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The Application of One-Hour Static Qigong Program to Decrease Needle Pain of Korean Adolescents With Type 1 Diabetes: A Randomized Crossover Design

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Abstract

The aim of this study was to describe application of a static Qigong program to decrease needle pain in Korean adolescents with type 1 diabetes and its pilot test results. The pilot study was a randomized crossover design including 26 adolescents randomized to Qigong or rest group. Participants received a 60-minute Qigong program consisted of warm up, deep breathing, imaginary, and a closing warm up. After 24-hour washout period, treatment assignments were switched. We collected before and after intervention using a self-administered questionnaire, which included the faces pain scale to assess expected and perceived pain during blood sugar testing and insulin injection and the Positive and Negative Affect Schedule. Only expected pain on insulin injection was significantly lower after intervention ($P = .025$). The results suggested that the devised static Qigong program was feasible intervention to decrease at least expected pain on insulin injection of adolescents with type 1 diabetes.

Keywords

type 1 diabetes mellitus, qigong, needle pain, positive affect, negative affect

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Standard of care for type 1 diabetes includes intensive life-long insulin treatment involving insulin injection and blood sugar testing (BST). This process of injection and BST is an unpleasant experience and causes significant trauma to patients,[1] particularly in children and adolescents. This trauma can be worse in children and adolescents where insulin pump and continuous glucose monitoring is not affordable in their countries, such as Korea.[2]

The unpleasant experience due to self-insulin injection and BST among adolescents with type 1 diabetes has been documented to be the result of pain,[3] fear,[4] and anxiety.[5] However, these experiences are difficult to differentiate in young patients. In fact, pain assessment and management is important part of standard of care, and is given higher priority than any other discomforts. According to International Association for the Study of Pain (1994),[6] pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." Howe et al[5] indicated that about 40% of children reported fear and 23% of adolescents reported pain associated with insulin injections. Furthermore, increased pain and fear of self-injection and self-testing are associated with frequent skipping of insulin injections and BST, poor glycemic control, and increased mortality among diabetes patients.[7,8]

Despite of impact of needle pain on diabetes management, somewhat surprisingly interventional efforts have been rarely studied. Procedural pain in children is often controlled using topical anesthetic ointment, but more holistic approaches can be beneficial to control acute and mild needle pain complicated with fear and anxiety. We became interested in a mind-body therapy called Qigong as a pain control strategy for Korean adolescents with type 1 diabetes. Qigong is an ancient East Asian relaxation exercise based on integration of body, mind, and spirit,[9] and many Asians, including Koreans, use it during

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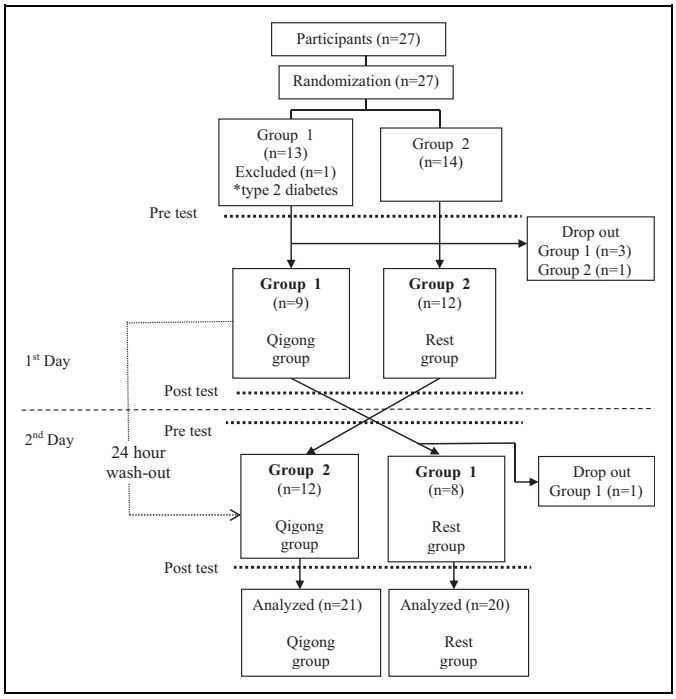

Figure 1. Study design.

their daily activities. Qigong is easily learnt and a feasible nonmedical strategy for controlling acute and mild pain.[10,11]

Therefore, we developed an acute, static style Qigong program to decrease needle pain in adolescents with type 1 diabetes. Acute-type programs can allow beginners to manage occasional circumstances and static Qigong requires a small space and a low to moderate level of activity,[12] and thus, is quite feasible for adolescents attending a camp. Accordingly, we undertook to apply a Qigong program to decrease needle pain in Korean adolescents with type 1 diabetes and preformed a small pilot study.

Methods

Study Design

This study was a randomized, with short time crossover design and data collected from January 8, 2015 to January 9, 2015 (Figure 1).

