Vol. 4 No. 2 July - December 2015

UERM
Memorial Medical Center, Inc.
Research Institute for Health Sciences

Health Sciences Journal

ISSN 2244-4378

From the desk. To the bench. To the bedside.

Student Edition

The HEALTH SCIENCES JOURNAL

is published by the
University of the East Ramon Magsaysay Memorial Medical Center, Inc.
Research Institute for Health Sciences

DISCLAIMER

The articles in this Health Sciences Journal are for general informational purposes only. They are the products of research which may not have been tested or approved by the Food and Drug Administration (FDA). They are not intended as professional medical counsel or advice, and should not be used as such. The reader should consult his/her health professional to obtain advice for his/her particular problem. The reader's use of this Health Sciences Journal does not create a doctor-patient relationship between any of the authors and the reader.

The University of the East Ramon Magsaysay Memorial Medical Center, Inc. (UERMMMCI) is not responsible for the contents of this Journal and does not necessarily sponsor, endorse or otherwise approve of the materials appearing herein. Furthermore, the opinions expressed in the materials in this Journal are the opinions of the individual authors and may not reflect the opinions of UERMMMCI, its officers and the editors. Consequently, UERMMMCI and the Health Sciences Journal shall not be liable for any adverse or undesirable effects that may occur from the use of any of the substances, devices or procedures discussed in this Journal.

Contents

63 The association of functionality and quality of life of families of children with autism to standard care versus applied behavioral analysis
Reinavelle Jeunesse D. Mateo; Ann Marie Lizette M. Marzan; Thaddeus Joseph C. Mata; Jennifer Carla P. Matias; Mark Joseph C. Lopez; Lorraine W. Lu; Maria Ana Patricia V. Luspo; Joanna Bianca B. Mabaga; Beverly Kaye C. Macagba; Shaira Anne C. Macahilas; Ma. Mercedes G. Macalma; Hannah A. Maclang; Ramon Jason M. Javier, MD, FPAFP (Adviser)

71 Knowledge, attitude, and practices of post-partum mothers on breastfeeding, hygiene and diet: A descriptive cross-sectional study
Janine C. Pulido

76 A correlational study between smartphone size and range of motion of the thumb
Maria Isabelli D. Hipol; Erikadasha Maeliza Mones; Gian Paolo Navor; Aldrin Jake F. Padua; Kathleen Kay O. Vila

81 Effects of backpack loads and position on the posture of elementary students
Marielle Ann R. Apostol; Kevin John G. Carmona; Lorenzo C. Chacon Jr.; Jan Remigio A. Francisco; Micah Ann Rae S. Garcia

86 Curcuma longa (turmeric) as an adjunct to antihypertensive drugs among stage 1 and 2 hypertensive individuals: A randomized double-blind placebo-controlled study
Frances Elinzano; Jhean Dorado; Charlene Duante; Joana Dominguez; Rafilbin Daguplo; Issa D'Bayan; Kia de Asis; Denise de Guzman; Hashima Diamla

94 The effect of yacon (Smallanthus *sonchifolius*) syrup as adjunct to statins on the lipid profile of patients with dyslipidemia: A randomized controlled trial
John Patrick M. Dimarucot; Ola M. Fabiania; Audrey Aaron V. Fegarido; Raphael S. Figueroa; Princess Sittie Asiah A. Abdullah; Rachel Dominique G. Conti; Jeff Robert C. Costanilla; Jules Albert L. Crescini; Richelle V. Cunanan

101 Compliance of selected hospitals in the National Capital Region to the Department of Health functional indicators of safe hospitals in emergencies and disasters
Pura Jacobe T. Bascuña, Josue Antonio L. Baroña, Ann Lorraine M. Basilan, Arvinjay A. Bautista, Blessie C. Batac, Dana Gabrielle M. Arellano, Edshane L. Arevalo, Marie Grace A. Aseron, Beatrice April D. Austria, Mary Anne Claudine SP Avena

110 A randomized double-blind placebo-controlled trial on the effects of Capsicum annum as an adjunct for reducing blood pressure among hypertensive patients
Fidela Anne P. Salvador; Carmela A. Salvaña; Alexandra S. Sedano; Franklin John C. Yap; Loraine Alexis G. Yap; Maria Dawn Rosary B. Yap; Angelica Mae G. Yee, RPh; Carol Angeline G. Yu; Paulino Nathaniel H. Zamesa III, RN; Rachel Ann N. Zapanta, RN

The association of functionality and quality of life of families of children with autism to standard care versus applied behavioral analysis

Reinavelle Jeunesse D. Mateo; Ann Marie Lizette M. Marzan; Thaddeus Joseph C. Mata; Jennifer Carla P. Matias; Mark Joseph C. Lopez; Lorraine W. Lu; Maria Ana Patricia V. Luspo; Joanna Bianca B. Mabaga; Beverly Kaye C. Macagba; Shaira Anne C. Macahilas; Ma. Mercedes G. Macalma; Hannah A. Maclang; Ramon Jason M. Javier, MD, FPAFP (Adviser)

Abstract

Introduction Few studies have been conducted to determine family functionality and quality of life in relation to the type of therapy that the child is undergoing. This study aimed to determine the association of functionality and quality of life of families of children with autism with the type of treatment.

Methods Families of children with autism were identified and the primary caregivers were recruited. They were asked to answer the Family Adaptability, Partnership, Growth, Affection, Resolve (APGAR) and classified as functional (control) or dysfunctional (case). They we also asked to answer the World Health Organization Quality of Life-Brief Form (WHOQOL-BREF) questionnaire and classified as having good (control) or moderate/poor quality of life (case). The child's form of therapy was determined to be either standard care therapy or applied behavior analysis. The odds of having a dysfunctional family and having moderate/poor quality of life with a specific type of therapy were computed.

Results There was no significant difference in the odds of having a dysfunctional family between children undergoing standard care therapy and those undergoing applied behavior analysis (OR = 0.92). There was no significant difference in the odds of having a moderate/poor quality of life between children undergoing standard care therapy and those undergoing applied behavior analysis (OR=0.39).

Conclusion There is no association between family functionality and quality of life and the treatment approach.

Key words: Family functionality, quality of life, applied behavioral analysis

Correspondence:
Reinavelle Jeunesse D. Mateo, Department of Preventive and Community Medicine, College of Medicine, University of the East Ramon Magsaysay Memorial Medical Center Inc., Aurora Boulevard, Barangay Doña Imelda, Quezon City 1113; E-mail: reinavellemateo@gmail.com; Telephone: 9277905663

It is estimated that there are 67 million people affected by autism around the world. Philippine statistics show that during the 2000s, more than a thousand children were confirmed to have autism spectrum disorder (ASD) and this number is expected to increase to a total of 500,000 children diagnosed with autism. Autism spectrum disorder is characterized by (1) qualitative impairment in social interaction, (2) qualitative impairments in communication, and (3) restricted repetitive and stereotyped patterns of behavior, interests, and activities. Furthermore, it includes delays or abnormal functioning in at least one of the following areas, with onset prior to age 3 years: (1) social interaction, (2) language as used in social communication, or (3) symbolic or imaginative play. Finally, the disturbance should not better accounted for by Rett's disorder or childhood disintegrative disorder.[1]

Two interventions are currently being used to treat ASD: standard care therapy (SCT) and applied behavioral analysis (ABA). Applied behavioral analysis is characterized by highly structured, adult-directed teaching referred to as discrete trial instruction or training and may be traditional or contemporary. Traditional applied behavioral analysis focuses on teaching correct responses in regimented, prescriptive teaching formats. Contemporary applied behavioral analysis practice is characterized by more flexible, naturalistic teaching in natural routines and activities that focus on social initiation and spontaneity. Because of the significant limitations of traditional ABA practice, many applied behavioral analysis practitioners have moved away from the traditional practice to the contemporary practice, which has a much greater focus on social communication.[2]

The principal endpoints of ASD therapies, including SCT and ABA, are to reduce the complications and negative effects of symptoms, to take full advantage of learned and acquired skill of independence and quality of life, and to relieve stress in the family. Despite attaining these given goals, a family with a member diagnosed with autism still experiences more strain compared to other families.[3] Besides the actual condition of the child, many other factors contributing to this stress include the amount of time spent caring for the child's well being physically distresses the primary caregiver, added financial strain, and the severity of the autism of the child. Other problems that may arise include depression, anxiety, restrictions of roles and activities, and strain in marital relationships.[4] Parental apprehension over learning difficulties, possible bullying, role adjustment, and coping with stress can also add to the worry of the primary caregiver.[5, 6] Finally, the family's cohesion and adaptability may also be affected.[7]

Studies have explored the quality of life of primary caregivers and/or families with children with autism in different countries. However, the primary caregiver and/or the family's disposition are often not considered in choosing the treatment for the child. This research may be a step to filling the gaps of knowledge in the family's functionality and quality of life, while caring for a child with autism, as it discusses the individual relationships involved in the treatment of autism in the Philippines. The results may help in formulating a program suited to the needs of a particular household while caring for a child with autism. Furthermore, the findings may contribute in determining the need for an added intervention for the family due to possible dysfunctional relationships and low quality of life.

The main objective of the study was to determine the association of family functionality and quality of life of families of children with autism with the type of treatment. Specifically, the study aimed to determine (1) the proportion of functional and dysfunctional families/primary caregivers; (2) the proportion of families/primary caregivers with good and poor quality of life; (3) the odds of functional or dysfunctional family given a specific type of treatment; and (4) the odds of good or poor quality of life given a specific type of treatment.

Methods

A case-control study design was used to determine whether family functionality and the quality of life of selected families of children with autism differed between standard care therapy and applied behavioral analysis interventions. Children with autism in Quezon City were identified and recruited by purposive sampling. Their families were classified as functional (control) or dysfunctional (case) based on their Family Adaptability, Partnership, Growth, Affection, Resolve (APGAR) scores. The families were also classified as having good (control) or poor (case) quality of life based on their World Health

Organization Quality of Life-Brief Form (WHOQOL-BREF) scores. The type of intervention of each family – SCT or ABA - was determined. The odds of a functional or dysfunctional family and the odds of a good or poor quality of life given a certain type of intervention (SCT or ABA) were computed. The study was approved by the Ethics Review Committee (RIHS ERC # 0163/C/M/14/026).

Participants were families from Quezon City with at least one child diagnosed with classical autism based on the DSM-IV-TR criteria for at least three years who were 18 years or younger. Families of children with autism with other known medical conditions such as cardiac or pulmonary diseases, major accidents or distress in the last 6 months that could significantly affect the family quality of life were excluded. Additionally, family members or caregivers with a history of psychiatric illness or with sensory, motor, or cognitive impairments that might potentially affect the study results were excluded. A sample size of 72 per group was computed based on a study that 70% of families who have children with autism have a low family quality of life, a confidence interval of 95%, and 15% maximum difference in the frequencies to be detected. Purposive sampling was utilized to recruit the primary care giver of the child as the respondent.

The researchers contacted and coordinated with government and non-government institutions or organizations in Quezon City involved in the therapy for children with autism in order to facilitate recruitment. Public primary and secondary schools with special education (SPED) centers in Quezon City comprised majority of the sites visited for data collection. Permission from the Superintendent of the Division of Public Schools and the principals were obtained. Informed consent was secured from each family member who participated in the study.

A standard explanation of the survey to the participants was given and confidentiality assured before the questionnaire was distributed. Respondents were given time to go through the questions and ask clarifications before being given one week to answer the questionnaire. After one week, the researchers returned to the institutions to collect and review the questionnaires for completeness. If there were incomplete answers, the researchers retrieved the missing data from the respondent. The type of intervention - SCT or ABA - was determined after collection of the completed questionnaire.

Socio-demographic characteristics were collected using the Socio-Demographic Profile Questionnaire (SPQ) which consisted of seven items: age, sex, marital status, occupational status, religion, and number of children in the family. Family functionality and quality of life were then assessed using the Family APGAR and WHOQOL-BREF, respectively. The Family APGAR assessed general family function, or the extent to which a family works as a unit to cope and adjust to different situations based on five components: adaptability, partnership, growth, affection, and resolve. Families were categorized into highly functional, moderately dysfunctional and severely dysfunctional by the self-administered APGAR. The primary caregiver's response was based on the frequency of feeling satisfied with each of the five parameters using a 3-point Likert scale ranging from 0 (hardly ever), to 2 (almost always). The higher the score was, the higher the level of family function. The scale was then scored by summing the values for the five items for a total score that could range from 0 to 10. A score of 0-3 denoted a severely dysfunctional family, 4-7 a moderately dysfunctional family, and 8-10 a highly functional family. For this study a family whose score was 8 to 10 was considered functional (control) while a family whose score was less than 8 points was considered dysfunctional (case).

The WHOQOL-BREF consisted of 26 questions with a 5-point Likert scale that covered the physical, psychological, social relationships and environmental domains. Families were either categorized into families with good quality of life or poor quality of life based on the WHOQOL-BREF scores. Families whose score was above the standard deviation of the participant scores were categorized as having a good quality of life (control) while families whose score was below the standard deviation were regarded as having poor quality of life (case). The questionnaire was translated into Filipino, pilot tested in a similar population, and modified to ensure content validity.

A child was considered as being on SCT if intervention included any of the following: speech therapy, occupational therapy, physical therapy, and sensory integration therapy. A child was considered as undergoing ABA if intervention included a combination of psychological and educational

techniques modified according to each individual child's needs to alter his/her behavior. This involved the use of behavioral methods to measure behavior, teach functional skills, and evaluate progress. It worked on promoting communication, behavioral, social and academic skills.[4]

Data retrieved were checked for accuracy and completeness before being encoded. Measures of central tendency, proportions and standard deviations as identified in the Socio-Demographic Profile were computed using Microsoft Excel. Odds ratios and significance, determined through chi-square, were computed using SPSS.

Results

The socio-demographic characteristics of the study respondents are summarized in Table 1. Majority of the respondents were 26 to 40 years old with a mean age of 41 years. The respondents from the dysfunctional group were older than the functional group and those from the group with a poor quality of life were younger than those with a good quality of life. There were more female than male primary caregivers; most respondents were married, non-working and Catholic.

More than a third of the families were dysfunctional. Almost two-thirds of children in both functional and dysfunctional groups were on standard care therapy. As shown in Table 2, the odds of having a functional or dysfunctional family are not significantly different whether they are on SCT or ABA (p = 0.86).

Table 2. Association of family functionality and therapy used in caring for children with autism.

Exposure	Family Functionality		
	Dysfunctional	Functional	
Applied behavioral Analysis	12	22	OR = 0.92 p = 0.86
Standard care	23	39	

As shown in Table 3, almost 90% of families did not have a good quality of life and almost 70% of them were on SCT. More than half of the families with a good quality of life were under ABA. The odds of having a poor quality of life if the child was on ABA was decreased by 60% but this was not significant (p = 0.13).

Table 1. Socio-demographic characteristics of study respondents

		Family functionality (n = 96)		Quality of life (n = 96)	
		Dysfunctional	Functional	Poor	Good
Age (yr)	18-25	2.9	0	0	1.7
	26-40	41.2	56.5	66.7	41.7
	41-64	55.9	41.9	33.3	55
	>65	0	1.6	0	1.7
Sex	Male	8.8	17.7	13.9	15
	Female	91.3	82.3	86.1	85
Marital Status	Single	26.5	14.5	25	15
	Married	64.7	80.7	72.2	76.7
	Living-in	2.9	0	0	1.7
	Separated	2.9	3.2	2.8	3.3
	Widow	2.9	1.6	0	3.3
Occupational Status	Working	29.4	41.9	33.3	40
	Non-working	70.6	58.1	66.7	60
Religion	Catholic	76.5	80.7	88.9	73.3
	Christian	14.7	11.3	5.6	16.7
	Iglesia ni Cristo	5.9	1.6	2.8	3.3
	Others	2.9	6.5	2.8	6.7

Table 3. Association of quality of life (QoL) and therapy used in caring for children with autism.

Exposure	Quality of Life		
	Moderate to Poor Quality of Life	Good Quality of Life	
Applied behavioral Analysis	27	6	OR = 0.39 p = 0.13
Standard care	58	5	

As shown in Figure 1, 17 to 29% of families had good quality of life in the four WHOQOL-BREF domains. There was a bigger proportion of families with poor quality of life in the social relationships and environmental domains compared to the physical and psychological domains.

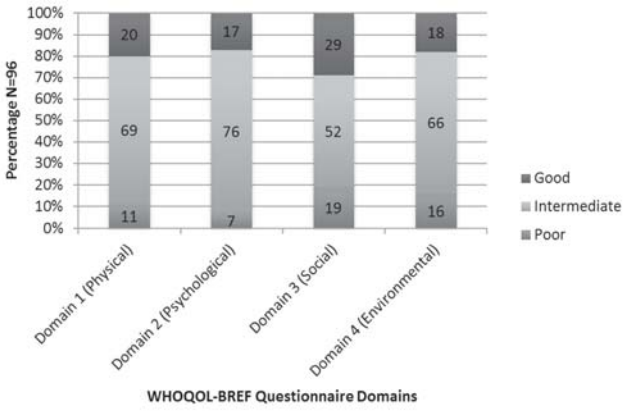

Figure 1. Proportion of quality of life according to the domains of the WHOQOL-BREF Questionnaire.

