assessment, antiemetic use, and meal planning.

Outcome measures and instruments

Primary outcome measures were nausea and vomiting (Morrow Assessment of Nausea and Emesis, MANE). Secondary outcome measures were anxiety (child and parent) [The Chinese version of A-State scale of the State–Trait Anxiety Inventory], quality of life (Play Performance Scale for Children), physiological indices (caloric intake, changes in body weight), use of antiemetics, satisfaction with care (4-point Likert scale indicating extremely unsatisfactory [0] to extremely satisfactory [3]), self-rating of the usefulness of intervention (6-point Likert scale indicating extremely useful [5] to not at all useful [0]), health diary noting PMR and GI practice.

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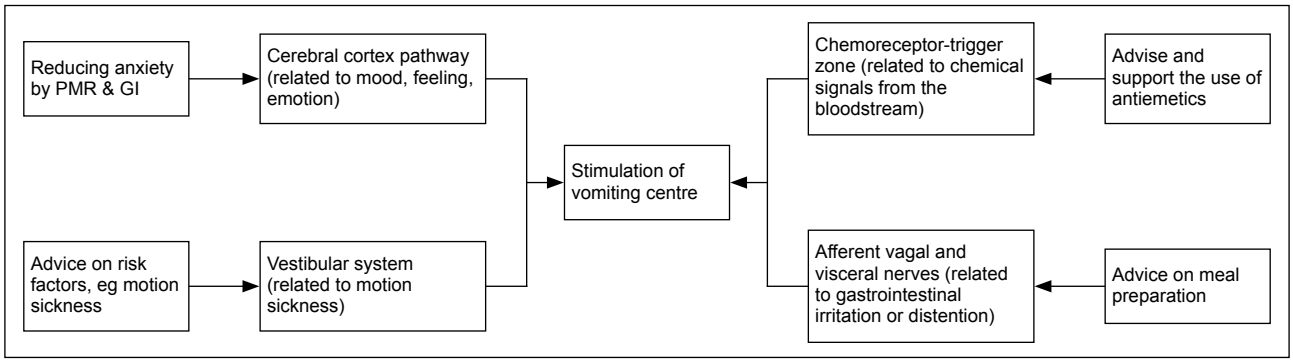

Fig. Rationale supporting the relationship between chemotherapy-associated nausea and vomiting and proposed intervention
PMR denotes progressive muscle relaxation, and GI guided imagery

Table 1. Inventions and data collection periods

Interventions*	Day†									
	0	1	2	3	4	5	6	7	30	60
Group 1 intervention: PMR (including GI)	√	√	√	√	√	√				
Group 2 intervention: education	√		√							
MANE	√	√	√	√	√	√	√	√		
Anxiety	√			√				√	√	√
Satisfaction with care	√			√				√	√	√
Caloric intake, body weight, antiemetic use	√	√	√	√	√	√	√	√		
Quality of life	√			√				√	√	√
Usefulness of intervention		√		√				√		
Intervention log	√	√	√	√	√	√				
Pulse and blood pressure (group 1 only)	√	√	√	√	√	√				
Health diary of PMR and GI (daily for 2 months continuously), group 1 only	√	√	√	√	√	√	√	√	√	√
Control group historical data: body weight, vomiting, antiemetic use	√	√	√	√	√	√	√	√		

* PMR denotes progressive muscle relaxation, GI guided imagery, and MANE Morrow Assessment of Nausea and Emesis
† Day 0=1 day prior to CT, day 1=CT commencing date

Procedure

All consenting subjects completed a full set of instruments at baseline, then 7 days post-CT making in total 8 days' measurements. Long-term data were collected 1 month and 2 months after the intervention and assessed quality of life, anxiety, compliance with PMR and GI (group 1 only), and satisfaction with care. The interventions and data collection periods are detailed in Table 1.

Setting and subjects

A total of 20 subjects were recruited from the paediatric oncology unit of a publicly funded hospital in Hong Kong. Inclusion criteria were: being aged from 4 to 11 years, having a diagnosis of cancer requiring CT, being chemotherapy-naive, being able to understand Cantonese, signed informed consent (both patients and parents). Exclusion criteria were patients with brain metastases and/or advanced stage cancer.