Participants

The participants were 26 Korean adolescents with type 1 diabetes. Participants were recruited from at a 3-day residential diabetes camp held by a multidisciplinary team of a university hospital in Incheon, South Korea. Adolescents were aged from 10 to 18 years and all had disease duration of greater than 6 months.

Intervention

Participants were randomized to 2 groups using computer-generated random numbers. On the first day of the camp, group 1 underwent a 60-minute Qigong program and group 2 was given free time as a control. After a 24-hour washout period, treatment assignments were switched, that is, those that underwent the Qigong program on the first day became controls on the second and those that functioned as controls on the first day underwent the Qigong program on the second day (Figure 1). The program was held in a quiet, heated seminar room containing mats.

The Qigong program was designed and instructed by one of the authors with more than 20 years of experience teaching Qigong in Korea and Japan, and was based on Korean style Qigong, "Hwalmyeon Qigong."[13,14] Hwalmyeon is a traditional Qigong style that was used by warriors as self-treatment regimen. Hwalmyeon static style is a training method that focuses on the maintenance of certain postures while performing controlled breathing and imagery. These postures can be performed while standing, sitting, and laying down. The program was designed to make it easy to learn and remember, and to be relaxing for adolescents. Therefore, they can continue to practice at home after learning the technique in the camp. The 60-minute program included 4 sections consisting of *warming up*, *relaxation*, *imaginary*, *and closing*.

Warming up was a preparatory session for Qigong practice. During the 10-minute warm-up period, adolescents performed clockwise and counterclockwise rotational movements of the neck, wrists, waist, knees, and ankles. This movement was followed by tapping to relax the body from upper to lower arms and then upper to lower legs. *Relaxation* was designed to relax body and mind. This 20-minute session included maintaining a meditation posture in sitting and lying positions. The *imaginary session* was of 20-minute duration and was conducted as a 3-step process. First, the instructor asked adolescents to imagine any object, such as an apple, and then asked to imagine more details of the object, for example, in the case of an apple, its color, taste, smell, and so on. Second, they were asked to imagine that they placed the object in a safe place. Third, they were asked to perform imaginary BST and insulin injection while thinking that they felt no pain or fear. *Closing* took 10 minutes and involved meditation, deep breathing, and tapping and rubbing of their entire bodies while sitting.

Measurements

Data were collected on age, gender, height, weight, diabetes information, needle pain, and their emotional affects. Height and weights were measured using a fixed stadiometer (Samhwa, Seoul, South Korea). Diabetes information, pain, and emotional affect were assessed using structured questionnaires. The diabetes information included duration of diabetes, recent HgbA1c, and amounts of insulin injected per 24 hours at home and during camp.

Needle pain included the intensities of 4 different types of pain, that is, expected and perceived pain during BST and insulin injection. Expected pain was defined as the imaginary pain participants believed they would feel if the procedure was performed at that time. Expected pain has been used as a pain indicator for clinical and research purposes in the dental and surgical fields.[15,16] Perceived pain was defined the actual pain participants experienced when they performed the target procedure. Both perceived and expected pain were assessed using the 0- to 10-point faces pain scale of Wong and Baker.[17] This was chosen because it provides a straightforward, valid measure of pain in children and adolescents.

Emotional affects were assessed using the Positive and Negative Affect Schedule (PANAS) developed by Watson et al.[18] This schedule is composed of 20 items, 10 assess positive affects and the other 10 negative affects, including fear and anxiety. Items are rated on a 5-point Likert-type scale, ranging from 1 = very slightly to 5 = extremely. PANAS can measure affect in a specified time frames in different contexts, such as, in the present or over the previous day, week, or year. In the present study, participants were asked to evaluate emotional

Table 1. Characteristics, Needle Pain, and Emotional Affect of Participants at Baseline (N = 26).