Discussion

The results of this study showed no significant differences between functionality of families with children with autism undergoing SCT compared to those with children undergoing ABA. This finding, however, was not the expected outcome based on previous studies that compared ABA with SCT as majority found better results with the ABA group in terms of intelligence quotient (IQ), language skills, and adaptive behavior. Given that several studies have shown that the ABA programs yield a better result among children with autism, it was expected that ABA group would show a higher number of families with better functionality as compared with the SCT group.

Our findings may be due to the differences in administration of the intervention, since some children may have had ABA administered by a trained practitioner while others underwent the same therapy through a parental figure. However, several studies comparing the efficacy of the interventions administered by clinical staff and parents revealed no significant outcome differences.[8] Another explanation suggested for this outcome was that the number of hours per week allotted for ABA had an effect on the outcome. Reed showed that the effectiveness of ABA decreased if done for more than 20 hours per week.[9] However, this study did not take into consideration the number of hours per week of therapy that the children were exposed to. Limitations in autism therapy intervention settings likewise have an impact on its effect on patients. A meta-analysis by Bellini and Peters found that a school-based social-skill intervention among children with autism was minimally effective among this population.[10] It had low generalization effects in participants, settings, and play stimuli.

Moes and Frea compared the outcome of prescriptive and contextualized treatment approaches on the behavior of the child with autism and his family. In the prescriptive approach in the child undergoes treatment is solely directed by the interventionist or the primary caregiver. Contextualized treatment, on the other hand, is family-directed, and considers the family dynamics in order to incorporate the behavioral support plan. In this approach, family assessment is done to determine the family characteristics and preferences, and from this, teaching methods are devised to fit the family's routine, ongoing practices, and interaction goals. The researchers found that with the contextualized approach, there was a significant reduction in the behavioral problem, and there was increased compliance during family routines. Their study concluded that more favorable results can be obtained from the contextualized approach in terms of the intervention outcome on the child with autism and his family. Taking into consideration the findings from this study, it may be noted that a positive outcome from interventions done on children with autism does not solely rely on the type of treatment approach done, i.e., ABA vs. SCT, since family

dynamics play a highly important role in its effect on the family functionality among patients undergoing various interventions.

It was also noted that there were participants who had other children who did not have autism. This context should also be explored in a sense that it could have had an impact on the disparity of our study compared with other research. Consideration could have been given to the siblings' adjustment to the family member who had the disorder. Allotting significant financial resources and time on the intensive ABA program may have a negative effect on the siblings. It was found that the severity of the autism being displayed by the patients had an effect on the behavioral adjustment of the siblings.[11] As previously mentioned, family dynamics has an important role in the outcome of the patient and the family functionality. Therefore, the adjustment of siblings may have an impact on the family functionality. Also, the severity of the characteristics of autism presented by the patients may have a bearing on family functionality, independent of the interventions used.

Similar to the result regarding family functionality there was no significant difference in the family's perceived quality of life, regardless of the type of intervention being used. Previous studies have shown varying findings on the effect of ABA in children with autism. Studies reviewed by Rogers and Vismara described a 50% "recovery" rate in children with autism when they were treated with ABA for several years.[12] On the other hand, Spreckley and Boyd noted a lack of evidence supporting better outcomes in children treated with ABA as compared to SCT.[13] This may be the reason why in this study, ABA had the same effect on the quality of life of the caregivers as those under SCT.

A study by Ahmad and Dardas revealed that parents of children with autism showed no significant differences in their physical, psychological, social, and environmental health. Both parents showed almost similar bivariate correlations between the reported quality of life levels and their parenting stress, coping strategies, and demographic characteristics.[14] This is in contrast with other studies which showed that those mothers of children with high functioning autism had poorer physical health and had poorer results in terms of physical and mental well-being compared to mothers who had children diagnosed with Asperger's syndrome.[15] Maternal health was related to behavior issues in children such as hyperactivity and conduct problems. Schieve also concluded that parenting a child with autism with recent special service needs seemed to be associated with unique stresses as compared to parenting a child with autism without such special service needs.[16] The need for special services may be related to severity of autism behavior difficulties and/or cognitive functioning, stability or lack of the child's current functioning, the parent's perception of severity and stability, or some combinations of these.

The data gathered showed that participants' perception of having a good quality of life was less than the combined quality of life of those who had a moderate and poor quality of life score in the physical, psychological, social relationships, and environmental domains of the WHOQOL-BREF. In the physical domain, majority of the participants in both ABA and SCT groups perceived a poor quality of life. This may be because caregivers of children with autism reflected poorer health than caregivers of children without developmental disabilities.[4] A similar result was observed in the psychological domain. Other studies showed that emotional stress was a significant factor and that women were more vulnerable.[4, 17] Our result may have been due findings that more than 80% of caregivers were women.

The outcomes in the social relationships and environmental domains may have been due to a number of factors. Kheir found that difficulties among female caregivers of children with autism were encountered during daily activities at work and their associations with peers and family. This is in relation to the results of the study where primary caregivers were mostly females.[4] Some parents may spend a significant amount of money to be able to sustain, or even possibly improve, the state of their children. Therefore, the whole family tends to suffer from compromising other finances for household needs, and because everything, from time to attention and resources, revolves around the child with a disability.[18]

Gomez and Gomez gave some insight on the quality of Filipino parents with children with autism. Although parents had a moderate satisfactory score with regard to their social relationships and environment domains, the participants still felt that support from their environment is mostly insufficient. The same study

also highlighted the level of parental education as a key factor in the environmental domain scores because it contributed to financial constraints they may experience and exhibited a direct proportion with the factors involved in the environmental domain.[17]

The discrepancy between the subjects' perception from their actual quality of life scores may be attributed mainly to different forms of bias. The investigators took into account the possible consequence of the Hawthorne effect. Since the participants were aware that they were being observed, they may have consciously or unconsciously given answers that were deemed acceptable. Thus, by not admitting the difficulties of having to care for a child with autism, the respondents' scores showed a good quality of life although the results in each of the domains indicated otherwise. Another factor noted by the investigators was information bias.[19]

In relation to the Hawthorne effect, parents may have been reluctant to admit that they themselves were not the primary caregivers of their children. The participants may have claimed that they were the primary caregivers, when in reality, someone else - a hired caregiver or governess - was the actual primary caregiver.[4] Also, families may not initially report concern about the children with autism because of their acceptance of the behavior of the child. They may have attributed it as a part of their normal process of development and may not have considered it to be symptomatic of any particular disorder.[18]

The results of our study did not support findings of other studies which may lead to the issue of whether or not ABA is a better option among children with autism. Several researches have concluded that ABA is the most effective option for children with autism, and that it is the "gold standard" of treatment. However, according to the National Research Council, USA, which is "the most comprehensive review of educational research to date"[2], there is no evidence that any one approach is superior to another for children 0-8 years of age based on the current state of research on autism.[20] Furthermore, a considerable number of studies on ABA demonstrated the effectiveness of specific aspects of this practice that were initially developed outside the confines of ABA.[2] In short, ABA has adapted so many elements, that certainly, all components of the intervention would be likely to work on the child with autism. It would mean that individual components of the intervention may, in itself, work effectively on children with autism without having to be included in ABA therapy. This may be the reason the families of children with autism exposed to ABA were not found to significantly differ from families undergoing SCT in terms of family functionality and quality of life.

Limitations of the study include: (1) children in the study were less than 18 years old and diagnosed using DSM-IV-TR criteria. Results may not correlate well with the general pediatric population and children who were newly diagnosed with autism spectrum disorder using the recently published DSM-V criteria; (2) financial status and other socio-demographic factors that may affect the well-being and quality of life of the families were not included as part of the socio-demographic data, and; (3) the severity of the signs and symptoms associated with autism were not included as part of the assessment. This may have affected the study results since the clinical presentation of the children may have contributed to the family's perception of their current situation.

In conclusion, the study found no significant differences between ABA and SCT in children with autism with respect to the outcome variables of family functionality and quality of life. Majority of the study participants were found to have functional families, with no statistical differences between odds of the families of children with autism undergoing applied behavioral analysis having a functional family as compared to families whose children were undergoing standard care therapy. Majority of the study participants were found to have a perception of moderate quality of life. Finally, the odds that the families of children with autism undergoing applied behavioral analysis are less likely to have a moderate to poor quality of life as compared to those families whose child are undergoing SCT was not statistically significant.

References

1. Pervasive Developmental Disorders. In: Sadock BJ, Sadock VA. Kaplan & Sadock's Synopsis of Psychiatry: Behavioral Sciences/Clinical Psychiatry. 10th ed. Philadelphia: Lippincott Williams & Wilkins; 2007.
2. Prizant BM. Treatment options and parent choice: Is ABA the only way? Autism Spectrum Quarterly 2009; 28-31.
3. Myers SM, Johnson CP. Management of children with autism spectrum disorders. American Academy of Pediatrics 2007; 120(2): 1162-82.

4. Kheir NM, Ghoneim OM, Sandridge AL, Hayder SA, Al-Ismail MS, Al-Rawi F. Concerns and considerations among caregivers of a child with autism in Qatar. BMC Research Notes 2012; 5: 1-7.
5. Lee LC, Harrington RA, Louie BB, Newschaffer CJ. Children with autism: Quality of life and parental concerns. Journal of Autism Developmental Disorders 2008; 38(6): 1147-60.
6. Safe A, Joosten A, Molineux M. The experiences of mothers of children with autism: managing multiple roles. Journal of Intellectual Developmental Disabilities 2012; 37(4): 294-302.
7. Higgins DJ, Bailey SR, Pearce JC. Factors associated with functioning style and coping strategies of families with a child with an autism spectrum disorder. Autism 2005; 9(2): 125-37.
8. Broadstock M, Lethaby A. The Effectiveness of Applied Behavior Analysis Interventions for People with Autism Spectrum Disorder. New Zealand: Report to the New Zealand Ministry of Education; 2008.
9. Reed P, Osborne LA, Corness M. Brief report: Relative effectiveness of different home-based behavioral approaches to early teaching intervention. Journal of Autism and Developmental Disorders 2007; 37(9): 1815-21.
10. Bellini S, Peters J. A meta-analysis of school-based social skills intervention for children with autism. Remedial and Special Education 2007; 28(3): 153-62.
11. Hastings R. Behavioral adjustment of siblings of children with children engaged in applied behavioral analysis early intervention programs: The moderating role of social support. Journal of Autism and Developmental Disorders 2003; 33(2): 141-50.
12. Rogers S, Vismara L. Evidence-based treatments for early autism. The Journal of Clinical Child and Adolescent Psychology 2008; 37(1): 8-38.
13. Spreckley M, Boyd R. Efficacy of applied behavioral intervention in preschool children with autism for improving cognitive, language, and adaptive behavior: A systematic review and meta-analysis. The Journal of Pediatrics 2009; 154: 338-44.
14. Ahmad M, Dardas L. Quality of life among parents of children with autistic disorder: A sample from the Arab world. Research in Developmental Disabilities 2014; 35(2): 278-87.
15. Allik H, Larsson J, Smedje H. Health related quality of life in parents of school-age children with Asperger syndrome or high-functioning autism. Health and Quality of Life Outcomes 2006; 4:1.
16. Schieve L, Blumberg S, Rice C, Visser S, Boyle C. The Relationship between autism and parenting stress. Journal of American Academy of Pediatrics 2007; 119: S114-S121.
17. Gomez IN, Gomez MG. Quality of life of parents of Filipino children with special needs. Education Quarterly 2013; 71(2): 42-58.
18. Bashir A, Khurshid S, Qadri F. Awareness and problems of parents of children with autism spectrum disorders. International Journal of Interdisciplinary Research and Innovations 2014; 2(2): 42-8.
19. Wickström G, Bendix T. The "Hawthorne effect" — what did the original Hawthorne studies actually show? Scandinavian Journal of Work, Environment & Health 2000; 26(4): 363-7.
20. Lord C, McGee J. Educating Children with Autism. Washington: National Academy Press; 2001.

Knowledge, attitude, and practices of post-partum mothers on breastfeeding, hygiene and diet: A descriptive cross-sectional study

Janine C. Pulido

Abstract

Introduction This study aimed to describe the knowledge, attitude and practices of post-partum mothers with regard to breastfeeding, proper hygiene and proper diet.

Methods This is a cross-sectional study involving 30 post-partum mothers in four lying-in clinics in Antipolo. A structured questionnaire was administered to the mothers to assess their knowledge, attitude and practices regarding post-partum breastfeeding, hygiene and diet.

Results At least 90% of respondents had adequate knowledge of 12 areas of breastfeeding, various aspects of proper hygiene and proper nutrition. All women showed good attitude in breastfeeding, and at least 83% showed good attitude on proper hygiene and proper diet and nutrition. At least 90% had good practice in breastfeeding and not less than 76% had good hygienic and dietary practice. The mean scores in the three areas of interest showed adequate knowledge, good attitude and good practice.

Conclusion Majority of respondents had adequate knowledge, good attitude and good practice of breastfeeding, proper hygiene and proper diet and nutrition.

Key words: breastfeeding, postpartum hygiene, postpartum diet

The World Health Organization (WHO) describes the postnatal period as the most critical and yet the most neglected phase in the lives of mothers and babies; most infant deaths occur during the postnatal period.[1] The focus of postpartum care is ensuring that the mother is healthy and capable of taking care of her newborn, equipped with all the information she needs pertaining to breastfeeding, childcare, reproductive health and contraception, and the imminent life adjustment. In view of the Millennium Development Goals 5 and 6 on reducing child mortality and improving maternal health, respectively, United Nations Children's Fund[2] emphasizes that an early initiation of breastfeeding, exclusive breastfeeding (EBF) for six months, appropriate complementary feeding and sustained breastfeeding for up to two years can prevent over 75% of deaths in early infancy and 37% of deaths in the second year. Furthermore, inappropriate feeding practices such as formula feeding has been associated with 19% of deaths in children under age five. Breastfeeding is not only beneficial for the child but also for the mother. Proven benefits of breastfeeding

Correspondence:
Janine C. Pulido, Department of Preventive and Community Medicine, College of Medicine, University of the East Ramon Magsaysay Memorial Medical Center Inc., Aurora Boulevard, Barangay Doña Imelda, Quezon City 1113;
E-mail: pulido.janine@yahoo.com; Telephone: 09277797515

include decreased post-partum blood loss, more rapid uterine involution, increased child spacing due to lactational amenorrhea, and reduced risk of chronic diseases such as hypertension, breast cancer and ovarian cancer.[3] Indeed, breastmilk is safe and has all the nutrients and antibodies needed for an infant's healthy development and protection from childhood illnesses according to WHO.[1] Despite this, results of the Philippine National Demographic and Health Survey[4] show that bottle-feeding is relatively still common in the Philippines; about 27% of infants under two months of age are being fed milk formula. The proportion of children given infant formula increases with age, and peaks at 9 to 11 months. A slight increase in the median duration of breastfeeding from 14.3 months in 2008 to 16.7 months in 2013 was recorded by the National Statistics Office (NSO) and ICF Macro.[5]

According to a NSO[6] survey in 2013, only about 27% of children in the Philippines were exclusively breastfed while 92% were breastfed for some time. It is alarming that despite the widespread campaigns for exclusive breastfeeding, only about a few manage to comply with this. The key to this dilemma is to assess the knowledge, attitude, and practices of post-partum mothers in breastfeeding, hygiene and nutrition. This study aimed to describe the knowledge, attitude, and practices of post-partum mothers on breastfeeding, hygiene and nutrition.

Methods

This was a descriptive cross-sectional study on the knowledge, attitudes, and practices of post-partum women in breastfeeding, hygiene, and diet conducted at four lying-in clinics in Antipolo, Rizal. The respondents were asked to answer a questionnaire on the topics of interest. The study was approved by the Ethics Review Committee.

The investigator recruited women who had delivered a live baby one day to six weeks earlier and were willing to participate in the study. Written informed consent was obtained from the participants. Excluded were those who were unable to read and write, and those who gave birth to preterm infants. The computed minimum sample size was 30 based on a confidence value of 95%; a precision of 25 and a margin of error of 10. Convenience sampling technique was used.

