Randomized controlled trial on the effect of pre-operative gum chewing on the level of postoperative anxiety among boys undergoing circumcision*

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Abstract

Introduction Circumcision is a Filipino tradition that persists today as a pre-adolescent coming-of-age surgery that, without sufficient mental preparation, may confer some level of psychological trauma. The procedure is made difficult by the anxiety of young boys prior to the operation. This study aimed to determine the effects of gum chewing in the pre- and post-circumcision anxiety of school-aged boys.

Methods Data were gathered from 241 boys, aged 7 to 13 years, who were present in medical missions in Quezon City in April 2013. The anxiety of the participants was assessed using the Yale Preoperative Anxiety Scale. Data were encoded and analyzed using EpiInfo™ 3.5.4. Percent change in mean anxiety scores during pre-intervention, post-intervention, and post-circumcision were compared between and within the group using T-test.

Results A 7.6% decrease in anxiety score was seen in the experimental group, while a 34.4% increase was seen in the control group.

Conclusion This study shows that gum chewing has an immediate anxiety-relieving effect which is carried over until the postoperative period in boys undergoing circumcision.

Key words: anxiety, circumcision, gum chewing, postoperative anxiety

Circumcision, as culturally dictated in the country, is one of the anxiety-provoking milestones in a school-age boy's life. Boys are circumcised as an act of religious dedication and mark of cultural identity. The procedure is usually made difficult by the anxiety of the young boys about to undergo the operation, identified in this study as pre-operative anxiety. In the study of Mahmoudi-gharaei and colleagues,[1] postoperative distress and the level of anxiety in the operative period were shown to be associated with the level of anxiety in pre-operative period. This anxiety, experienced in anticipation of the procedure, manifests as restlessness, irritability, aggression or depression and often leads to uncooperative behavior, emotional outbursts, and combative behavior peri-operatively. This eventually leads to negative postoperative outcomes including physical injury or emotional and psychological trauma to the child.[2] Menage,[3] Boyle[4] and Freud[5]

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viewed circumcision as an act of bodily mutilation; thus, without sufficient mental preparation, it may confer some level of psychological trauma, which may sometimes lead to development of aggressive behavior and nightmares. Further studies[6,7] also reported a direct causal relationship between circumcision and the subsequent development of post-traumatic stress disorder (PTSD) among young boys, since the experience involves extreme physiological and behavioral responses, which cause trauma to the patient.[8]

In the Philippines, where the population of males aged 5 to 14 years is more than 10 million,[9] circumcision can be considered to be one of the surgical procedures done mostly among the male pediatric population. In 2007, 42% of boys circumcised were under 10 years, 52% 10 to 14 years, and 5% 15 to 18 years.[6] The high demand for this outpatient minor surgical procedure has been addressed by the medical community in the form of medical missions or "tuli missions" done in the communities. These missions, however, because of the makeshift nature of recreating a medical set-up in the community setting, are often lacking in facilities for comfort and health education; thus, adding to the anxiety experienced by the patients. Both external and internal factors could aggravate the anxiety of the child.[6] No measures are currently offered to the children to address the anxiety they feel prior to the procedure.

A proposed anxiety-distraction[10] measure to decrease pre-operative anxiety associated with circumcision is gum chewing. Kamiya,[11] Young[8] and Scholey[12] stated in three different researches that gum chewing decreases pain response, enhances serotonin release and helps in pre-operative relaxation, and decreases self-rated task-induced anxiety. Thus, this study aimed to determine the effectiveness of gum chewing in reducing the pre-operative and post-operative anxiety of school-age boys undergoing circumcision.

Methods

This was a randomized controlled trial involving boys for circumcision from three barangays in Quezon City last April 2013. Postoperative anxiety levels were compared between the experimental group who were iven chewing gum before circumcision and a control group.

Boys present at medical missions in Barangays San Perfecto, Doña Imelda and Doña Aurora in Quezon City who satisfied the following inclusion criteria were recruited: 7 to 13 years old, a resident of Quezon City, able to read and write in Filipino, without any co-morbidities, and accompanied by a parent or guardian. The computed sample size was 256 subjects. Assent and consent were both obtained from the boys and parents, respectively. Participation was voluntary and anonymous. Ethical approval for the study was granted by the Ethics Review Committee of the institution.