	Total	Group 1 (n = 12)	Group 2 (n = 14)	*t* or χ^2 (*P*)
Age, y, mean ± SD (range)	13.5 ± 1.8 (10-17)	13.6 ± 1.9	13.4 ± 1.7	0.32 (.753)
Male gender, n (%)	12 (46.1)	5 (41.7)	7 (58.3)	1.81 (.671)
Height, cm, mean ± SD (range)	158.6 ± 8.5 (135.6-176.8)	158.2 ± 8.2	160.0 ± 9.0	−0.22 (.830)
Weight, kg, mean ± SD (range)	53.3 ± 11.7 (28.7-86.8)	53.6 ± 12.8)	53.0 ± 11.1	0.12 (.906)
Duration of diabetes, mo, mean ± SD (range)	55.4 ± 37.8 (4-144)	69.1 ± 43.2	43.6 ± 29.0	1.79 (.087)
HgbA1c, %, mean ± SD (range)	8.5 ± 1.5 (6.6-11.5)	8.3 ± 1.6	8.6 ± 1.4	−0.41 (.685)
Amount of insulin injection, U/kg/d, mean ± SD (range)				
At home	0.9 ± 0.3 (0.2-1.5)	0.9 ± 0.4	1.0 ± 0.3	−0.88 (.388)
During a camp	0.7 ± 0.3 (0.0-1.2)	0.7 ± 0.3	0.7 ± 0.3	0.49 (.629)
Perceived pain on (n = 22), mean ± SD (range)				
BST	1.9 ± 1.6 (0-6)	2.0 ± 1.3	1.8 ± 1.8	0.24 (.811)
Insulin injection	2.6 ± 1.7 (0-6)	3.0 ± 1.7	2.2 ± 1.8	1.19 (.249)
Expected pain on (n = 25), mean ± SD (range)				
BST	1.9 ± 1.8 (0-6)	2.0 ± 1.5	1.9 ± 2.0	0.20 (.847)
Insulin injection	2.6 ± 1.6 (0-6)	2.6 ± 1.6	2.7 ± 1.7	−0.26 (.800)
PANAS (n = 25), mean ± SD (range)				
Positive affect	22.7 ± 8.5 (11-39)	21.8 ± 9.2	23.4 ± 8.1	−0.46 (.647)
Negative affect	16.4 ± 7.8 (10-41)	16.3 ± 9.9	16.6 ± 6.2	−0.09 (.927)

Abbreviations: BST, blood sugar test; HgbA1c, glycated hemoglobin; PANAS, Positive and Negative Affect Schedule; SD, standard deviation.

affects in the present. Internal consistencies in the present study for positive and negative affects were 0.87 and 0.98, respectively.

Data Collection Procedures

Data were collected after obtaining approval from our institutional review board. Written assent was obtained from all study participants and informed consent from all parents. Basic characteristics, including height, weight, and diabetes information, were extracted from the camp data which were taken on the first day at camp. Expected pain and PANAS were assessed before and after intervention. Perceived pain was assessed immediately after BST and insulin injection at the first occurrence after intervention.

Data Analysis

SPSS version 21.1 (Chicago, IL, USA) was used for the statistical analysis. Descriptive analysis was performed using frequencies with percentages and means with standard deviations and ranges. The independent *t* test, the Mann-Whitney *U* test, and the chi-square (χ^2) test were used to determine differences of characteristics of study participants between groups. The change of needle pain and emotional affect in the Qigong and rest group was compared between the first and second day using the Mann-Whitney *U* test and no statistical difference was found. Therefore, the data were pooled for further analysis. All statistical tests were conducted at the 5% significance level.

Results

The data of 26 adolescents were subjected to analysis (Figure 1). Baseline characteristics of participants were comparable between groups 1 and 2 (Table 1). The change of needle pain and emotional affect in the Qigong and rest group was compared between the first and second day and no statistical difference was found (Table 2). After pooling the data of the first and second days, the change of needle pain and emotional affect in the Qigong and rest group was compared again (Table 3). In this analysis, only change of expected pain on insulin injection was significantly different between the Qigong and rest groups ($U = 143.50$, $P = .025$).

Discussion

In the present study, we applied a static Qigong program to reduce needle pain associated with insulin injection and BST in Korean adolescents with type 1 diabetes and performed a pilot test to evaluate its effectiveness. To our knowledge, this is the first interventional study performed on this topic using randomized groups, although the control group was delayed intervention group and the sample size was small. Qigong program was feasible in this population, but its effect was statistically significant only in expected pain on insulin injection. However, it did not ameliorate perceived pain or emotional discomfort. Also, after first and second days, interventions were not significant on pain and affects.

One possible explanation of our study results might be the small effect size of the study cohort. Although the Qigong program is known to be an effective pain management,[10,11] most studies on the subject have been performed in adult populations. In fact, static Qigong programs may work better with older children than younger ones, as older children find it easier to maintain posture and remain still. Static Qigong has similarities with mindfulness, nonmovement, deep breathing, and meditation. According to Burke,[19] when mindfulness is

Table 2. Comparison (Mann-Whitney *U* Test) of Changes of Pain and Emotional Affect Between Groups 1 and 2 on the First and Second Days.