The instrument used was a 39-item questionnaire in English and Filipino that assessed the respondents' knowledge, attitude and practices regarding breastfeeding, hygiene and diet (Table 1) formulated by the investigator based on a review of the literature. The knowledge part consisted of 21 Likert-type questions with the following responses: 4 (strongly agree), 3 (agree), 2 (disagree), and 1 (strongly disagree). The attitude and practice parts had items answerable by yes or no and the other practice questions were multiple choice type. The questions on knowledge of breastfeeding included items on the benefits, timing, positioning of the baby, effects on the mother and misconceptions. The questions on knowledge of proper hygiene included items on bathing, cleansing of nipples, boiling water and sterilization of items used. The questions on knowledge of proper diet included items on foods that stimulate lactation, the role of iron and lack of appetite. The questions on attitude towards breastfeeding included items on the advantage of breast milk over milk formula, colostrum and exclusive breastfeeding. The questions on attitude towards good hygiene included items on bathing after delivery, and maintaining cleanliness of the wound site and breasts. The questions on attitude towards good diet included items on belief in foods that promote the health of the mother and lactation. The questions on practice of breastfeeding included items on timing of initiation, duration and colostrum feeding. The questions on practice of good hygiene included items on bathing and washing the nipples. The questions on practice of good diet included items on drinking water and other fluids, eating iodine-rich food and food preferences. The questionnaire was pretested in another group of postpartum women with similar characteristics as the respondents.

Every response in the questionnaire was rated and a total score was obtained for the post-partum mother's knowledge, attitude and practice. For knowledge part, those who answered "agree" and "strongly agree" were considered as having adequate knowledge per item. For the attitude and practice subparts, the "yes" response is considered "good" and a "no" response was "bad". The number and percentage of respondents with adequate knowledge and good attitude and good practice in each area were computed and reported. The researcher set cut-off values for knowledge, attitude and practice in breastfeeding, proper hygiene and proper diet, respectively, to determine adequate knowledge and good attitude and good practice in each area.

Results

All 30 postpartum women recruited returned validly answered questionnaires. As seen in Table 2, all respondents had adequate knowledge in five of 12 areas of breastfeeding, 96.7% in four other areas and at least 90% of them had adequate knowledge in the remaining areas. All respondents had adequate knowledge of good hygiene insofar as cleaning the wound, boiling of water for drinking, and sterilization of items used was concerned as seen in Table 3. Twenty-six women knew that they could bathe on the first postpartum day and all but one knew that nipples should be cleaned with water alone. All respondents had adequate knowledge in proper diet and nutrition.

Table 1. The distribution of questions in each subpart.

	Breast-feeding	Hygiene	Diet	Total
Knowledge	12	5	4	21
Attitude	3	3	3	9
Practices	4	2	3	9
	19	10	10	39

Table 2. Frequency and percentage of post-partum mothers who have adequate knowledge on breastfeeding (n=30).

Question	Mothers with adequate knowledge n (%)
Best for babies to achieve good health and be protected	30 (100)
First milk from the breast of the mother on the first three days is nutritious and should be given	30 (100)
Immediate breastfeeding after birth	29 (96.7)
Exclusive breastfeeding should be done in 6 months	30 (100)
It will not cause sagging of the breast	27 (90)
It will not cause sore nipples	30 (100)
It will not cause any pain in nipples	28 (93.3)
Knew that she should hold the baby close to her body	30 (100)
Knew that not only the nipples should be sucked	28 (93.3)
Knew that the nose should not be covered by the breast of the mother	29 (96.7)
Knew that the lower lip of the infant must protrude outward	29 (96.7)
Size of the breast don't matter to have adequate milk production	29 (96.7)

Table 3. Frequency and percentage of post-partum mothers who have adequate knowledge on proper hygiene (n=30).

Question	Mothers with adequate knowledge n (%)
Taking a bath after first postpartum day should be done	26 (86.7)
Cleaning the suture site should be done daily to avoid infection	30 (100)
Water alone should be use in cleaning nipples	29 (96.7)
Drinking water should be boiled	30 (100)
Things to be used should be sterilized	30 (100)

All respondents had good attitude towards breastfeeding based on their responses to three items on the advantage of breast milk over milk formula, colostrum, and exclusive breastfeeding. About 83.3% had good attitude towards hygiene, with only five respondents believing that taking a bath should not be done immediately after giving birth. At least 29 postpartum women had good attitude towards proper diet in terms of belief in foods that promote the health of the mother and lactation.

All respondents were able to let their babies suck their colostrum and all except one initiated breastfeeding within 24 hours; 90% were still breastfeeding at the time of the study. The reasons for stopping breastfeeding were no milk and preference for am or milk formula. In terms of hygiene, 23 women took a bath within the day after giving birth while 28 washed their nipples regularly with water. The reasons of the seven women who did not bathe immediately were fear of cold, fear of becoming ill and weakness from the stress of childbirth. Majority of the participants had good practices in terms of their diet: they drank water; ate soup, rice porridge and other hot foods. However, about 23.3% of the sample did not eat fish or seafood products. Their reason for not eating fish/seafood products is their belief that seafood products delay wound healing after delivery. The preferences of 70% of respondents were malunggay and green leafy vegetables, followed by fruits and protein-rich foods.

As shown by the mean scores in Table 4, the cohort had adequate knowledge of breastfeeding, proper hygiene and proper diet. The mean scores in Tables 5 and 6 show good attitude and practice, respectively, of the respondents in the three areas of interest.

Table 4. Mean scores and interpretation of post-partum mothers' knowledge of breastfeeding, proper hygiene and proper diet.

Area (# of items)	Mean Score	Interpretation
Breastfeeding (12)	11.07	Adequate (≥6)
Proper hygiene (5)	4.40	Adequate (≥3)
Proper diet (4)	3.87	Adequate (≥2)

Table 5. Mean scores and interpretation of post-partum mothers' attitude on breastfeeding, proper hygiene and proper diet.

Area (# of items)	Mean Score	Interpretation
Breastfeeding (3)	3.0	Good (≥ 2)
Proper hygiene (3)	3.0	Good (≥ 2)
Proper diet (3)	3.0	Good (≥ 2)

Table 6. Mean scores and interpretation of post-partum mothers' practice of breastfeeding, proper hygiene and proper diet.

Area (# of items)	Mean Score	Interpretation
Breastfeeding (4)	4.0	Good (≥ 2)
Proper hygiene (2)	2.0	Good (≥ 1)
Proper diet (3)	3.0	Good (≥ 2)

Discussion

This study shows that mothers have adequate knowledge in breastfeeding, hygiene and diet. Our findings are different from a study in Kenya where 72% of respondents had inadequate knowledge of the components of postnatal health care, particularly exclusive breastfeeding and self-care.[7] A study among undergraduate students in China showed a moderate level of knowledge.[8] Another study in Saudi Arabia showed similar results.[9] A previous study among mothers attending primary healthcare units in Ismailia City revealed that in spite of the low socio-economic status of the setting of the study, the participants presented with adequate knowledge on breastfeeding.[10]

Unlike the results of our study, others found that knowledge did not necessarily translate into practice, specifically in exclusive breastfeeding.[10, 11] Hauck reported that in Western Australia, the reasons for quitting breastfeeding were insufficient milk supply, infant-related reasons, pain and discomfort, and emotional reasons.[12] This is almost similar with the result of the present study in which insufficient milk production was given as a reason to quit breastfeeding early. Mbada found a direct correlation between the effectiveness of breastfeeding techniques and a positive attitude, as well as on exclusive breastfeeding.[13]

It is essential to assess the knowledge and awareness of women regarding dietary practices during lactation, infancy and pregnancy because the health of the family as well as the infant rotates around the mother. The majority of the participants in this study had adequate knowledge, good attitude and practices towards proper diet and nutrition. However, about 23.3% of the respondents did not eat fish or seafood products after giving birth. This is similar to the findings of Kuzma where more than half of the lactating mothers admitted that food restrictions were imposed by their culture.[14] Breaking those taboos was believed to cause the child to become sick. Having inadequate knowledge leading to a compromised attitude and practice is the presenting case; sometimes, even with good nutrition knowledge there will still be noncompliance with proper practice.[15, 16] Cultural beliefs and practices affected the nutrient intake of the lactating mother. Other foods were avoided because they were believed to affect the smell and taste of breastmilk. In the present study, the only misconception was about the delayed wound healing due to seafood intake seen in a few participants. Majority of the participants demonstrated no barriers in their good practice in nutrition as proven by high percentage of awareness and positive attitude towards proper nutrition.

The respondents of this study have adequate knowledge in breastfeeding, proper hygiene and diet. They also demonstrate good attitude and practice in the three subparts. Intention to breastfeed before childbirth is closely associated with mothers' actual breastfeeding practice[17] and that positive attitudes are associated with increased duration of breastfeeding and percentage of exclusive breastfeeding.[18] It supports the result of this study that adequate knowledge and positive attitude in breastfeeding, proper hygiene and proper diet lead to good practice in these three areas. In summary, the respondents of this study have adequate knowledge in breastfeeding, proper hygiene and proper diet. They also demonstrated good attitude and practice in the three areas of interest.

Acknowledgements

The researcher would like to thank and acknowledge Mr. and Mrs. Pulido for supporting her financially

and emotionally, and Dr. Jose Ronilo Juangco, for being an effective research adviser.

References

1. World Health Organization. Retrieved from: http://apps.who.int/iris/bitstream/10665/97603/1/9789241506649_eng.pdf. 2013.
2. United Nations Children's Fund. Retrieved from: http://www.unicef.org/sowc09/docs/SOWC09-FullReport-EN.pdf. 2009.
3. Pilliterri A. Maternal and Child Health Nursing: Care of the Child-Bearing and Child-Rearing Family. 5th ed. New York: Lippincott Williams & Wilkins; 2007.
4. Philippine National Demographic and Health Survey. Retrieved from: https://dhsprogram.com/pubs/pdf/FR294/FR294.pdf. 2013.
5. National Statistics Office and ICF Micro. Retrieved from: http://dhsprogram.com/pubs/pdf/SR175/SR175.pdf. 2009.
6. National Statistics Office. Retrieved from: http://psa.gov.ph/content/breastfeeding-immunization-and-child-mortality. 2013.
7. Kamau IW. An assessment of postnatal care education given to mothers pre-discharge in health facilities in Nairobi county. PhD Thesis. University of Nairobi; 2013.
8. Lou Z, Zeng G, Orme J, Pang X and Huang L. Breastfeeding knowledge, attitudes, and intention in a sample of undergraduate students in Mainland, China. Journal of Human Lact 2014; 30(3): 123-5.
9. Alfaleh K. Perception and knowledge of breastfeeding among females in Saudi Arabia. Journal of Taibah University Medical Sciences 2014; 9(2): 139-42.
10. Mahmuod N, Megahed N. Assessment of knowledge and practice of proper breastfeeding among mothers attending El-Shohada Primary healthcare units, Ismailia City. International Journal of Health Sciences 2014; 2(1): 70-8.
11. Agu U, Agu MC. Knowledge and practice of exclusive breastfeeding among mothers in a rural population in south eastern Nigeria. Trop J Med Research 2011; 15(2): 39-44.
12. Hauck Y, Fenwick J, Dhaliwal S, Butt J. A western Australian survey of breastfeeding initiation, prevalence and early cessation patterns. Maternal Child Health Journal 2011; 15: 260-8.
13. Mbada CE, Oyinlola FC, Olatunbosun TO, Awotidebe TO, Arije OO, Johnson OE, Fashote EO. Is baby-friendly breastfeeding mother-friendly. J Women's Health Phys Ther 2013; 37(1): 19-28.
14. Kuzma J. Knowledge, attitude, and practices related to infant feeding among women in Rural Papua New Guinea: A descriptive, mixed method study. International Breastfeeding Journal 2013; 8: 16.
15. Ongosi AN. Nutrient intake and nutrition knowledge of lactating women (0-6 months postpartum) in a low socio-economic area in Nairobi, Kenya. PhD Thesis. University of Pretoria; 2010.
16. Nuss H, Freeland-graves J, Clarke K, Klohe-lehman D, Milani T. Greater nutrition knowledge is associated with lower 1-year postpartum weight retention in low-income women. J Am Diet Assoc 2007; 107: 1801-6.
17. Dungy CI, Losch M, Russell D. Maternal attitudes as predictors of infant feeding decisions. Journal of the Association for Academic Minority Physicians 1994; 5(4): 159–64.
18. Cernadas JM, Noceda G, Barrera L, and Martinez AM. Maternal and perinatal factors influencing the duration of exclusive breastfeeding during the first six months of life. J Hum Lact 2003; 19(2): 136-44.

A correlational study between smartphone size and range of motion of the thumb

Maria Isabelli D. Hipol; Erikadasha Maeliza Mones; Gian Paolo Navor; Aldrin Jake F. Padua; Kathleen Kay O. Vila
College of Allied Rehabilitation Sciences

Abstract

Introduction A thumb working in extreme range of motion during manipulation of a smartphone may contribute to the development of musculoskeletal disorders. This research was conducted to determine the relationship of the range of motion of the thumb with the size, activities done, and manner of manipulation of the smartphone.

Methods The passive range of motion of the carpometacarpal, metacarpophalangeal and interphalangeal joints of the thumbs were measured with a goniometer and correlated with the dimensions of the phone, type of activities done on the phone and type of manipulation using the Spearman rho statistic.

Results There was moderate correlation between extension of the metacarpophalangeal and interphalangeal joints of both thumbs and the width of the phone. Web browsing, texting and calling showed a weak negative correlation with specific movements of some joints. Manipulation of the phone using both thumbs showed a negative weak correlation with flexion of the right interphalangeal joint and left metacarpophalangeal and interphalangeal joints.

Conclusion There was weak correlation between size of the phone, type of activity and type of manipulation and the range of motion of the thumb and its joints.

Key words: 1st CMC joint, thumb, range of motion, smartphones and hypermobility

With the growing population and advances in technology, the use of smartphones has been constantly rising. Cellular phones today are more than just for calling and texting. They have been revolutionized to keep up with the advancing technology. Smartphones are used by many people in the country. There are different sizes of phones with various features to fit the requirements of their users.

The manipulation of a phone varies from person to person. Hoober mentioned that the one-handed use with the thumb manipulating the controls is the most common way a person manipulates a smartphone.[1] According to Ladd the thumb requires a breadth of motion to perform tasks that are uniquely human, from forceful grasp to fine pinch.[2] The thumbs are subjected to large amounts of force, and this allows us to do many things, such as grasp and manipulate objects.[3] The dimensions of smartphones vary over time and as technology is updated. Smartphones have become larger and requires more than the normal range of motion of

Correspondence:
Maria Isabelli D. Hipol, College of Allied Rehabilitation Sciences, University of the East Ramon Magsaysay Memorial Medical Center Inc., Aurora Boulevard, Barangay Doña Imelda, Quezon City 1113; E-mail: midhipol@gmail.com; Telephone: 09273184579

the thumb to manipulate. Thumb postures during texting are affected by the size of mobile phone.[4] A thumb working on extreme range of motion may contribute to the development of musculoskeletal disorders.[5]

Hypermobility and repetitive motion of the joint can lead to several disorders. Hypermobility caused by weakening of ligaments, lesser strength to restrict the joint, thinning of ligaments upon imposing high load in pinch and grasp actions is also a predisposing factor to developing osteoarthritis. Thus, this research was conducted to determine the relationship between the range of motion of the thumb and the size of the smartphone. Generally, this study aimed to determine the relationship between the size of the smartphone, activities done and manner of manipulation with the range of motion of the first carpometacarpal, first metacarpophalangeal and first interphalangeal joints of the thumb.

Methods

This was correlational study done in 2015 among college students from a private university in Quezon City to determine the relationship between the subjects' activities on the smartphone and smartphone's dimensions with the subjects' first carpometacarpal, first metacarpophalangeal and first interphalangeal joints' range of motion as measured by a licensed physical therapist using a goniometer. The study was approved by the Ethics Review Committee.

College students currently enrolled in the third or fourth year in a private university in Quezon City, male or female, 18 to 25 years old who had been using a smartphone for at least 12 months were recruited. Those who felt pain in the thumb prior to or at the time of the study, or were diagnosed with de Quervain's tendinitis/tenosynovitis, carpal tunnel syndrome, osteoarthritis of the thumb and trigger thumb were excluded. Those who agreed to participate and signed an informed consent were further screened by the researchers. The qualified students were asked to fill up a personal demographic sheet that inquired about the subject's age, gender, course, year level, handedness, hand used in manipulating the phone, use of thumb in manipulating the phone and number of hours of use daily. The brand and model of the phone used by the subject was noted and the dimensions were obtained from the official website of the manufacturer.

A licensed physical therapist measured each subject's passive range of motion (ROM) of the carpometacarpal (flexion, extension, abduction, adduction), metacarpophalangeal (flexion, extension), and interphalangeal joints (flexion, extension) of each hand with a gionometer.[6] The values were recorded on a data sheet. According to a previous study, a goniometer has inter-tester and intra-tester reliabilities (r) of .86 and .89, respectively.[7]

The demographic characteristics of the subjects, activities using the smartphones, dimension of the smartphones and subjects' first carpometacarpal, first metacarpophalangeal and first interphalangeal joints range of motion were analyzed through descriptive statistics: mean and standard deviation. The relationship between the subjects' first carpometacarpal (CMC), first metacarpophalangeal (MCP), first interphalangeal (IP) joints range of motion and subjects' activities on the smartphones and the smartphones' dimensions were analyzed using Spearman rho (r) correlation statistics. All statistical levels of significance were set at $p < 0.05$.