The anxiety level of the participants was assessed using the Yale Preoperative Anxiety Scale (YPAS), an observational instrument which measured the children's anxiety during preoperative and postoperative periods. It consisted of 22 items in five categories: activity, emotional expressivity, state of arousal, localization, and use of parents. The highest behavioral level/number observed in each category was the score for that particular category. Since each category had a different number of items, partial weights were calculated by dividing the observed level with the total number of items in that category. The partial weights were then added; the sum of the partial weights was multiplied by 100 to get the percentage and then divided by five, yielding the total adjusted score which ranged from 23 to 100. The total adjusted score or the YPAS score was classified into low-anxiety level (23 to 48), moderate-anxiety level (49 to 74), and high-anxiety level (75 to 100). YPAS was used to measure the baseline, post-intervention and post-circumcision anxiety scores of the subjects. Researchers underwent standardized training prior to the implementation of the study in order to prevent inter-observer bias. The designated observers were blinded to prevent subjective bias in the YPAS scoring.

Subjects were randomly allocated to either experimental or control group by drawing lots. The baseline anxiety levels were determined for both groups. The experimental group was then asked to chew sugar-free gum (Orbit®) for five minutes, 5 to 10 minutes before circumcision. The post-intervention anxiety level was then determined. The post-circumcision anxiety levels were determined.

Baseline, post-intervention, and post-circumcision anxiety scores for both control and treatment groups

were encoded using EpiInfo™ 3.5.4; data was analyzed using EpiInfo™ 3.5.4 and OpenEpi 3.01. An independent T-test used to compare the scores between groups and a paired T-test was used to compare the data within the same group. A chi-square test was used to compare the change in anxiety level between and within both groups.

Results

A total of 261 participants qualified for the study; of these, 20 (7.66%) were excluded due to 1) sudden withdrawal, either before or while the participant was on the operating table and 2) failure to pass the medical criteria for circumcision as assessed by physician volunteers but in whom chewing gum had already been given. The remaining 241 participants consisted of the experimental group with a mean age of 10.7 years comprising 46.9% of the subjects, and the control group with a mean age of 10.8 years comprising 53.1% of the subjects. Table 1 shows that the two groups are comparable in terms of age, caregiver and previous hospitalization.

Table 2 shows that the baseline mean anxiety scores of the chewing gum group were significantly higher than that of the control. After being given chewing gum, the experimental group's mean anxiety score decreased by 1.4% while the control group's score increased by 20% pre-operatively. The difference in percentage change from baseline to post-intervention between the two groups was significant. The percent change from post-intervention to post-circumcision score was then compared between and within the groups. In the control group, a significant 12% increase in anxiety score was seen, while a 6.2% decrease was observed in the experimental group. A net increase in anxiety score was observed in the control group, while a net decrease in anxiety score was observed in the experimental group as seen in Table 2. The differences were significant. Figure 1 shows a decreasing trend in the anxiety scores in the experimental group from baseline to the post-circumcision period (7.6% decrease) while an increasing trend is seen in the control group (34.4% increase).

Table 1. Demographic characteristics of participants.

	E n = 113	C n = 128	p-value
Age (years)			
7	1 (0.9%)	3 (2.3%)	0.99
8	2 (1.8%)	6 (4.7%)	0.98
9	15 (13.3%)	14 (10.9%)	0.99
10	28 (24.8%)	32 (25.0%)	1.0
11	31 (27.4%)	33 (25.8%)	0.99
12	28 (24.8%)	27 (21.1%)	0.98
13	8 (7.1%)	13 (10.2%)	0.98
Caregiver			
Mother	85 (75.2%)	96 (75.0%)	1.0
Father	23 (20.4%)	25 (19.5%)	0.99
Both	5 (4.4%)	5 (3.9%)	1.0
Others	0	2 (1.6%)	0.99
Previous Hospitalization			
With	69 (61.1%)	85 (66.4%)	1.0
Without	44 (38.9%)	43 (33.6%)	0.99

E: experimental; C: Control

Table 2. Mean anxiety scores and corresponding percent changes in different periods of anxiety: experimental vs. control.