Results

During the study period, 24 subjects who met the eligibility criteria were approached and 20 of these agreed to participate in the intervention groups. Ten historical control cases who matched the characteristics of group 1 subjects formed group 3. Another 10 historical control cases who matched the characteristics of group 2 subjects formed group 4.

Baseline characteristics of the study sample

The mean age was 8.6 years. The majority (n=20) had acute lymphocytic leukaemia, followed by osteosarcoma (n=12). None had vomited immediately after CT at baseline (day 0). There was no difference in diagnoses, age, body weight, and episodes of vomiting at baseline between the subjects in the intervention and control groups.

Subjects in group 1 had significantly lower levels of child anxiety (Z= –2.14, P=0.032) than those in group 2 at baseline. Parents of subjects in group 1 also had a lower mean score of anxiety, although this result was not statistically significant.

Comparison between intervention groups and control groups

The Kruskal Wallis test did not detect a significant difference (P>0.05) between the groups at each data collection time. All groups had a slight decrease in body weight (<1 kg) over the 8-day period. Significant within-group changes in body weight were detected only in group 2 (P=0.01) using the Friedman test (Table 2).

In terms of vomiting after CT commenced, a significant

Table 2. Body weight of each study group from day 0 to 7

Group		Body weight (kg)							
		Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	Mean	37.93	38.29	38.08	37.69	37.54	37.80	37.49	37.43
	SD	16.52	16.96	16.97	16.57	16.38	16.30	15.97	15.76
2*	Mean	41.29	41.65	41.51	41.18	40.82	41.02	40.95	40.93
	SD	14.63	14.80	14.96	14.59	14.40	14.30	14.40	14.19
3	Mean	40.83	40.99	40.87	40.49	40.31	40.14	40.24	40.20
	SD	19.16	19.57	19.39	19.28	19.22	19.26	19.33	19.10
4	Mean	45.19	44.88	44.85	44.66	44.56	44.49	44.30	44.28
	SD	17.37	17.64	17.52	17.57	17.60	17.71	17.65	17.44
Total	Mean	41.31	41.45	41.32	41.00	40.80	40.86	40.74	40.71
	SD	16.54	16.81	16.78	16.61	16.52	16.50	16.46	16.26

* P<0.05

Table 3. Number of patients experiencing nausea, vomiting and their antiemetic intakes from day 0 to 7, by group

	Group	Day							
		0	1	2	3*	4	5	6	7
Intake of antiemetic	1	5	5	4	2	1	1	0	1
	2	7	6	3	5	4	4	0	0
	3	0	3	8	3	2	1	1	0
	4	0	4	10	3	3	3	1	0
Vomiting after chemotherapy*	1	0	0	2	4	3	2	2	4
	2	0	0	3	7	7	1	2	1
	3	0	1	3	6	7	5	6	5
	4	0	0	7	10	6	6	5	5
Nausea after chemotherapy	1	0	2	5	4	4	4	5	6
	2	0	5	6	8	8	8	4	6
Nausea before chemotherapy	1	1	1	2	3	2	2	3	3
	2	1	3	4	6	6	4	2	2
Vomiting before chemotherapy	1	5	0	1	2	1	1	1	2
	2	3	0	3	5	3	1	1	1

* P<0.05

difference was detected on day 3 only (Chi squared=8.54, P=0.036). Fewer patients in the PMR group (group 1) experienced vomiting. There was no significant difference in the intake of antiemetic between groups. Descriptive data show that more patients in the control groups than those in the intervention groups took antiemetics on day 2. There was also a trend for more patients in the intervention group to take antiemetics before beginning CT (on day 0) but fewer patients in these groups took antiemetics from day 2 onwards. In contrast, none of the patients in the control groups took antiemetics on day 0 but more patients in these groups began to take antiemetics on day 2 (Table 3).