Results

Majority of 34 subjects included in the study were women. Nine out of 10 subjects were right-handed and manipulated their phones with the same hand using the right thumb or both thumbs. Around 70% used their phones from 4 to 12 hours daily for texting, calling and surfing the internet. Their characteristics are shown in Table 1. As seen in Table 2, the right thumb and its joints, which is dominant in 90% of subjects, has a wider range of motion in five of the eight movements. The values are beyond the normal set by Norkin.[6] Table 3 shows that there is no correlation between the range of motion of either thumb and the dimensions of the smartphone and the use of a casing except for moderate correlation between extension of the MCP and IP joints of both thumbs and the width of the phone, and MCP flexion of both thumbs and the case.

Table 4 shows the relationship between phone activity and range of motion of the thumb. Web browsing showed a significant weak negative correlation with extension, abduction and adduction of the right CMC joint. Texting and calling also showed a significant weak negative correlation with right CMC abduction. There was no correlation

Table 1. Characteristics of 34 subjects.

Variables	
Age (yr, mean ± SD)	20 ± 1.13
Gender (females)	19 (55.9%)
Handedness (right handed)	31 (91.2%)
Hand manipulator (right hand)	31 (91.2%)
Smartphone height (mm, mean ± SD)	128.6 ± 15.37
Smartphone width (mm, mean ± SD)	64.4 ± 12.38
Smartphone depth (mm, mean ± SD)	9.5 ± 1.63
Casing (with casing)	12 (35.3%)
Time on the Phone (%)	
22 - 24 hr	1 (2.9%)
19 - 21 hr	0
16 - 18 hr	1 (2.9%)
13 - 15 hr	2 (5.9%)
10 - 12 hr	8 (23.5%)
7 - 9 hr	10 (29.4%)
4 - 6 hr	7 (20.6%)
0 - 3 hr	5 (14.7%)
Phone Activity	
Gaming	23 (67.6%)
Texting and calling	32 (94.1%)
Web browsing	30 (88.2%)
Picture taking	21 (61.8%)
Video recording	15 (44.1%)
Phone Manipulation	
One thumb	32 (94.1%)
Both thumb	27 (79.4%)
Index finger	9 (26.5%)
Others	2 (5.9%)

Table 2. Thumb range of motion and the participants.

Range of motion		Right (degrees ROM, mean ± SD)	Left (degrees ROM, mean ± SD)
CMC	Flexion	25.6 ± 8.61	23.1 ± 7.24
	Extension	21.2 ± 10.20	19.9 ± 10.74
	Abduction	71.8 ± 5.73	73.5 ± 14.49
	Adduction	32.3 ± 33.26	27.1 ± 31.91
MCP	Flexion	69.1 ± 17.10	65.4 ± 18.26
	Extension	14.8 ± 16.70	19.4 ± 19.83
IP	Flexion	86.2 ± 11.36	87.8 ± 17.80
	Extension	15.0 ± 16.04	12.2 ± 16.10

between the other joints of the right thumb and joints of the left thumb with the different phone activities. Table 5 shows the correlation between the type of phone manipulation with range of motion of the thumbs and forefinger. Manipulation of the phone using both thumbs showed a negative weak correlation with flexion of the right IP joint. Manipulation of the phone using both thumbs showed a negative weak correlation with flexion of the left MCP and IP joints. Manipulation of the phone using the index finger showed a negative weak

Table 3. Correlation of smartphone dimensions, casing and thumb rom.

Thumb range of motion			Height		Width		Depth		Case	
			r	p	r	p	r	p	r	p
Right	CMC	Flexion	.02	0.92	.18	0.32	.16	0.36	-.04	0.84
		Extension	-.00	0.99	-.32	0.06	-.26	0.14	-.16	0.38
		Abduction	-.28	0.12	-.20	0.25	-.08	0.66	.17	0.33
		Adduction	.10	0.56	.08	0.63	.08	0.65	.35	0.05
	MCP	Flexion	.16	0.36	.03	0.86	.20	0.25	.38	0.03
		Extension	.11	0.52	.46	0.01	-.03	0.88	.06	0.73
	IP	Flexion	.16	0.37	-.06	0.74	.09	0.60	.15	0.39
		Extension	-.12	0.50	.45	0.01	.06	0.73	.03	0.89
Left	CMC	Flexion	.05	0.78	.29	0.09	.01	0.96	.30	0.08
		Extension	.20	0.26	-.15	0.38	-.27	0.12	-.30	0.09
		Abduction	.09	0.61	.05	0.80	.11	0.53	-.21	0.24
		Adduction	.09	0.62	.08	0.66	.15	0.40	.13	0.47
	MCP	Flexion	.10	0.57	.18	0.32	.09	0.61	.45	0.01
		Extension	.05	0.79	.45	0.01	-.00	0.99	.06	0.75
	IP	Flexion	.20	0.24	.07	0.68	.11	0.54	.18	0.30
		Extension	.13	0.46	.47	0.01	.76	0.67	-.04	0.84

Table 4. Correlation of phone activity and thumb range of motion.

Thumb range of motion			Gaming		Texting calling		Web browsing		Picture taking		Video recording	
			r	p	r	p	r	p	r	p	r	p
Right	CMC	Flexion	-.003	0.99	-.02	0.91	.18	0.30	.09	0.62	.03	0.88
		Extension	-.09	0.58	-.08	0.66	-.42	0.02	.13	0.45	.24	0.17
		Abduction	-.18	0.29	-.41	0.02	-.37	0.03	-.01	0.97	.07	0.71
		Adduction	-.14	0.44	-.20	0.26	-.35	0.04	-.05	0.77	.12	0.49
	MCP	Flexion	-.01	0.96	-.10	0.57	.03	0.86	.11	0.52	.08	0.67
		Extension	.19	0.29	.26	0.14	-.16	0.36	.36	0.33	.17	0.34
	IP	Flexion	-.22	0.21	-.17	0.33	-.07	0.70	-.13	0.46	-.06	0.72
		Extension	.10	0.56	.03	0.86	.05	0.79	-.21	0.24	-.12	0.49
Left	CMC	Flexion	.00	1.00	.15	0.40	-.10	0.56	-.08	0.65	-.15	0.39
		Extension	.15	0.39	-.31	0.08	-.24	0.17	-.17	0.34	-.01	0.95
		Abduction	.23	0.19	-.02	0.91	.08	0.67	.03	0.85	.14	0.42
		Adduction	-.16	0.35	-.13	0.47	-.32	0.06	-.221	0.21	.01	0.96
	MCP	Flexion	-.14	0.42	.01	0.94	-.02	0.90	.04	0.82	.08	0.65
		Extension	-.03	0.86	.05	0.80	-.04	0.81	.28	0.11	.15	0.41
	IP	Flexion	-.19	0.27	-.19	0.27	-.02	0.91	-.25	0.16	-.26	0.10
		Extension	.03	0.85	.07	0.68	-.05	0.76	-.01	0.94	-.03	0.86

Table 5. Correlation of type of phone manipulation and thumb range of motion.

Thumb range of motion			One thumb		Both thumbs		Index finger		Others	
			r	p	r	p	r	p	r	p
Right	CMC	Flexion	-.26	0.14	.03	0.85	.06	0.74	.08	0.62
		Extension	.19	0.27	.09	0.63	.14	0.44	-.01	0.95
		Abduction	-.14	0.43	-.04	0.82	-.20	0.26	.04	0.82
		Adduction	.27	0.12	-.16	0.35	-.02	0.89	.20	0.26
	MCP	Flexion	-.12	0.52	-.25	0.15	-.31	0.08	.36	0.04
		Extension	-.07	0.68	.28	0.11	.09	0.61	.23	0.19
	IP	Flexion	.06	0.75	-.42	0.01	-.22	0.21	-.20	0.26
		Extension	-.04	0.80	.05	0.79	.10	0.56	-.07	0.68
Left	CMC	Flexion	-.12	0.51	-.03	0.85	-.11	0.52	.24	0.17
		Extension	-.01	0.97	-.06	0.75	.12	0.49	-.16	0.38
		Abduction	.01	0.97	.22	0.20	.15	0.42	-.13	0.48
		Adduction	-.09	0.61	-.26	0.14	-.22	0.22	.07	0.70
	MCP	Flexion	-.03	0.86	-.36	0.03	-.31	0.08	.42	0.01
		Extension	-.11	0.53	.03	0.88	-.01	0.98	.21	0.22
	IP	Flexion	-.01	0.94	-.37	0.03	-.34	0.04	-.04	0.84
		Extension	-.07	0.68	.03	0.86	-.103	0.56	-.21	0.24

correlation with flexion of the left IP joint. Manipulation using one or both thumbs or the index finger did not correlate with other movements of either right or left thumbs.

Discussion

Our results showed that the right thumb and its joints, which was dominant side in 90% of subjects, had a wider range of motion in five of eight movements.

There was no strong correlation with either size of the phone, type of activity or type of manipulation and the range of motion of the thumb and its joints.

Previous studies have suggested that handheld devices that promote the use of single thumb while performing tasks on the device[7] and that a thumb that works on extreme ROM has a higher chance of developing musculoskeletal disorders.[5] Previous studies of hypermobility have focused on general joints and used scales to diagnose hypermobility on their subjects.

Other studies also failed to include different device sizes and failed to measure specific thumb motions. In this study, the researchers used a standard goniometer to measure the passive range of motion of the subject's thumb joints and check for hypermobility. Furthermore, movement of thumb towards flexion, extension, abduction and adduction occur simultaneously when manipulating the smartphone and it is the reason why it is difficult to measure the kinematics of the thumb.[8] Inward movements require a large degree of flexion of the IP and MCP joints, pushing the thumb to its limit of range of motion and resulting in an increase in passive joint forces.[9, 10]

Our findings on the type of activities and ROM are different from those of Gustafsson.[4] According to her study, upon entering SMS message, thumbs are placed in abduction. When the young adults enter a SMS messages using their own phone versus a standard phone that was used on her study, their thumbs were less abducted. Hypermobility has been noted in people with bigger and wider phones. This may be due to the increased rotational motion of the joint due to a longer distance from the pivot to the application of the force. Working at extreme range of motion may cause recurrent minor injuries that stretch the normal capsuloligamentous restraints, eventually resulting in hyperlaxity of the joints.

The researchers were aware of the difûculty in measuring thumb movement due to the complexity of its function. Among the factors investigated in the study, the researchers did not include the measurement of the case thickness of the subject's smartphone. Other factors that might have contributed to the increase in the thumb's range of motion that were not included and assessed were: the compensatory motions that the subjects were doing in order to accomplish their usual smartphone activities, the posture of the subject while using their smartphones as to whether the subjects were sitting or standing. Thumb movement and postures among the males and females were not compared. The range of motion of the thumb was not measured during mobile phone use. The study was only focused on thirty four subjects. Lastly, the range of motion of the thumb was not compared between smartphone and non-smartphone users.

In summary, there was weak correlation between size of the phone, type of activity and type of manipulation and the range of motion of the thumb and its joints.

References

1. Hoober S. How do users really hold mobile devices? UXmatters RSS 2013 Feb. Retrieved from: http://www.uxmatters.com/mt/archives/2013/02/how-do-users-really-hold-mobile-devices.php. [Accessed Oct 29, 2014].
2. Ladd AL, Weiss AC, Crisco JJ, Hagert E, Wolf JM, Glickel SZ, Yao J. The thumb carpometacarpal joint: Anatomy, hormones, and biomechanics. Instr Course Lect 2013; 62: 165-79. [Accessed Oct 29, 2014].
3. Wentzel R. Be gentle on your hands – osteoarthritis of the thumb explained. Wenzel Hand Therapy 2014. Retrieved from: http://offnicol.co.za/wp content/uploads/2014/03/Wentzel-Hand-Therapy-article-March-2014.pdf. [Oct 30, 2014].
4. Gustafsson E, Johnson P, Hagberg M. Thumb postures and physical loads during mobile phone use – a comparison of young adults with and without musculoskeletal symptoms. Journal of Electromyography and Kinesiology 2009; 20(1): 127-35.
5. Deepak S, Ajeeesh PS. Risk factors and clinical features of text message injuries. Work 2102; 41: 1145-8.
6. Norkin CC. Measurement of Joint Motion a Guide to Goniometry. 4th ed. Philadelphia: FA Davis; 2009.
7. Deepak S, Mathankumar M, Rameshkumar R, Jose J. Musculoskeletal disorders of the upper extremities due to extensive usage of hand held devices. Annals of Occupational and Environmental Medicine 2014; 26(1): 22-5.
8. Ong F. Thumb motion and typing forces during text messaging on a mobile phone. 13th International Conference on Biomedical Engineering, IFMBE Proceedings 2009; 23: 2095-98.
9. Trudeau M, Udtamadilok T, Karlson AK, Dennerlein JT. Thumb motor performance varies by movement orientation, direction, and device size during single-handed mobile phone use.Thumb Movement 2012. Retrieved from: http://research.microsoft.com/pubs/163594/. [Accessed Oct 30, 3014].
10. Keir P, Wells R, Ranney D. Passive properties of the forearm musculature with reference to hand and finger postures. Clinical Biomechanics 1996; 11: 401-9.

Effects of backpack loads and position on the posture of elementary students

Marielle Ann R. Apostol; Kevin John G. Carmona; Lorenzo C. Chacon Jr.; Jan Remigio A. Francisco;
Micah Ann Rae S. Garcia
College of Allied Rehabilitation Sciences

Abstract

Introduction Backpack loads and their position affect the posture of elementary students. This study aimed to determine the relationship between backpack loads and position with posture of grade school students.

Methods This was a quasi-experimental study on elementary school students from a private school in Pasig City to determine the effect of backpack load and position on their posture. Licensed physical therapists determined the back, arms and legs posture of the students without and with their backpacks, and with their backpacks adjusted to the S2 level, using the Ovako Working posture Analysis System.

Results Without their backpacks, 73% of subjects stood on two legs, with good posture and arms below the shoulders. When the subjects were asked to wear their backpacks, the percentage with straight back decreased to 36% and the number with bent and/or twisted backs increased. Adjusting the position of the backpacks to the S2 level resulted in an increase in the proportion of students with straight backs to 78%.

Conclusion The postural deviations that occur in elementary school children when they carry their backpacks may be corrected by positioning the lower end of their backpacks to correspond to the S2 level. Positioning the backpack this way will minimize the stress and strain on the children's back and result in im-proved posture.

Key words: OWAS, elementary students, backpack loads, posture

In recent years, there has been a wide interest in the use of backpacks among children and teenagers. A backpack is a bag that is carried on the back with straps (usually two) that goes over the shoulder or across. They are also widely known as rucksacks, knapsacks, packs and packsacks. Backpacks come in all sizes, colors, fabrics, and shapes and help children express their own personal sense of style. Modern backpacks are designed to carry heavy loads, and children take full advantage. They fill their packs with textbooks, notebooks, video games, lunch, snacks, water bottles, and just about anything else handy.[1] Many students prefer using a backpack due to its portability, convenience, and sometimes, for fashion. There is a growing concern that overloaded children's and adolescents' backpacks may lead to low back pain and other musculoskeletal disorders.[2] Normal posture is difficult to define as everyone has a unique anthropometric and biomechanical profile.[3] However, placing an excessive load on the back, as occurs when carrying a backpack, commonly causes postural

Correspondence:
Marielle Ann R. Apostol, College of Allied Rehabilitation Sciences, University of the East Ramon Magsaysay Memorial Medical Center Inc., Aurora Boulevard, Barangay Doña Imelda, Quezon City 1113; E-mail: marielleapostol@yahoo.com; Telephone: 9176540322

deviations,[4] musculoskeletal pain[5] and may contribute to deformities such as scoliosis, kyphosis and lordosis.[6-7] A history of these symptoms in childhood is the strongest predictor of musculoskeletal discomfort and back pain as an adult.[8]

There is little published research that indicates what weights of the backpack load may compromise posture and gait in children. Issues still arise regarding the best backpack placement since most studies used different methods of measurements.[9] High school students have been extensively studied but less attention has been paid to grade school students. Education and habits acquired during grade school and childhood are still practiced by children as they grow older. The posture of high school students and adults is greatly influenced by what they perceived as proper posture during their childhood years.

The questions still remains on how can backpack load affect the posture of grade school students? Hence, additional studies on backpack loads are needed regarding its effects on the posture of grade school students. The study aimed to determine the relationship between backpack loads and position with posture of grade school students. In this paper, we introduced a novel method of ruling out the possible effects of backpack loads on the posture of students.

Methods

This was a quasi-experimental type on elementary school students from a private school in Pasig City to determine the effect of backpack load and position on their posture. Licensed physical therapists determined the back, arms and legs posture of the students without and with their backpacks, and with their backpacks adjusted to the S2 level, using the Ovako Working posture Analysis System. The study was approved by the Ethics Review Committee.

The researchers recruited by purposive sampling male or female grade 3 to grade 5 students from a private elementary school in Pasig City who regularly used backpacks. Students with recent fractures, congenital and acquired postural abnormalities, or unwilling to cooperate were excluded. The parents or guardians of the children were asked to sign an informed consent. The researchers obtained the demographic characteristics of those who fulfilled the inclusion and exclusion criteria and agreed to join the study: age, gender, grade level, mode of transportation to school, weight, height, vertical back length and weight of backpack. The students were asked to bring their usual backpacks and not change school bags.