Period of Anxiety	E	C	Statistical test
	Mean	Anxiety Scores	P-value
B	32.7	29.9	0.044
PI	32.2	35.9	0.014
PC	30.2	40.2	$<1x10^{-7}$
% Change in	Mean	Anxiety Score	T-test
B to PI	1.4% ↓	20% ↑	14.30
PI to PC	6.2% ↓	12% ↑	17.57
B to PC (Net Change)	7.6% ↓	34.4% ↑	23.93

E: Experimental; C: Control; B: Baseline; PI: Post-intervention; PC: Post-circumcision

Table 3 shows the proportion of participants in each anxiety level. In all three assessment periods, most participants were in the low-anxiety group. Among the control, there was a decreasing number in the low-anxiety group and an increasing number in the moderate-anxiety group, while the reverse was observed among the experimental group. A comparison of the two groups' composition showed

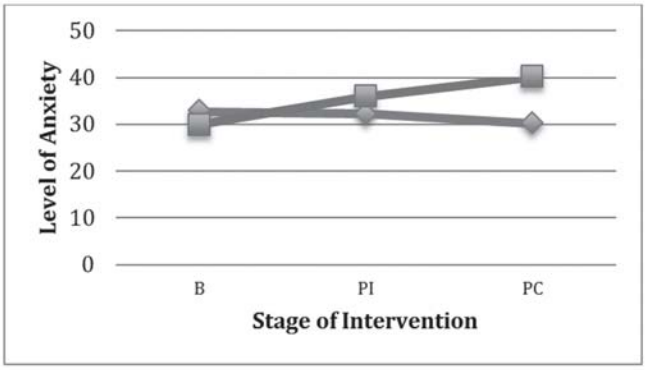

Figure 1. Comparison of the trend in the mean YPAS scores from baseline/pre-intervention (B), post-intervention (PI), to post-circumcision (PC).

that baseline distribution of the subjects was similar (P = 0.11), while both post-intervention and post-circumcision were significantly different (P < 0.05). Within the group, chi square test showed no significant changes in the distribution of subjects in the experimental group from baseline to post-intervention (P = 0.21) and from baseline to post-circumcision (P = 0.13); however, the opposite was noted in the control group. Significant increases in the proportion of moderate/high anxiety subjects in the control group were seen from baseline to post-intervention (P = 0.004), and from post-intervention to post-circumcision (P = 0.02).

Discussion

The current study evaluated the effectiveness of preoperative gum chewing on postoperative anxiety among boys undergoing circumcision. Baseline YPAS scores obtained in both arms indicated some level of anxiety among the subjects. This anxiety may be attributed to the extreme physiological and behavioral responses brought about by circumcision.[12] According to Cansever, the experience of circumcision lends a feeling of reality to the repressed fantasies, which amplifies the anxiety associated with it.[13] Apart from the external threatening situation, and an internal anxiety is presented for the child's ego to face.

The increasing trend in the mean anxiety scores of the control group immediately before and after the procedure exemplifies the natural course of a child undergoing circumcision based on its accompanying psychological effects – one of which is castration-anxiety.[12] In a study by Yilmaz, several forms of anxiety disorders such as multiple anxieties, overanxious disorder, simple and social phobias, and separation anxiety were observed to be remarkably high in their subjects undergoing circumcision.[6]

A decrease in mean YPAS score in the experimental group between baseline and post-intervention period and an increase in the control group suggests an immediate anxiety-decreasing effect in the experimental group which may be attributed to gum chewing. This is supported by Menage, who found that regular gum chewing may decrease anxiety in the healthy young adult population.[3] Another study by Scholey reports a decrease in self-rated anxiety and stress associated with gum chewing on task-induced stress.[12] Lastly, a study by Otomaru states that regular gum chewing improves anxiety, mood and fatigue.[14]

Post-operative distress and the level of anxiety in the operative period are associated with the level of anxiety in pre-operative period.[1] Thus, the researchers wanted to know if the effect of the gum-chewing would persist even after the circumcision. The further decrease in the post-circumcision YPAS score in the experimental group suggests a lasting effect of gum chewing on anxiety until the post-circumcision period.

Since there were no other interventions made to this arm aside from gum administration and care was done to ensure an equal setting among arms, it its highly likely that the decreasing trend in anxiety level in the experimental group effect came from the gum chewing. This is consistent with the study of Kamiya that prolonged rhythmic gum chewing activates the

Table 3. Percent distribution of subjects according to level of anxiety.