	First Day, Δ Mean (SD)[a]	Second Day, Δ Mean (SD)[a]	*U* (*P*)
Qigong group	Group 1 (n = 9)	Group 2 (n = 12)	
Perceived pain on			
BST	−0.2 (1.2)	0.0 (0.9)	48.50 (.600)
Insulin injection	−0.7 (1.7)	−0.3 (0.8)	49.00 (.654)
Expected pain on			
BST	−0.7 (1.0)	−0.2 (0.6)	40.50 (.159)
Insulin injection	−1.3 (1.4)	−0.5 (0.9)	36.00 (.134)
PANAS			
Positive affect	−0.8 (1.6)	−2.0 (2.5)	38.50 (.259)
Negative affect	−2.1 (5.1)	−2.3 (3.8)	46.00 (.557)
Rest group	Group 2 (n = 12)	Group 1 (n = 9)	
Perceived pain on			
BST	−0.2 (0.6)	0.0 (0.0)	44.00 (.414)
Insulin injection	−0.2 (1.3)	0.5 (1.8)	39.00 (.430)
Expected pain on			
BST	−0.2 (0.6)	−0.3 (0.7)	46.00 (.767)
Insulin injection	−0.33 (0.8)	0.3 (0.7)	35.00 (.106)
PANAS			
Positive affect	−0.3 (4.0)	1.0 (5.9)	46.50 (.907)
Negative affect	−1.0 (3.1)	−0.9 (2.2)	43.00 (.695)

Abbreviations: BST, blood sugar test; PANAS, Positive and Negative Affect Schedule; SD, standard deviation.
[a]Changes of mean after the intervention

Table 3. Comparison (Mann-Whitney *U* test) of Changes of Pain and Emotional Affect Between the the Qigong and Rest Groups in the Pooled Data.

	Qigong Group (n = 21), Δ Mean (SD)[a]	Rest Group (n = 20), Δ Mean (SD)[a]	*U* (*P*)
Perceived pain on			
BST	−0.1 (0.1)	−0.1 (0.5)	209.50 (.983)
Insulin injection	−0.5 (1.3)	0.1 (1.5)	175.50 (.284)
Expected pain on			
BST	−0.4 (0.8)	−0.2 (0.6)	191.00 (.418)
Insulin injection	−0.9 (1.2)	−0.1 (0.8)	143.50 (.025)
PANAS			
Positive affect	−1.5 (2.2)	0.3 (4.7)	174.00 (.340)
Negative affect	−2.2 (4.3)	−1.0 (2.7)	207.50 (.947)

Abbreviations: BST, blood sugar test; PANAS, Positive and Negative Affect Schedule; SD, standard deviation.
[a]Changes of mean after the intervention

applied to children attention must be paid to age-related development needs (attention span, cognitive capacity, physicality, relevant content). When we compared the baseline characteristics of participants who experienced a reduction in expected pain and those that did not, participants who experienced a reduction tended to be older, taller, and heavier, and had a longer duration of diabetes. This finding is consistent with our opinion that older children benefit more from Qigong in terms of pain management.

The other explanation concerns the nature of needle pain in adolescents with type 1 diabetes and means of measuring pain. In the present study, perceived pains for insulin injections and BST were measured 1 to 2 hours after intervention at dinner times to avoid additional needle pain for research purpose. Therefore, our results may have been affected by a tendency to underrate pain. Indeed, our study participants reported more pain for insulin injection than BST, and thus, the effect of Qigong on pain was probably greater for insulin injection than BST which was lower enough at baseline. Howe et al[5] also noticed that children with type 1 diabetes reported more pain for insulin injection than BST.

Limitations

The study participants were recruited form one diabetes camp in Korea, and the sample size was small. Accordingly, the generalizability of our results is limited. Jaccard et al[20] mentioned that small sample sizes are common in studies that explore the psychosocial issues of children in clinical settings. Collaborative multicenter studies are needed to overcome the sample size issue for future studies. Furthermore, we did not collect data on potential confounders, such as, types of insulin, needles, and glucometers, which may have affected pain. The main weakness of cross over design, contamination of the intervention among study participants remains in this study. Although study participants were randomly assigned to groups, they participated in other programs together and were able to communicate freely with each other. The length of our program

might be too long for adolescents who were young or had minimal pain, although it was designed to be for Qigong beginners. Different length and content of Qigong program should be applicable to adolescents based on their experience with Qigong and types and intensity of their discomfort in the future. Furthermore, the study design had a 24-hour washout period for crossover of intervention switch as previously documented[21]; however, this period might be not long enough to prevent residual effect of Qigong. Future studies are needed in evaluation of short- and long-term effect of Qigong program among a wider spectrum of participants with different health conditions and developmental ages.

Conclusion

In this study, we present meaningful evidence that a Qigong program helped reduce in certain type of pain, though limited to expected pain on insulin injection of adolescents with type 1 diabetes. The devised program was found to be feasible and easily learnt. The program also did not require cumbersome equipment and could be performed almost anywhere. Therefore, we believe the described program may offer a nonpharmacological option for adolescents with type 1 diabetes who experience pain on insulin injection.

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Author Contributions

EK was involved in designing the study, developing and performing the intervention, and writing the manuscript. JEL was involved in designing the study and writing the manuscript. MS was involved in designing the study, data analysis, and writing manuscript.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethical Approval

This study protocol was approved by the institutional review board of Inha University, Incheon, South Korea (approval number: 141031-2A).

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