On a day designated by the researchers and known only to them and to the school authorities, a licensed physical therapist came and assessed the following: the level of the spine where the lowest part of the backpack was placed and using a tape measure, vertical back length from C7 to L5. Pictures of each participant's posture were taken using a Nikon D3100 camera placed 150 cm in front of the child. The subject was asked to stand in front of the camera with hands at the side and in their relaxed standing state for three scenarios: (1) without their backpack; (2) wearing their own backpack and (3) wearing the backpack with its lowest portion at S2 vertebral level. The researchers took two pictures per scenario: a front shot and a side shot with the subject facing towards his/her right side. The placement of the backpack at the S2 vertebral level was done by the researchers.

The pictures of the subjects in the three scenarios were given to another licensed physical therapist to identify each child's posture of the back (4 categories), arms (3 categories), and legs (7 categories) using the Ovako Working posture Analysis System (OWAS). The effects of the backpack loads and position on the subject's posture were analyzed using the Wilcoxon signed-rank test with a level of significance set at $p < 0.05$.

Results

Of 150 students enrolled, 132 returned the consent forms and 122 were allowed by their parents to participate. Of these, 107 were qualified but only 102 students were present in the day of the implementation of the study. Almost two-thirds of the subjects came from Grade 4 and 90% of them took school service, a tricycle or private car to and from school. The average weight of their backpacks was less than 10% of their body weight. Two-thirds of the subjects had backpacks within 10% of their body weight and one out of four children had loads 11 to 15% of their weight. Around 80% of the children had their backpacks within 10 cm below the S2 level. The characteristics of the subjects are summarized in Table 1.

Table 2 shows that without their backpack, most subjects stood on two legs, with good posture and arms below the shoulders. When the subjects were asked to wear their backpack, the percentage with

Table 1. Profile of subjects from a private elementary school, 2015 (n = 102).

Variable	Mean ± SD/number (%)
Age (yr)	9.7 ± 0.82
Gender (female)	51 (50%)
Grade level	
Grade 3	14 (13%)
Grade 4	63 (62%)
Grade 5	25 (25%)
Mode of transportation	
School service	50 (49%)
Tricycle	25 (24%)
Private car	14 (14%)
Jeepney	1 (1%)
Bus	2 (2%)
Walking	9 (9%)
Bicycle	1 (1%)
Weight (kg)	38.6 ± 11.21
Height (cm)	139.8 ± 9.38
Vertical back length (cm)	38.8 ± 3.11
Backpack load (kg)	3.3 ± 1.77
Body mass index (kg/m^2)	19.5 ± 4.22
Backpack load percentage	9.0 ± 5.37
1 - 5% BW	29 (28%)
6 - 10% BW	40 (39%)
11 - 15% BW	23 (23%)
16 - 20% BW	6 (6%)
21 -25% BW	3 (3%)
> 25% BW	1 (1%)
Backpack position	
S2	6 (6%)
≤ 5 cm below S2	41 (40%)
> 5 to ≤ 10 cm below S2	39 (38%)
> 10 cm below S2	16 (16%)

straight back decreased to one-third and an increase in the number with bent and/or twisted backs was noted. Adjusting the position of the backpacks to the S2 level resulted in an increase in the proportion of students with straight backs by 42%. This was slightly higher than the percentage of students with straight backs without their backpacks.

Discussion

The findings show that adjusting the position of the backpack to the S2 level significantly improved the posture of the subjects. Other studies have shown the effect of backpack loads and position on the posture of the students. Heavy backpack weight has been correlated with musculoskeletal pain and may require treatment, resulting in lost school time.[10] The researchers found that most of the subjects carried their backpacks with loads of 6 to 10% of their body weight, affecting the standing posture of the students. This is similar to the findings of Candotti[11] but different from other studies.[10, 12]

Other investigators have concluded that backpacks should not exceed 10 to 15% of the child's body weight.[13, 14] Carrying a backpack weighing 15% or more caused significant increases in the trunk-forward lean and cranio-vertebral angle (head forward position), and inability to maintain cervical and shoulder postural alignment.[2, 15] These changes in posture present a risk for neck pain[16] and compromise pulmonary function.[7, 17] These findings have led other investigators to recommend load limits to less than 20% of body weight.[18-20]

The present study has shown that backpack position affects the posture of the subjects. This is

Table 2. Posture of subjects from a private elementary school with and without backpack, and the effect of placing backpack at S2, 2015 (n = 102).

Posture	Without backpack	With backpack	Backpack at S2	p-value
1. Back posture				
Straight	74 (73%)	37 (36%)	79 (78%)	0.00
Bent	21 (21%)	36 (35%)	20 (20%)	
Twisted	5 (5%)	12 (12%)	2 (2%)	
Bent and twisted	2 (2%)	17 (17%)	1 (1%)	
2. Arms posture				
Both below shoulder	102 (100%)	102 (100%)	102 (100%)	---
One above shoulder	0	0	0	
Both above shoulder	0	0	0	
3. Legs posture				
Standing on two legs	99 (97%)	98 (96%)	102 (100%)	0.04
Standing on one leg	3 (3%)	4 (4%)	0	

contrary to the findings of Rosker, Markovic and Sarabon who suggested that the elevation of the body center of mass from a lower to a higher position systematically decreases the postural control during quiet standing, and consequently, increases the intensity of the balancing task.[21] Brackley, Stevenson and Selinger showed that significant changes occurred in trunk-forward lean and cranio-vertebral angle when the backpack was 15% of body weight.[2] The low load placement produced fewer changes in the cranio-vertebral angle compared with high and mid placements. When all measures were assessed, there were fewer changes in lordosis angle in the low load placement. A lower backpack position has been shown to decrease erector spinae and upper trapezius muscle activity and reduce postural adjustment to backpack load.[4] Our simulator findings that looser shoulder straps (and therefore a lower backpack position) is preferable are consistent with these studies.

According to Singh and Koh, positioning the load low on the back affected the spatiotemporal parameters more than when loads were placed high in the back. The findings on spatiotemporal parameters indicate that a reduction in gait velocity and cadence and an increase in double support time for the 20% lower configuration could be a compensatory mechanism for children to minimize either the induced gait instability or mechanical strain on the musculoskeletal system. Their results also showed a higher forward trunk lean for dynamic conditions compared to static conditions indicating differences in strategies employed to maintain balance for static and dynamic conditions.[18]

The results of the present study may be supported by the concept of center of mass and equilibrium. The center of mass, or balance point of the body, is considered to be the best estimate of the body's location.[22] As gravity acts on all parts of the body, one's entire weight can be considered as concentrated at a point where the gravitational pull on one side of the body is equal to the pull on the other side. This point is the body's center of gravity, and it constitutes the exact center of body mass. When the center of gravity is above the base of support and the pull of gravity is successfully resisted by the supporting members, an equilibrium of forces or a state of balance is reached and no motion occurs. While the position of center of mass can be estimated through various methods, its relative position varies with changes in the body segments such as occurs with limb movements.[24,25] However, the center of mass is commonly accepted to be around S2 vertebra level in the normal upright posture.

Carrying a heavy school bag for long periods of time could result in repetitive stress injuries to the growing body. This follows the shifting of the child's center of gravity in the direction of the load when carrying a backpack. To compensate, the child will lean in a direction opposite to the force. Another common strategy is to support on the shoulder straps by hand during lumbar hyperextension. Such postural deviations can hamper the natural shock absorption abilities of the spine and require greater muscle activity to prevent the individual from falling as a result of the increased forces and moments about the spine. These heavy school bags result in several postural changes at the head and trunk placing soft tissues at a biomechanical disadvantage resulting in fatigue and injury.[26] The shape and design of the spine affords efficient distribution and balancing of body mass. There is minimal spinal muscle involvement required for maintaining static equilibrium in erect stance. Changes in spinal shape, however, are likely to disrupt this balance. An increase in sagittal curvature may alter physiologic loading through the spine as a consequence of a shift in trunk mass, leading to increased flexion moments and compression and shear forces imposed on spine segments. In addition to increased mechanical loading, changes in spinal posture may compromise back extensor strength (force-generating capacity) and the normal function of paraspinal musculature. Increased curvature in the thoracic spine is associated with higher spinal loads attributable to gravity and muscle force, and a strong linear relationship exists between the magnitude of load and thoracic kyphosis.[27]

In summary, the postural deviations that occur in elementary school children when they carry their backpacks may be corrected by positioning the lower end of their backpacks to correspond to the S2 level. Positioning the backpack this way will minimize the stress and strain on the children's back and result in improved posture.

Acknowledgements

The authors would like to express their sincere gratitude to their adviser, Prof. Gerald Lester Caoili, for his continuous support, guidance, patience, motivation, enthusiasm and immense knowledge;

their thesis panel Dr. Carmina Ann Jerez-Cortez, Prof. Illuminada Santos and Prof. Grace Margaret Ona, for their insightful comments and encouragement; and Mrs. Zaide Calaylay and Mrs. Angelita Punzalan, for allowing the study in their school.

References

1. Woolston C. Backpacks and Kids. HealthDay 2013. Retrieved from http://consumer.healthday.com/encyclopedia/children-s-health-10/kids-ailments-health-news- 434/backpacks-and-kids-645623.html.
2. Brackley HM, Stevenson JM, Selinger JC. Effect of backpack load placement on posture and spinal curvature in prepubescent children. Work: A Journal of Prevention, Assessment and Rehabilitation 2009; 32(3); 351-60. doi: 10.3233/WOR-2009-0833.
3. Trew M, Everett T (editors). Human Movement: An Introductory Text (4th ed). Edinburgh: Churchill Livingstone; 2001.
4. Grimmer K, Dansie B, Milanese S, Pirunsan U, Trott P. Adolescent standing postural response to backpack loads: A randomized controlled experimental study. BioMed Central Musculoskeletal Disorders 2002; 3(10). doi:10.1186/1471-2474-3-10.
5. Iyer SR. An ergonomic study of chronic musculoskeletal pain in schoolchildren. Indian Journal of Pediatrics 2001; 68(10): 937-41.
6. Korovessis P, Koureas G, Zacharatos S, Papazisis Z. Backpacks, back pain, sagittal spinal curves and trunk alignment in adolescents: A logistic and multinomial logistic analysis. Spine 2005; 30(2): 247-55.
7. Lai JP, Jones AY. The effect of shoulder-girdle loading by a schoolbag on lung volumes in Chinese primary school children. Early Human Development 2001; 67: 79-86.
8. Kistner FE. Backpacks as a risk factor for musculoskeletal disorders 2012. Retrieved from: http://www.itracefoundation.org/wp-content/uploads/2012/10/backpack.pdf.
9. Abdullah AM, McDonald R, Jaberzadeh S. The Effects of backpack load and placement on postural deviation in healthy students: A systemic review. International Journal of Engineering Research and Applications 2012; 2(6): 466-81. Retrieved from: www.ijera.com>papers>Vol2_issue6.
10. Matlabi H, Behtash HH, Rasouli A, Osmani N. Carrying heavy backpacks and handbags amongst elementary students: Causes and solutions. Science Journal of Public Health 2014; 2(4): 305-8. doi: 10.11648/j.sjph.20140204.20.
11. Candotti CT, Noll M, Roth E. Assessment of weight and mode of transport of school material in high school students. Revista Paulista de Pediatria 2012; 30(1): 100-6. doi: 10.1590/S0103-05822012000100015.
12. Barkhordari A, Ehrampoush MH, Barkhordari M, Derakhshi F, Barkhordari M, Mirzaii M. Assessment of school backpack weight and other characteristics in elementary schools, Yazd, Iran. Journal of Community Health Research 2013; 2(1): 2-7.
13. Lavigne V. Weight limit recommendation in backpack use for school-aged children. Journal of Clinical Chiropractic Pediatrics 2014; 14(2): 1156-9.
14. Kistner F, Feibert I, Roach K, Moore J. Postural compensation and subjective complaints due to backpack loads and wear time in school children. Pediatrics Physical Therapy 2013; 25(11): 15-24. doi: 10.1097/PEP.0b013e31827ab2f7.
15. Chansirinukor W, Wilson D, Grimmer K, Dansie B. Effects of backpacks and students: Measurement of cervical and shoulder posture. Australian Journal of Physiotherapy 2001; 47(2): 110-6. doi: 10.1016/S0004-9514(14)60302-0.
16. Hundekari J, Chilwant K, Vedpathak S, Wadde S. Does alteration in backpack load affects posture of school children? Journal of Dental and Medical Sciences 2013; 7(4): 71-5.
17. Balamurugan J. School bags and musculoskeletal pain among elementary school children in Chennai City. International Journal of Medical Science and Clinical Invention 2014; 1(6): 302-9.
18. Singh T, Koh M. Effects of backpack load position on spatiotemporal parameters and trunk forward lean. Gait and Posture 2009; 29(1): 49-53. doi: http://dx.doi.org/10.1016/j.gaitpost.2008.06.006.
19. Talbott NR. The effect of the weight, location and type of backpack on posture and postural stability of children. PhD Dissertation, University of Cincinnati; 2005.
20. Chow DHK, Kwok MLY, Cheng JCY, Lao MLM., Holmes AD, Yao Au-Yang A, Yao FYD, Wong MS. The effect of backpack weight on the standing posture and balance of schoolgirls with adolescent idiopathic scoliosis and normal controls. Gait and Posture 2005; 24(2): 173-81. doi: http://dx.doi.org/10.1016/j.gaitpost.2005.08.007.
21. Rosker J, Markovic G, Sarabon N. Effects of vertical center of mass redistribution on body sway parameters during quiet standing. Gait and Posture 2010; 33(3): 452-6. doi: http://dx.doi.org/10.1016/j.gaitpost.2010.12.023.
22. Engsberg JR, Lenke LG, Hollander KW, Uhrich ML, Commean PK, Lee JR, Bae KT. Methods to locate center of gravity in scoliosis. Spine 2003; 28(23): 483-9.
23. Schafer RC. Clinical Biomechanics: Musculoskeletal Actions and Reactions. Baltimore: Williams & Wilkins; 1983.
24. Lafond D, Duarte M, Prince F. Comparison of three methods to estimate the center of mass during balance assessment. J Biomech 2004; 37(9): 1421-6. *doi*: 10.1016/S0021-9290(03)00251-3.
25. McKinon W, Hartford C, Di Zio L, Van Schalkwyk J, Veliotes D, Hofmeyr A, Rogers G. The agreement between reaction-borad measurements and kinematic estimation of adult male human whole body centre of mass location during running. Physiol Meas 2004; 25(6): 1339-54. *doi*: 10.1088/0967-3334/25/6/001.
26. Mwaka ES, Munabi IG, Buwembo W, Kukkiriza J, Ochieng J. Musculoskeletal pain and school bag use: a cross-sectional study among Ugandan pupils. BMC Research Notes 2012; 7: 222. doi: 10.1186/1756-0500-7-222.
27. Briggs AM, van Dieen JH, Wrigley TV, Greig AM, Phillips B, Lo SK, Bennell KL. Thoracic kyphosis affects spinal loads and trunk muscle force. Journal of Physical Therapy 2007; 87(5): 595-607. doi: 10.2522/ptj.20060119.

Curcuma longa (turmeric) as an adjunct to antihypertensive drugs among stage 1 and 2 hypertensive individuals: A randomized double-blind placebo-controlled study

Frances Elinzano; Jhean Dorado; Charlene Duante; Joana Dominguez; Rafilbin Daguplo; Issa D'Bayan; Kia de Asis; Denise de Guzman; Hashima Diamla and Jose Ronilo G. Juangco, MD (Adviser)

Abstract

Introduction Turmeric has been shown to have the potential to alleviate the disease burden of hypertension through its atherosclero-protective effect. This study was done to determine the efficacy and safety of turmeric as an adjunct to antihypertensive medications in the management of stage 1 and 2 hypertension

Methods Using a randomized double-blind placebo-controlled clinical trial, subjects were assigned to receive turmeric capsules or placebo for four weeks. Intra- and intergroup analysis of a significant decrease in the blood pressure was determined after treatment. A repeated measure ANOVA was used to determine significant difference in the BP readings. Side effects of taking turmeric capsule were determined.

Results Systolic blood pressure in the turmeric group started to decline after the first week of treatment, but the decrement became statistically significant starting only in the third through the fourth week. There was a statistically significant decrease in the mean systolic blood pressure for those taking turmeric. Treatment success was sig-nificantly higher among the turmeric group.

Conclusion Turmeric may be an effective adjunct to antihypertensive drugs in controlling and maintaining systolic blood pressure.

Key words: Turmeric, hypertension, athero-scleroprotective

Hypertension is often asymptomatic early in its course, posing no health problems, leaving an individual unaware of its cardiovascular effects until symptoms start to manifest. It is responsible for increased mortality and morbidity among the non-communicable diseases - cardiovascular diseases, stroke, and kidney failure - as a result of its long-term complications. It is a lifetime burden to anyone diagnosed with it because it cannot be cured; however, blood pressure can be lowered and maintained within normal range.