	Level of Anxiety					
	Experimental			Control		
	L	M	H	L	M	H
B	85.8	13.3	0.9	92.2	7.8	0
PI	91.2	8.0	0.9	79.7	19.5	0.8
PC	92.0	6.2	1.8	67.2	30.5	2.3

*B - Baseline; PI - Post-intervention; PC - Post-circumcision; L - Low Anxiety; M - Moderate Anxiety; H - High Anxiety

ventral part of prefrontal cortex augmenting activity of 5-HT neurons in the dorsal raphe nucleus, which in turn suppresses nociceptive responses.[11]

The classifications of subjects according to their levels of anxiety - low, moderate and high - were analyzed for a more clinical application. Chi-square was used to determine the significance in the change in distribution in these classifications, from baseline to post-circumcision, between groups and within groups. Baseline data showed that both groups had similar distributions initially. Within the experimental group, even though there was an increase in the number of subjects in the low-anxiety group from baseline to post-circumcision, this change in the distribution of subjects across levels of anxiety was not significant. However, the fact that there was a decreasing trend is significant because previous studies[1] showed that even experimental groups would have an increasing trend in anxiety score and that intervention would just decrease the increment in the postoperative anxiety. On the other hand, more subjects changed from low-level to moderate-high level anxiety in the control group as the circumcision neared, with a significant change from baseline to post-intervention and from post-intervention to post-circumcision. This increasing trend in anxiety would be expected from anyone undergoing a surgical operation. This means that the administration of gum chewing to the experimental group prevented an increase in anxiety level, contrary to what was experienced by the controls.

However, the presence of other factors may have contributed to the aforementioned results. This includes the lack of blinding among subjects which may have rendered subjective bias. Gum chewing in the experimental group might have caused a placebo effect and a counterpart increase in the anxiety levels of those who were not given chewing gums. Another factor may have been inter-observer bias. Individual differences among the observers in terms of observational skills possibly caused variation in scoring of the subjects despite training prior to data gathering. The duration of the procedure may also have contributed to variations in anxiety level carryover. A short procedure might have reflected a carry-over in post-circumcision anxiety, whereas, a long procedure may have exhausted the low anxiety carry-over of the gum chewed. The surgical difficulty of the procedure based on individual physical differences of each participant or intra-operative complications were not taken into account. These differences may have led to variations in anxiety levels intra-operatively which subsequently led to variations in anxiety level postoperatively apart from the effects of gum chewing. Furthermore, there was a dropout of 20 participants which might have increased the P-value.

With results suggesting reduced state anxiety[5] and reduced perceived levels of stress,[6] therapeutic use of chewing gum as pre-circumcision modality seems promising as the method is simple, inexpensive and easy to administer. Since circumcision is a prevalent practice in our country[15] then its implications are highly favorable for this nation's youth. However, further studies that serve to eliminate limitations mentioned are encouraged to further investigate the role of gum chewing in circumcision anxiety level reduction.

This study showed that gum chewing has an immediate anxiety-relieving effect pre-operatively in boys undergoing circumcision; this effect was carried over until the post-operative period. Thus, the researchers recommend the inclusion of a pre-operative anxiety assessment in the surgical checklist of pediatric patients. Anxiety should be considered as a fifth vital sign that assesses the psychological readiness of the child and thus should be addressed through anxiety-reducing modalities such as gum chewing.

Implications of the study as a possible modality in improving preoperative patient care in relation to development of postoperative psychological trauma, aggressive behavior, nightmares and later on post-traumatic stress disorder should be considered. Thus, an immediate and accessible anxiety control modality such as gum chewing should be advocated by mental health practitioners for those who have poor or immature psychological defense mechanisms such as children and those with anxiety disorders as an emergent therapy for anxiety-provoking situations to allay symptoms and prevent further morbidities.

A follow-up study may be done on the effects of gum chewing on circumcision. To improve validity, points for improvement would be employment of stratification to ensure comparable baseline values, participants should be blinded to prevent a placebo effect and subjective bias, parents or guardians should be instructed not to give their children gums to avoid contamination of controls, and surgical factors should be considered in evaluating carry-over of the

decrease in anxiety level. Furthermore, a separate study may be conducted to modify the YPAS scale to include assessment for intraoperative anxiety and to tailor the assessment tool to the specific age group being assessed. The modified tool would be beneficial for parallel studies conducted including minor surgery postoperative anxiety assessment for both pediatric and adult age groups.

The results of our study show that gum chewing - a simple, inexpensive and accessible non-pharmacologic modality - can decrease the pre-circumcision anxiety, an effect carried over until the post-circumcision period; the researchers strongly recommend the provision of gum among boys prior to circumcision. Additional studies involving other minor surgical procedures conducted not just among the pediatric group but also among adults are also recommended.

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