Comparison between the PMR group and education group

There were no statistically significant differences (P>0.05) in body weight, experience of nausea and vomiting, and antiemetic intake between the two intervention groups. The Friedman test found that both groups 1 and 2 had significant within-group changes in parent anxiety levels (group 1 at P=0.005, group 2 at P=0.001) and that the parents' anxiety levels decreased over time from day 0 to 60.

There was no significant difference in the child's quality of life and parent's satisfaction with care between the PMR group (group 1) and the education group (group 2). The children's quality of life was lower from day 3 to 30 after the commencement of CT in both groups.

There was no significant difference in calorie intake between the PMR and education groups. There was a trend for patients in both groups to have their lowest calorific intake on days 2 to 3. Their calorie intakes gradually improved from day 4 to 7. The Friedman test found that a within-group change in calorie intake in group 2 was significant (P=0.001), with a drastic reduction in calories on days 2-3.

Process evaluation

Analysis of the health diaries indicated that the majority of patients practised PMR 3 to 4 times a week at home, indicating moderate compliance with PMR self-practice. Mann-Whitney *U* tests did not detect significant changes in blood pressure and pulse rates after practising PMR.

Patients' and parents' perceptions of the usefulness of the interventions were that they were moderately useful. The Mann-Whitney *U* test found a significant difference only in day 1 anxiety reduction (Z= –0.314, P=0.032); the PMR was perceived as more useful in anxiety reduction. There was a trend toward higher overall usefulness of the intervention scores in the PMR group.

Discussion

Subject recruitment for this pilot study was feasible but took longer than expected. It took 18 months to recruit 20 eligible and consenting patients. This raises a concern about adequate recruitment for a larger full study. All patients in the intervention groups adhered to the intervention and completed the instruments without difficulty, indicating the appropriateness of these age-appropriate interventions and the data collection process.

Progressive muscle relaxation was found to significantly reduce vomiting on day 3 after the commencement of chemotherapy, the day that the majority of patients in this study experienced CANV and reported lower quality-of-life levels and less satisfaction with care. Moreover, fewer patients in both intervention groups suffered from vomiting from day 2 to day 7, when compared with the control groups. The theoretical framework of the neural pathways involving in transmitting emetic stimuli (Fig)[3] suggests that PMR and education may be reducing vomiting by interfering with the transmission of stimulation of the cerebral cortex pathway, the vestibular system, the chemoreceptor trigger zone, and the afferent vagal and visceral nerves.

Although there was no statistical difference in antiemetic intake between the intervention and control groups, it appears that more patients in the intervention groups took antiemetics on day 0 prior to the CT, whereas none of the patients in control group did. This could be due to a greater awareness of nausea and vomiting and an accompanying increase in knowledge about and motivation to take antiemetics as a preventive measure, as a result of participating in the intervention. This preventive measure may have led to less vomiting from day 2 to day 7 in the intervention groups. As the severity of CANV is cumulative over time, this finding supports the importance of giving preventive measures to CT-naive patients prior to the commencement of CT.

There is no evidence supporting the superiority of PMR or patient education in terms of managing CANV and the maintenance of body weight. In both intervention groups, parents' anxiety levels lessened significantly over time, supporting their potential effects on parental anxiety reduction. This is an important benefit of the intervention, as a significant correlation between CANV and parental anxiety has been reported previously.[2]

The only difference found between PMR and education was the effect on calorie intake. It is surprising to note that the calorie intake was drastically reduced on day 2 to 3 within the education group as the education session is supposed to help patients to select a diet able to promote their calorie intake. In contrast, the PMR group's calorie intake appears to have been more stable, suggesting that relaxation has a beneficial effect on dietary intake, a finding in line with that of a previous study.[5]

Conclusion

This pilot study supports the feasibility and appropriateness of the study design including subject recruitment, randomisation, implementation of the interventions, and measurement of the outcomes. Although we have not statistically proven any beneficial effects of PMR and education as a means of reducing CANV in this pilot study, descriptive data suggest the intervention achieved a reduction in vomiting and promoted the use of antiemetics as a preventive measure.

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