Maintenance medications are crucial in the management of hypertension. However, at times, intake of such drugs is not enough to control blood pressure. Hence, plants or plant products have been explored as probable supplements to antihypertensive drugs to achieve a better control of blood pressure. *Curcuma longa*, commonly known as turmeric, is an

Correspondence:
Frances Riel B. Elinzano, Department of Preventive and Community Medicine, College of Medicine, University of the East Ramon Magsaysay Memorial Medical Center Inc., Aurora Boulevard, Barangay Doña Imelda, Quezon City 1113; E-mail: riel.elinzano@gmail.com; Telephone: 9053562387

Indian spice that contains curcuminoids in the form of demethoxycurcumin, bisdemethoxycurcumin, and curcumin.[1] Curcumin is the most active among the three and is implicated in most of the medicinal properties of turmeric.[1]

This study was done to determine the efficacy and safety of turmeric as an adjunct to antihypertensive medications in the management of stage 1 and 2 hypertension.

Methods

This was a randomized, double-blind, placebo-controlled trial comparing the efficacy of turmeric as an adjunct to antihypertensive medications among adult stage 1 and 2 hypertensive patients from San Juan in May to June 2015. Subjects were randomized to receive either turmeric or placebo capsules for four weeks. The mean change in the systolic and diastolic blood pressure within and between the turmeric and placebo groups at the end of four weeks was compared with the baseline measurements. The study was approved by the Ethics Review Committee.

Subjects were randomized following a computer-generated randomization schedule. Blinding was performed by an uninterested individual who was not part of the research team. This individual was responsible for the packaging of the capsules into their respective containers before the capsules were distributed to the subjects by the researchers. The placebo capsules were identical to the turmeric capsules and were manufactured by Interchemex Laboratories, Inc. The turmeric capsules were in a 400-mg dose preparation and were obtained from Rockglen Nutri-Pharma, Inc.

The subjects were recruited from Barangay San Perfecto, San Juan City via a purposive sampling. Eligible participants were male or female, 50 to 70 years old with stage 1 or 2 hypertension who were taking antihypertensive drugs for at least 60 days prior to the start of the study. Patients with co-morbid diseases (active malignancy, end-stage renal disease, congestive heart failure) were excluded based on the personal interview done by the researchers. Also excluded were those who had recently undergone surgery, pregnant or breastfeeding women, those who were taking herbal supplements with turmeric for the past 14 days prior to start of the study, and those who refused to participate and had failed to sign the informed consent after the goals and possible risks involved were clearly stated and explained.

The minimum sample size computed for this study was six for each treatment group. The sample size was determined by setting the confidence level (Z_α) at 95%, the power of the tests (Z_β) at 80%, and the standard deviation at 3 mm Hg^2, to detect a difference of 5 mm Hg in the study.

Treatment success was defined as a decrease of at least 5 mm Hg in the systolic component of the blood pressure measured at the end of the study period. Treatment failure was a decrease in systolic blood pressure of <5 mm Hg, no decrease, or an increase in the systolic blood pressure after the intervention.

The sociodemographic characteristics of the subjects were obtained by conducting a personal interview and writing down the data in an information data sheet. The baseline blood pressure was taken on the first day of week 0. The subjects were given 21 capsules each, which were to be consumed for a whole week, and instructed to take the capsules thrice a day without stopping their antihypertensive regimen (either beta-blockers, calcium-channel blockers, angiotensin II receptor blockers, or thiazide diuretics). A monitoring sheet was given to each subject at the start of the study and collected at the end of each week and replaced with a new one thereafter. The monitoring sheet was used to determine the compliance of the subjects, as well as the side effects they had experienced.

Blood pressure was measured using an aneroid blood pressure apparatus and a stethoscope. Measurement was taken by the researcher assigned for that particular week. The subject was made to rest for 10 minutes and seated down with feet flat on the ground before the researcher took the blood pressure. The cuff was placed on the subject's left arm, 2-3 inches above the cubital area. The palpatory blood pressure measurement was taken and the auscultatory blood pressure after one minute. The cuff was inflated 30 mmHg above the obtained palpatory blood pressure level. The participants were followed up every last day of the week to monitor their blood pressure and to refill their capsule containers. The distribution of capsules was done per week to ensure good compliance and complete consumption by the participants.

Data obtained were encoded using Microsoft Excel and were analyzed using Stata: Data Analysis and Statistical Software Version 12. One-tailed Fisher's exact test was done on nominal or categorical data, as well as in determining the statistical

significance of the relative risk. Paired or unpaired t-test was performed on the continuous data. A multivariate analysis was done to determine differences among the results obtained based from the various antihypertensive drug groups maintained by the subjects. A repeated measure ANOVA with Dunnett post hoc test was used to evaluate the weekly blood pressure measurements. The level of significance was set at a probability value of 0.05.

Results

A total of 66 individuals were recruited, 34 of which were enrolled after satisfying the inclusion and exclusion criteria. Table 1 shows that the turmeric and placebo groups were comparable with regard to age, gender, body mass index, cigarette smoking, alcohol drinking, family history of cardiovascular disease, employment status, baseline blood pressure, and antihypertensive drug at the start of the study.

Table 2 shows a 10% decrease in the systolic blood pressure of the turmeric group and no change in the placebo group. The weekly blood pressure measurements of the subjects were analyzed using a repeated measure ANOVA, revealing a significant difference in the decrease in the mean systolic blood pressure of the turmeric group. As seen in Figure 1, a divergence in the systolic blood pressure between the turmeric and placebo groups was observed as early as the end of the first week. Dunnett post hoc analysis further showed that the difference was significant starting on week 3 and sustained through week 4. There was no change in the diastolic blood

Table 1. Baseline demographic characteristics of the turmeric and placebo groups (N = 29).

Parameter	Turmeric (n=15) Mean ± SD, Frequency (%)	Placebo (n=14) Mean ± SD, Frequency (%)	p-value
Age (in years)	58.2 ± 6.3	59.2 ± 6.8	0.6792[b]
Sex			
Male	2 (13.3 %)	5 (35.7%)	0.166[c]
Female	13 (86.7%)	9 (64.3%)	
BMI (kg/m^2)	24.7 ± 2.6	23.81 ± 3.2	0.3783[b]
Cigarette Smoking			
Smoker	6 (40.0%)	6 (42.9%)	0.587[c]
Non-smoker	9 (60.0%)	8 (57.1%)	
Alcohol			
Drinker	4 (26.7%)	5 (35.7%)	0.450[c]
Non-drinker	11(73.3%)	9 (64.3%)	
Family Member with CVD	1.3 ± 1.2	1.2 ± 1.3	0.234[d]
Employment Status			
Employed	12 (80.0%)	7 (50.0%)	0.095[c]
Unemployed	3 (20.0%)	7 (50.0%)	
Baseline BP			
Systolic	135.3 ± 17.3	137.9 ± 12.5	0.6578[b]
Diastolic	82.0 ± 12.1	83.6 ± 9.3	0.6990[b]
Antihypertensive Drug			
Beta-Blocker	4 (26.7%)	4 (28.6%)	
CCB[a]	6 (40.0%)	4 (28.6%)	
ARB[a]	3 (20%)	5 (35.7%)	0.596[d]
TZD[a]	0	1 (7.1%)	
Dual Therapy	2 (13.3%)	0	

[a]Ca^{2+}-Channel Blocker, Angiotensin Receptor Blocker, Thiazide Diuretic
[b]Independent t-test
[c]1-sided Fisher's Exact Test
[d]Fisher's Exact Test

pressure. The mean decrease in the systolic blood pressure of the turmeric group was significantly larger than that of the placebo group (14.0 vs 0.71 mm Hg, p = 04, unpaired t-test).

Although the subjects were on different antihypertensive maintenance drugs, Table 3 shows that the type of antihypertensive drug used by the subjects had no significant effect on the mean decrease in systolic and diastolic blood pressure measurements for both the groups. Table 4 shows that using turmeric as an adjunct to antihypertensive medications resulted in a three-fold increase in the probability of treatment success. This increase is not significant.

Table 2. Mean blood pressure levels of turmeric and placebo groups before and after intervention.

	Baseline (Mean ± SD)		Post-intervention (Mean ± SD)		Mean Decrease (Mean ± SD)			
	SBP	DBP	SBP	DBP	SBP	p-value[b]	DBP[a]	p-value[b]
Turmeric	135.3 ± 17.3	82.0 ± 12. 1	121.3 ± 10.6	84.0 ±5.1	14.0 ± 17.2	0.0072	-2.0 ± 10.8	0.4860
Placebo	137.9 ± 12.5	83.6 ± 9.3	137.1 ± 9.9	84.3 ± 7.6	0.71 ± 14.9	0.7202	-0.7143 ± 12.0	0.8282

[a]negative values indicate mean increase
[b]Paired t-test

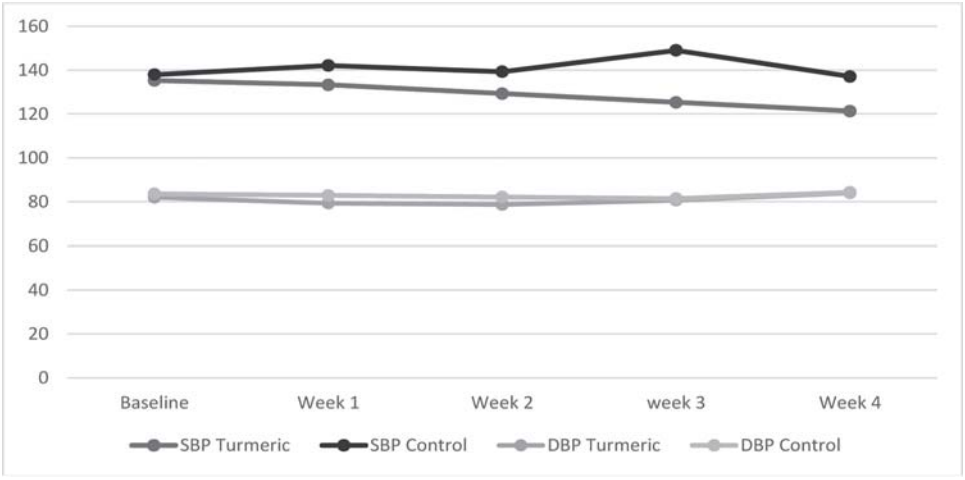

Figure 1. Comparison of weekly blood pressure measurements of the turmeric and placebo groups.

Table 3. Effect of antihypertensive drugs used in the turmeric and placebo groups.

	Baseline (Mean ± SD)		Post-intervention (Mean ± SD)		Mean Decrease (Mean ± SD)			
	SBP	DBP	SBP	DBP	SBP	p-value[b]	DBP[a]	p-value[b]
Turmeric	135.3 ± 17.3	82.0 ± 12. 1	121.3 ± 10.6	84.0 ±5.1	14.0 ± 17.2	0.0072	-2.0 ± 10.8	0.4860
Placebo	137.9 ± 12.5	83.6 ± 9.3	137.1 ± 9.9	84.3 ± 7.6	0.71 ± 14.9	0.7202	-0.7143 ± 12.0	0.8282

[a]negative values indicate mean increase
[b]Paired t-test

As shown in Table 5, only two side effects, epigastric pain and diarrhea, were noted throughout the course of the study after intake of turmeric. On further evaluation, the hazard ratio suggests that subjects given turmeric supplements were approximately three times more likely to develop these adverse effects than the subjects in the control group. The hazard ratio for each side effect was not statistically significant. On the other hand, the number needed to harm would indicate that for every approximately 17 subjects given turmeric, one will experience either of the side effects noted.

Discussion

Hypertension is linked with an increased risk of cardiovascular diseases and is associated with a strong lifestyle component. In 2007, 1% of Filipino children, 28% of adult Filipinos, and 54.3% of elderly Filipinos, equivalent to 14 million of our whole population, were known to be hypertensive.[3] From 2008 to 2013, there had been a slight decrease in the prevalence of hypertension from 25.3 to 22.3.[4] Despite this, the incidence of hypertension increased with advancing age and wealth.[4]

There is no cure for hypertension, however; controlling blood pressure is the key to prevent debilitating consequences. With this, maintenance antihypertensive drugs are an essential part in the management of this disease. The 2014 Guidelines for Management of High Blood Pressure formulated by the Eighth Joint National Committee (JNC 8) recommends antihypertensive drugs from four drug groups: angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), Ca^{2+}-channel blockers (CCB), and thiazide diuretics.[5] Consequently, initiation of pharmacologic intervention is highly recommended among patients 60 years or older with a systolic blood pressure of ≥150 mm Hg and a diastolic blood pressure of ≥90mm Hg to achieve a goal of < 150/90 mm Hg.[5] Alternatively, in patients below 60 years with a diastolic blood pressure of ≥90 mm Hg, pharmacologic treatment is advised only to attain a diastolic level of < 90 mm Hg since there is insufficient evidence to control the systolic blood pressure in this age group.[5] However, experts nevertheless recommend to maintain a target systolic blood pressure of less than 140 mm Hg among individuals younger than 60 years with a systolic blood pressure of 140mm Hg or higher.[5]

The Philippine Society of Hypertension (PSH), likewise, recommends monotherapy, with choices ranging from any of the five antihypertensive drug groups (diuretics, ACE inhibitors, ARBs, beta-blockers, and calcium channel blockers), as an initial approach to management of hypertension except when co-morbidities and/or target organ damage are already evident.[6] The appropriate management of uncomplicated hypertension and hypertension with co-morbid diseases are tabulated accordingly in the Philippine Clinical Practice Guidelines on the Detection and Management of Hypertension 2011.[6]

Table 4. Effectiveness of turmeric versus placebo as adjunct to antihypertensive drugs.

	Treatment success	Treatment failure	Relative Risk (95% CI)
Turmeric (n = 15)	9	6	2.8 (0.95, 8.29), p = 0.04[a]
Placebo (n = 14)	3	11	

[a]Fischer's exact test

Table 5. Comparison of hazard ratio and number needed to harm (NNH).

	Turmeric (n = 14)	Placebo (n = 14)	Hazard Ratio (95% CI)	NNH	P value[a]
Epigastric pain	1	0	2.8 (0.12 - 63.83)	16	1.00
Diarrhea	1	0	2.8 (0.12 - 63.83)	16	1.00

[a]Fisher's exact test

The PSH further reiterates the importance of patient compliance, which includes maintaining the antihypertensive regimen after achieving a normalized blood pressure, as well as adhering to follow-up schedules for monitoring blood pressure level.[6]

As a non-pharmacological approach, lifestyle modification is strongly advised and promoted by both guidelines.[5, 6] This includes: (1) reducing consumption of dietary salt, (2) limiting alcohol intake, (3) following the Dietary Approaches to Stop Hypertension (DASH) diet consisting of vegetable, fruits, and low-fat food, (4) losing weight and maintaining the target weight, and (5) committing to regular physical exercise with at least 30 minutes of moderate intensity dynamic aerobic exercise 5-7 days per week.[7] The European Society of Cardiology and European Society of Hypertension further recommends cessation of smoking and reduction of caffeine intake.[8] Despite the abundance of medicinal plants in the Philippines, the PSH reported that, to date, no indigenous herbal preparations have been identified to lower blood pressure.[6]

Turmeric is one of the most studied herbs worldwide and is used medicinally for over thousands of years. Its effective dose is still unknown; however, it is usually given at a dose of 400-600 mg thrice daily for therapeutic purposes.[9] This is equivalent to 60 g of fresh turmeric root or 15 g of turmeric powder.[9] The recommended dosage and dosing frequency is based on its short half-life and low bioavailability following oral administration.[9] Despite these limitations, intake of turmeric has been reported to be well-tolerated.[10-13]

As a traditional drug, it is used as a remedy for various illnesses including malignancy, obesity, type 2 diabetes, hyperlipidemia, and chronic kidney disease among others, which are steadily increasing globally. It is proposed that curcumin, its active compound, exhibits antihypertensive effect due to its atherosclero-protective properties, which includes: cholesterol and triglyceride lowering capacity, reduction of lipid peroxidation of low density lipoproteins (LDL), and inhibition of platelet aggregation.[1] Atherosclerosis has been implicated in the pathogenesis of hypertension due to its effect on arterial vasculature, which consequently affects hemodynamic. Another property of curcumin that may contribute to lowering of blood pressure is its ability to improve endothelium function by increasing the reactivity of blood vessels to certain compounds like adenosine, acetylcholine, or isoproterenol for a more effective vasorelaxant effect.[4] It can also indirectly influence vasorelaxation through reduction in the contractile effects of 5-hydroxytryptamine.[14] Furthermore, it has been hypothesized that curcumin can induce the expression of endothelial nitrogen oxide synthase gene.[15]

The mean decrease in systolic blood pressure (Table 2) was about half of that observed by Hlavackova.[16] The results in Table 3 are consistent with the findings of Khajehdehi and Akazawa, who both reported a decrease in the systolic blood pressure on patients with lupus nephritis and postmenopausal women, respectively, following treatment with turmeric.[17, 18] The mechanism behind this is probably the anti-oxidative and anti-inflammatory properties of turmeric, which eventually leads to an atherosclero-protective effect.

Free radicals, resulting from cellular oxidative damage, are implicated in the pathogenesis of atherosclerosis and other cardiovascular diseases through the occurrence of lipid peroxidation.[19, 20] The resulting oxidized LDL facilitates the formation of macrophage foam cells by promoting cholesterol accumulation.[21] This event sets the stage for a pro-inflammatory response, which can be countered by the anti-inflammatory property of turmeric. Specifically, a decrease in the serum levels of IL-6, TNF-a, and MCP-1 was reported in apoE knockout mice after curcumin treatment.[21] As observed in rat models, the anti-oxidative property of curcumin correlated well with the normalization of blood pressure and vascular responsiveness following a dose-dependent manner. Curcumin was also noted to play a role in vascular remodeling.[15]

The role of curcumin in cholesterol regulation has been well-established. It has been shown that it can decrease cholesterol accumulation brought about by oxidized LDLs, as well as, increase the cholesterol efflux in a process mediated by apoAI.[21] Similarly, it has been found that turmeric can also facilitate this process via an SREBP-1-independent upregulation of the caveolin-1 gene, thus increasing plaque stabilization and decreasing plaque size.[22]

Another mechanism through which turmeric aids in lowering cholesterol is by increasing the LDL-receptor mRNA level.[23] Consequently, this leads to an increase in LDL receptors, primarily in the

hepatocytes, hence augmenting cholesterol sequestration in the body.[23] In another study, a higher rate of cholesterol catabolism is observed and is attributed to an increased hepatic cholesterol-7a-hydroxylase activity.[24] A number of studies also reported an increase in HDL level following turmeric supplementation, thus further strengthening its cardioprotective ability.[19, 21, 22]

Two side effects were noted in this study, epigastric pain and diarrhea. This finding is consistent with the commonly reported adverse effect following turmeric intake, which includes gastric upset manifesting as diarrhea, nausea, and an increase in gastrointestinal motility.[9, 11, 12]

Although there were dropouts, the attrition rate (15%) is not significant and is below 20%, hence leaving the internal validity of the study uncompromised.

This study shows a statistically significant lowering of the systolic blood pressure among individuals with stage 1 and 2 hypertension following 4 weeks of turmeric supplementation. The intervention had minimal side effects and is deemed safe for consumption, using the dosage and dosing frequency administered in this study. Thus, turmeric may be an effective adjunct in the control of blood pressure, specifically the systolic component, and may be used as a supplement in controlling and maintaining blood pressure levels within the normal range.

References

1. Akram M, Uddin S, Ahmed A, Usmanghani K, Hannan A, Mohiudin E, Astif M. Curcuma longa and curcumin: A review article. Rom J Biol – Plant Biol 2010; 55(2): 65-70.
2. Sugawara J, Akazawa N, Miyaki A, Choi Y, Tanabe Y, Imai T, Maeda S. Effect of endurance exercise training and curcumin intake on central arterial hemodynamics in postmenopausal women: Pilot study. American Journal of Hypertension 2012; 25(6): 651-6.
3. Sison J, Arceo L, Trinidad E et al. PRESYON 3: Report of the Council on Hypertension. Philippine Heart Association Annual Convention, May 2013.
4. Food and Nutrition Research Institute and Department of Science and Technology. 8th National Nutrition Survey: Clinical Health and Survey Component [pdf slides]. 2013. 13 slides: color.
5. James PA, Oparil S, Barter BL et al. 2014 Evidence-based guideline for the management of high blood pressure in adults: Report from the panel members appointed to the Eight Joint National Committee (JNC 8). JAMA 2014; 311(5): 507-20.
6. Philippine Society of Hypertension. Philippine clinical practice guidelines on the detection and management of hypertension—2011 (also known as the 140/90 Report). Compendium of Philippine Medicine 15th ed. 2013.
7. Chobanian AV, Bakris GL, Black HR et al. The seventh report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure. JAMA 2003; 289(19): 2561-73.
8. The Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and the European Society of Cardiology (ESC). 2013 ESC/ESH guidelines for the management of arterial hypertension. J Hypertension 2013; 31(7): 1281-1357.
9. Asher GN, Spelman K. Clinical utility of curcumin extract. Alternative Therapies 2013; 19(2): 20-2.
10. Lao CD, Ruffin MT, Normolle D, et al. Dose escalation of a curcuminoid formulation. BMC Complement Altern Med 2006; 6(10): 1-4.
11. Sharma RA, Euden SA, Platton SL, et al. Phase I clinical trial of oral curcumin: Biomarkers of systemic activity and compliance. Clin Cancer Res 2004; 10: 6846-54.
12. Sharma RA, McLelland HR, Hill KA, et al. Pharmacodynamic and pharmacokinetic study of oral curcuma extract in patients with colorectal cancer. Clin Cancer Res 2001; 7: 1894-1900.
13. Cheng AL, Hsu CH, Lin JT, et al. Phase I clinical trial of curcumin, a chemoprotective agent, in patients with high-risk or premalignant lesions. Anticancer Res 2001; 21: 2895-2900.
14. Zahid AM, Huaasinb ME, Fahim M. Anti-atherosclerotic effects of dietary supplementations of garlic and turmeric: Restoration of endothelial functions in rats. Life Sci 2005; 77(8): 837-57.
15. Nakmareong S, Kukongviriyapan U, Pafdeechote P, et al. Effect of curcumin on hemodynamic status and aortic elasticity in L-NAME hypertensive rat. Srinagarind Med J 2101; 25: 240-2.
16. Hlavackova L, Janegova A, Ulicna O, et al. Spice up the hypertension diet—curcumin and piperine prevent remodeling of aorta in experimental L-NAME induced hypertension. Nutrition & Metabolism 2011; 8: 72.
17. Khajehdehi P, Zanjaninejad B, Aflaki E, Nazarinia MA, Azad F, Malekmakan L, Dehghanzadeh GR. Oral supplementation of turmeric decreases proteinuria, hematuria, and systolic blood pressure in patient suffering from relapsing or refractory lupus nephritis: A randomized and placebo-controlled study. Journal of Renal Nutrition 2012 Jan; 22(1): 50-7.
18. Akazawa N, Choi Y, Miyaki A, Tanabe Y, Sugawara J, Ajisaka R, Maeda S. Curcumin ingestion and exercise training improve vascular endothelial function in postmenopausal women. Nutrition Research 2012; 32: 795-9.
19. Ramirez-Bosca A, Soler A, Carrion M, Diaz-Alperi J, Bernd A, Quintanilla C, Almagro EQ, Miquel J. An hydroalcoholic extract of Curcuma longa lowers the apo B/apo A ratio: Implications for atherogenesis prevention. Mechanisms of Ageing and Development 2000; 119: 41-7.
20. Quiles JL, Mesa MD, Ramirez-Tortosa CL, Aquilera CM, Battino M, Gil A, Ramirez-Tortosa MC. Curcuma longa extract supplementation reduces oxidative stress and attenuates aortic fatty streak development in rabbits. Arterioscler Thromb Vasc Biol 2000; 22: 1225-31.

21. Zhao JF, Ching LC, Huang YC, Chen CY, Chiang AN, Kou YR, Shyue SK, Lee TS. Molecular mechanism of curcumin on the suppression of cholesterol accumulation in macrophage foam cells and atherosclerosis. Mol Nutr Food Res 2012; 56: 691-701.
22. Yuan HY, Kuang SY, Zheng X, Ling HY, Yang YB, Yan PK, Li K, Liao DF. Curcumin inhibits cellular cholesterol accumulation by regulating SREBP-1/caveolin-1 signaling pathway in vascular smooth muscle cells. Acta Pharmacol Sin 2008 May; 29(5): 555-63.
23. Peschel D, Koerting R, Nass N. Curcumin induces changes in expression of genes involved in cholesterol homeostasis. J Nutr Biochem 2007; 18(2): 113-9.
24. Suresh BP, Srinivasan K. Hypolipidemic action of curcumin, the active principle of turmeric (Curcuma longa) in streptozocin-induced diabetic rats. Mol Cell Biochem 1997; 166(1-2): 169-75.

The effect of yacon (Smallanthus *sonchifolius*) syrup as adjunct to statins on the lipid profile of patients with dyslipidemia: A randomized controlled trial

John Patrick M. Dimarucot; Ola M. Fabiania; Audrey Aaron V. Fegarido; Raphael S. Figueroa;
Princess Sittie Asiah A. Abdullah; Rachel Dominique G. Conti; Jeff Robert C. Costanilla; Jules Albert L. Crescini;
Richelle V. Cunanan and Jose Ronilo G. Juangco, MD (Adviser)

Abstract

Introduction Yacon (*Smallanthus sonchifolius*), a tuber vegetable native to the Philippines has been shown in previous studies to be a potentially effective antidyslipidemic. This study aimed to determine the effect of the intake of yacon as adjunct to statins on the lipid profile of patients with dyslipidemia.

Methods This was a randomized controlled trial comparing adult dyslipidemic patients treated with statins alone or statin plus yacon syrup over a 6-week period. The total cholesterol, high density lipoprotein (HDL), low density lipoprotein (LDL) and triglyceride levels after the treatment period were compared with the baseline levels. The mean difference between the statin alone and statin plus yacon syrup groups were compared.

Results Yacon syrup and statin combination therapy significantly reduced LDL ($p < 0.05$) and increased HDL ($p = 0.02$) as compared to the control group. Yacon syrup was generally well tolerated with the most frequent side effects being flatulence, early satiety, and increased defecation frequency.

Conclusion These findings suggest a possible role for yacon syrup supplementation in the management of patients with dyslipidemia.

Key words: Yacon, *Smallanthus sonchifolius*, dyslipidemia

Cardiovascular diseases (CVDs) are the leading cause of mortality in the world. CVDs cause more deaths than any other disease annually. According to the World Health Organization (WHO), CVDs were responsible for approximately 17.5 million deaths in 2012, accounting for 31% of the total global deaths.[1] In the Philippines, an estimated 33% of the total deaths in 2014 were attributed to CVDs.[2] More than 80% of these diseases are associated with lifestyle-related risk factors, all of which are preventable.[3] These risk factors, if not corrected, could lead to metabolic and physiologic derangements that could predispose an individual to the development of a multitude of diseases, including CVDs. One such risk factor is dyslipidemia, which is defined as an elevated total cholesterol or

Correspondence:
John Patrick M. Dimarucot, Department of Preventive and Community Medicine, College of Medicine, University of the East Ramon Magsaysay Memorial Medical Center Inc., Aurora Boulevard, Barangay Doña Imelda, Quezon City 1113; E-mail: jpdimarucot@gmail.com; Telephone: 9175141416

low-density lipoprotein (LDL) levels, or a low high-density lipoprotein (HDL) level[4].

Hypercholesterolemia, or a high total cholesterol level, contributes to a third of all ischemic heart diseases globally and is responsible for about 2.6 million deaths, and 29.7 million disability-adjusted life years (DALYs) annually.[1] Among the components of total serum cholesterol, LDL is the one most associated with increased risk for CVDs and shows a linear relationship with cardiovascular disease incidence.[4] On the other hand, a high level of HDL is associated with a reduced risk.[5]

Despite the advent of HMG-CoA reductase inhibitors (statins), which have been shown to be very effective in reducing total cholesterol and LDL, with a variable effect on HDL, the prevalence of dyslipidemia and consequentially CVDs, continues to be quite high. In the Philippines, according to the 2013 National Nutrition Survey (NNS) published by the Food and Nutrition Research Institute (FNRI), the prevalence of borderline to high total cholesterol level in persons aged 20 years and above is 46.9%, especially in women 50 to 59 years. Moreover, the overall prevalence of high LDL and low HDL cholesterol level in the same population is at 47.2% and 71.3% respectively.[3]

The continued high prevalence of dyslipidemia and its devastating clinical consequences emphasizes the need to come up with control measures that do not only bring blood cholesterol and its components to optimal levels but are also cost-effective, sustainable, and, in a low-income country like the Philippines, affordable.

Some studies have shown that yacon (*Smallanthus sonchifolius)*, a tuber vegetable that is native to many provinces in the Philippines, may be an effective anti-dyslipidemic agent. However, the findings of these studies are conflicting, and thus not entirely conclusive. In addition, as far as the researchers know, its effects and side effects on the Asian population, particularly Filipinos, haven't been established.

This study aimed to address this gap in knowledge by determining the effect of the intake of yacon as adjunct to HMG-CoA reductase inhibitors (statins) on the lipid profile of Filipino patients with dyslipidemia.

Methods

This was a randomized controlled trial comparing adult dyslipidemic patients recruited from the UERMMMCI Outpatient Clinic treated with statins alone or statin plus yacon syrup over a 6-week period.[7] The total cholesterol, high density lipoprotein (HDL), low density lipoprotein (LDL) and triglyceride levels after the treatment period were compared with the baseline levels. The mean difference between the statin alone and statin plus yacon syrup groups were compared. The study was approved by the UERMMMCI Ethics Review Committee.

Male or female patients consulting at the Outpatient Clinic, aged 30 to 65 years, with a total cholesterol > 5.1 mmol/L, LDL > 1.7 mmol/L, or HDL < 0.6 mmol/L, were recruited by purposive sampling. Those with diseases that contraindicated their participation and those who were mentally incompetent were excluded. The subjects were randomized via a fishbowl method into the treatment and control groups. The treatment group took a statin and 0.14g/KBW/day of yacon,[8] while the control group took a statin alone. Previous studies showed that the standard deviation in the cholesterol level of patients with dyslipidemia was 0.6 mmol/L.[8] The estimated difference between the cholesterol of the treatment and control group post-treatment was set at 0.8 mmol/L.[8] Type I (α) error was set at 5%, with 80% power. The computed sample size was nine per group, for a total of 18 subjects.

The yacon syrup was supplied by Doalnara, a yacon tuber farm in Misamis Oriental. The preparation process included meticulous tuber selection, washing and peeling, two rounds of coarse grinding to extract the juice from the tubers, and boiling over low heat for at least 24 hours until the desired consistency of the syrup was reached. These were then bottled and labelled. A random sample of the yacon syrup was sent to a private laboratory where the fructooligosaccharide content was determined to be 27.88% through a fructan assay method. Yacon syrup as a product has a very long shelf life with or without refrigeration. It does not spoil and its chemical composition does not change even after 12 years of storage.[8]

After the researchers were granted permission by the head of the Outpatient Clinic, recruitment of participants commenced. The nature, risks, objectives and methodology of the study were fully explained to the prospective study subjects. After voluntarily agreeing to participate, they were asked to sign the informed consent form.

Once recruited, the subjects' demographic characteristics, namely age, sex, weight, height, BMI, and the statin were determined. Age, sex, and current statin were determined via an interview. The subjects were asked to come back the following day for determination of weight, height, and blood extraction for baseline serum total cholesterol, triglycerides, LDL, and HDL. The lipid profile was done by the hospital laboratory. Weight was taken with a digital weighing scale, with the respondents fasted for 10 hours, wearing minimal clothing, no slippers, and with an empty bladder. Height was taken while the patient is standing up and under the same conditions. BMI was computed using the formula, BMI = weight (kg)/height $(m)^2$.

The subjects were then instructed to pick a piece of paper from a bowl which contained an odd or an even number corresponding to their participation in the control or treatment group, respectively. The dose of the yacon syrup for the 6-week treatment period, computed at 0.14g/KBW/day, along with a medicine cup for accurate dose measurement, were given to the subjects in the treatment group at this time. They were instructed to divide the prescribed daily dosage in two doses, once in the morning and once at night, and to take the syrup 1 hour before meals. After completion of the 6-week study period, serum lipid profile values were again measured under the same aforementioned conditions. To encourage compliance, the subjects were followed-up every week via an SMS. There was also continuous monitoring for possible side effects throughout the study period. All respondents were given a number which they would contact in case of any side effects experienced.

Treatment success was defined as post-treatment lipid profile values of total cholesterol <5.2 mmol/L (200 mg/dL), triglycerides < 1.7 mmol/L (150 mg/dL), HDL ≥ 1.5 mmol/L (60 mg/dL), and LDL < 2.6 mmol/L (100 mg/dL). Treatment failure was defined as inability to meet these conditions.

The data gathered were tabulated using Microsoft Excel. The data for age, height, weight, BMI, type of statin taken, baseline and post-treatment lipid profile values were expressed as mean ± SD. Data for sex and side effects were expressed as frequencies. The significance in the difference between age, height, weight, BMI, and baseline and post-treatment lipid profile values between the treatment and control group was determined using an independent t-test. The significance in the difference between the baseline and post-treatment lipid profile values within the control or treatment group was determined using a paired t-test. An independent t-test was employed to determine if there is a significant difference between the mean difference in lipid profile values of the treatment and control group. Significant difference between the sex of the respondents and the type of statin they were taking was determined using the chi-square test with the p-value set at 0.05.

The effectiveness of yacon syrup as adjunct to statin in achieving treatment success as compared to statin alone was determined using relative risk (RR). Additionally, the hazard ratio (HR) and number needed to harm (NNH) were determined as an indicator of the risk of developing adverse reactions with the intake of yacon syrup. The p-value was also set at 0.05. All computations were done using Statistical Package for Social Sciences (SPSS) 22.0.

Results

A total of 22 subjects were recruited for the study. Two subjects, one from the control group and one from the treatment group were lost to follow-up. Another subject from the treatment group was dropped from the study because of an illness which prevented him from taking the syrup, leaving 19 subjects to complete the study. Table 1 shows that the treatment and control groups were comparable although there were more women in the statin plus yacon group. Majority of the subjects in both groups used atorvastatin as their maintenance medication.

Table 2 shows significant decreases in the mean serum total cholesterol, triglycerides, LDL and significant increases in the HDL levels of the treatment and control groups before and after treatment except for the HDL of the control group. The decreases in the HDL and LDL between the treatment and control groups were significant as seen in Table 3. The decrease in cholesterol was greater in the statin plus yacon group but the difference was not significant. There was no difference in the decrease of triglyceride levels between the two groups. Table 4 shows that treatment success in the statin plus yacon group is 3.3 times more likely as compared to the control group. However, this was not statistically significant.

Table 5 shows that there were more side effects reported in the treatment group, the highest of which were frequency of defecation and flatulence, which were reported by four subjects. The relative risk of

Table 1. Demographic characteristics of subjects in the treatment and control groups.

Characteristic	Treatment n = 9	Control n = 10	p-value
Age (yr)	55.44	52.7	0.37[a]
Sex			
Male	2 (22.2%)	6 (60%)	0.09[b]
Female	7 (77.8%)	4 (40%)	
Anthropometrics			
Weight (kg)	64	63.35	0.89[a]
Height (m)	1.6	1.63	0.43[a]
BMI (kg/m^2)	24.94	23.81	0.37[a]
Baseline lipid profile			
Total cholesterol	7.39	7.04	0.25[a]
Triglycerides	2.14	2.32	0.51[a]
HDL	1.16	1.13	0.67[a]
LDL	5.19	4.78	0.17[a]
Type of statin			
Atorvastatin	8 (88.8%)	7 (70%)	0.51[b]
Simvastatin	1 (12.2%)	2 (20%)	
Rosuvastatin	0	1 (10%)	

[a] Independent t-test
[b] Chi-Square

Table 3. Mean difference in serum total cholesterol, triglycerides, HDL and LDL reduction of treatment group and control group post-treatment.

	Treatment mean (SD)	Control mean (SD)	p-value[a]
Total cholesterol	2.98 (0.76)	2.46 (0.84)	0.17
Triglycerides	0.70 (0.33)	0.70 (0.38)	1
HDL	-0.27 (0.11)[b]	-0.10(0.16)[b]	0.02
LDL	2.96 (0.75)	2.27 (0.66)	< 0.05

[a] Independent t-test
[b] Negative values indicate a mean increase.

Table 4. Relative risk of achieving treatment success with yacon syrup as adjunct to statins.

	Success	Failure	RR (95% CI)	p-value
Treatment	1	8	3.3	
				0.47
Control	0	10	(0.15, 72.09)	

Table 2. Lipid profile levels of subjects in the treatment and control groups before and after treatment.

	Baseline mean (SD)	Post-treatment mean (SD)	Difference	p-value[a]
Total cholesterol				
Treatment	7.39 (0.70)	4.40 (0.36)	2.98	< 0.01
Control	7.04 (0.57)	4.58 (0.67)	2.46	< 0.01
Triglycerides				
Treatment	2.14 (0.61)	1.44 (0.45)	0.70	<0.01
Control	2.32 (0.52)	1.62 (0.49)	0.70	<0.01
HDL				
Treatment	1.16 (0.07)	1.42 (0.13)	-0.27[b]	<0.01
Control	1.13 (0.16)	1.23 (0.13)	-0.10[b]	0.07
LDL				
Treatment	5.19 (0.73)	2.23 (0.30)	2.96	<0.01
Control	4.78 (0.49)	2.51 (0.56)	2.27	<0.01

[a] Paired t-test
[b] Negative values indicate a mean increase.

Table 5. Side effects, their corresponding relative risk (RR) and number needed to harm (NNH).

	Treatment	Control	HR (95% CI)	p-value	NNH
Increased defecation frequency	4	1	4.5 (0.62, 32.38)	0.13	3
Flatulence	4	0	9.9 (0.61, 161.74)	0.11	3
Early satiety	3	0	7.7 (0.45, 131.37)	0.16	4
Dizziness	1	1	1.11 (0.08, 15.28)	0.94	90
Drowsiness	1	0	3.3 (0.15, 72.09)	0.45	10

experiencing these side effects is also shown, which were not significant on statistical analysis. The numbers needed to harm (NNH) are lowest for increased defecation frequency and flatulence, and highest for dizziness. Increased defecation frequency and flatulence were most prominent during the first week of treatment and disappeared with continued use. Early satiety was persistent throughout the duration of the study.

Discussion

Our results showed that the yacon and statin combination therapy significantly reduced the total cholesterol, triglycerides, and LDL, and also significantly increased HDL. The differences in the reduction in LDL and the increase in HDL were significant compared with the control group but the decreases in total cholesterol and triglycerides were not significant. Thus, the effect on the total cholesterol and triglycerides could not be attributed solely to the yacon syrup but could also be due to the effect of the statin. The increase in HDL was not seen in the control group and a significant difference between the mean difference of the baseline and post-treatment HDL values of the treatment and control group was found. This means that yacon syrup supplementation produced a significant positive effect on the HDL levels of the subjects in the treatment group. A significant difference was also found between the mean difference in LDL of the treatment and control groups. This could mean that the combination of yacon syrup and a statin produced a significantly greater reduction in LDL as compared to statin monotherapy.

The anti-dyslipidemic effect of yacon comes from its high fructooligosaccharide (FOS) content. These are short-chain carbohydrates that are resistant to degradation and absorption in the small intestine and therefore reach the large intestine unaltered, making them potent prebiotics. Prebiotics are "indigestible fermented food substrates that selectively stimulate the growth, composition, and activity of microflora in gastrointestinal tract."[9] Specifically, the fermentation of FOS by intestinal flora selectively stimulates the proliferation of beneficial lactose-fermenting bacteria such as *Lactobacillus*.[10]

Several mechanisms have been proposed on the cholesterol reducing effect of *Lactobacillus* strains and other lactic acid bacteria (LAB). Aside from their direct cholesterol-reducing effects by binding cholesterol in the small intestines, incorporation of cholesterol into their cell membrane and co-precipitation of cholesterol to deconjugated bile, they also express bile salt hydrolase (BSH), an enzyme that catalyzes the deconjugation of bile salts.[10] These *Lactobacillus* strains are very efficient in deconjugating bile salts. In an in vivo study, cultures of *Lactobacillus* strains were able to deconjugate 60 to 90% of bile salts.[11]

Deconjugation of bile salts leads to the release of free taurine and glycine which are reabsorbed and free cholic acid which is excreted in the feces[10]. This increased excretion of free cholic acid leads to a decreased hepatic pool of bile acids, leading to the

de-downregulation of cholesterol-7-α-hydroxylase. Cholesterol-7-α-hydroxylase (CYP7A1) catalyzes the first rate-limiting step of bile acid synthesis from cholesterol. Thus, activation of this enzyme leads to increased usage of serum and hepatic cholesterol for the synthesis of bile acids.[12] Decreased hepatic cholesterol, in turn, leads to increased expression of LDL-receptors in the hepatocytes[12]. These mechanisms probably account for the LDL and total cholesterol reducing effect of increased bile acid secretion.

On the other hand, the HDL-increasing effect of interrupting the enterohepatic circulation of bile is just starting to be fully elucidated. Farnesoid-X receptor (FXR), a member of the nuclear receptor superfamily that is expressed in hepatocytes, is activated by primary bile acids. Activation of this receptor represses the gene expression of apoprotein A1 (ApoA1), the major protein found in HDL.[12] It also represses the expression of the apoprotein M (ApoM) gene, a protein responsible for HDL maturation.[13] Thus, decreased activation of the FXR receptor by decreased hepatic bile acid levels may lead to an increased expression of the ApoA1 and ApoM gene, possibly accounting for the increased HDL that is seen with increased bile excretion. Indeed, numerous studies have shown that increasing fecal bile excretion decreases total cholesterol, LDL, while increasing the levels of HDL cholesterol.[12]

The use of yacon as an agent for dyslipidemia, is a relatively new area of study. Only a few studies on human subjects are currently available. A study done by Genta et al, on the effect of yacon syrup supplementation to obese and slightly dyslipidemic pre-menopausal women found that daily intake of yacon syrup over a 120-day period produced a significant reduction in LDL with a moderate increase in HDL, with no effect seen on the total cholesterol and triglycerides.[8] These findings are congruent with the results of the current study suggesting that yacon is effective even with a shorter treatment duration. Animal studies have shown the same results of reduced total cholesterol[14, 15] and triglycerides,[16] and increased HDL.[16]

Subjects in the treatment group were 3.3 times more likely to achieve target lipid profile values as prescribed by the American Academy of Clinical Endocrinologists. However, this was not found to be significant. There could be a temporal factor to this finding, and further investigation is warranted. Still, a greater change in the LDL and HDL values warrants consideration when it comes to managing dyslipidemia. The inverse relationship of LDL levels with the risk of major cardiovascular events (MCE) is fairly established. A meta-regression analysis of statin trials done in 2012 found that for every 1 mmol/L decrease in LDL, there is a corresponding 19% reduction of risk of MCE.[17] In contrast, the relationship between increasing HDL levels and the risk of MCE is more controversial. The same meta-regression analysis found that there is no risk reduction seen per 1 mmol/L increase in HDL.[17] On the other hand, another meta-analysis done in 2013 found that HDL levels are indeed associated with a reduced risk of MCE.[18] Still yacon supplementation can be a consideration in managing dyslipidemic patients if only for its effect on LDL alone. Moreover, we did not find any literature associating any risks with increased HDL.

Side effects identified with the intake of yacon included increased frequency of defecation, flatulence, and early satiety. These effects could be attributed to the FOS in yacon. FOS, as discussed earlier, are non-digestible carbohydrates that reach the colon largely unaltered, allowing them to add bulk to the intestinal contents. This could account for the increased frequency of defecation. Early satiety, which could be an indirect effect of slower gastric emptying and appetite suppression, which are consequences of the glucagon-like protein 1 (GLP-1), GIP, and ghrelin modulation effects of FOS.[8] Flatulence is due to the gas produced as a by-product of the fermentation of FOS by gut bacteria.[19] Increased defecation frequency and flatulence were most prominent during the first few weeks of treatment which could suggest a period of adaptation. Interestingly, increased defecation frequency and early satiety were not considered to be bothersome by the subjects. Rather, most of the subjects felt that these side effects were actually beneficial as most of them had problems with constipation and weight reduction. The risk of experiencing side effects with yacon intake is moderate, with NNH ranging from 3 to 90. Nonetheless, these symptoms were perceived to be mild, lessen in severity with continued treatment, and even desirable.

The findings of this study could serve as a basis for a larger clinical trial that could examine the long-term effects of yacon in the management of dyslipidemia, and its effect on the incidence of cardiovascular diseases. Further research could also

be done on the possible role of yacon in the management of patients with dyslipidemia but do not require statin therapy. The effect of increased defecation frequency and early satiety necessitates further investigation on the use for yacon in the management of constipation and in weight reduction, respectively. In conclusion, our results suggest a possible role for yacon syrup as adjunct to statins in the management of patients with dyslipidemia.

References

1. World Health Organization. Cardiovascular Diseases. Geneva: World Health Organization; 2015. Available from: http://www.who.int/mediacentre/factsheets/fs317/en/. [Accessed Aug 6, 2015].
2. Food and Nutrition Research Institute. National Nutrition Survey. Manila: Department of Science and Technology; 2013. Available from: http://obesity.org.ph/v4/wp-content/uploads/2013/04/8thNNSResultsNCD.pdf. [Accessed Aug 8, 2015].
3. World Health Organization. Global status report on noncommunicable diseases. Geneva: World Health Organization; 2011. Available from: http://www.who.int/nmh/publications/ncd_report2010/en/. [Accessed Aug 14, 2014].
4. Fodor G. Primary prevention of CVD: Treatment of dyslipidemia. Am Fam Physician 2011 May; 83(10): 1207-8. Available from: http://www.aafp.org/afp/2011/0515/p1207.html. [Accessed Aug 24, 2015].
5. Mitchell RN, Schoenn FJ. Blood Vessels. In: Kumar V, Abbas A, Fausto N, Aster J, editors. Robbins and Cotran Pathologic Basis of Disease. 8th ed. Philadelphia: Saunders Elsevier; 2010.
6. American Association of Clinical Endocrinologists. Lipid and Atherosclerosis Guidelines. Endocr Pract 2012; 18(Suppl 1). Available from: https://www.aace.com/files/lipid-guidelines.pdf. [Accessed Aug 28, 2015].
7. Sivieri K, Morales ML, Saad SM, Adorno MA, Sakamoto IK, Rossi EA. Prebiotic effect of fructooligosaccharide in the simulator of the human intestinal microbial ecosystem (SHIME model). J Med Food 2014 Aug; 17(8): 894-901. Available from: https://www.clinicalkey.com/#!/content/medline/2-s2.0-24654949. [Accessed Aug 28, 2015].
8. Genta S CW, Habib N, Pons J, Carillo IM, Grau A, Sanchez S. Yacon syrup: beneficial effects on obesity and insulin resistance in humans. Clin Nutr 2009 Apr; 28(2): 182-7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19254816. [Accessed Aug 11, 2014].
9. Roberfroid MB. Prebiotics and probiotics: Are they functional foods? Am J Clin Nutr 2000 June; 71(6): 1682S-90S. Available from: http://www.scopus.com/record/display.url?eid=2-s2.0-0034045571&origin=inward&txGid=0290CC844922BD45CF8094CF2B219F23.53bsOu7mi7A1NSY7fPJf1g%3a2. [Accessed Aug 11, 2014].
10. Anandharaj M, Sivasankari B, Rani RP. Effects of probiotics, prebiotics, and synbiotics on hypercholesterolemia: A review. Chinese Journal of Biology 2014; Available from: http://www.hindawi.com/journals/cjb/2014/572754/. [Accessed Aug 9, 2014].
11. Brashears MM, Gilliland SE, Buck LM. Bile salt deconjugation and cholesterol removal from media by Lactobacillus casei. J Dairy Sci 1998 Aug; 81(8): 2103-10. Available from: https://www.clinicalkey.com/#!/content/medline/2-s2.0-9749373. [Accessed Aug 28, 2015].
12. Staels B, Fonseca V. Bile acids and metabolic regulation: Mechanisms and clinical responses to bile acid sequestration. Diabetes Care 2009 Nov; 32(2): 5237-45. Available from: http://care.diabetesjournals.org/content/32/suppl_2/S237.full.pdf+html. [Accessed Aug 28, 2015].
13. Kardassis D, Mosialou I, Kanaki M, Tiniakou I, Thymiakou E. Metabolism of HDL and its regulation. Curr Med Chem 2014 Jan; 21(25): 2864-80. Available from: http://www.whba1990.org/uploads/4/0. [Accessed Aug 28, 2015].
14. Genta S, Cabrera W, Grau A, Sanchez S. Subchronic 4-month oral toxicity of dried Smallanthus sonchifolius (yacon) roots as a diet supplement in rats. Food Chem Toxicol 2005 Nov; 43(11): 1657-65. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15979774./1/1/4011882/kardassis_hdl_regulation_review.pdf. [Accessed Aug 11, 2014].
15. Delgado GT TW, Marostica Junior MR, Pastore GM. Yacon (Smallanthus sonchifolius): a functional food. Plant Foods for Hum Nutr 2013 Sep; 68(3): 222-8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23709016. [Accessed Aug 11, 2014].
16. Roselino MN P-SN, Cavallini DC, Celiberto LS, Pinto RA, Vendramini RC, Rossi EA. A potential synbiotic product improves the lipid profile of diabetic rats. Lipids Health Dis 2012 Sep; 11:114. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22963080. [Accessed Aug 11, 2014].
17. 23 Ference BA, Mahajan N, Yoo W, Afonso L, Flack F. The clinical benefit of therapies that raise high-density lipoprotein cholesterol added to treatment with a statin. J A Coll Cardiol 2012 Mar; 59(13): E1376. Available from https://www.clinicalkey.com/#!/content/journal/1-s2.0-S0735109712613771. [Accessed Aug 28, 2015].
18. Boekholdt SM, Arsenault BJ, Hovingh GK, Mora S, Pedersen TR, Larosa JC, et al. Levels and changes of HDL cholesterol and apolipoprotein A-I in relation to risk of cardiovascular events among statin-treated patients. Circulation 2013 Oct; 128(14): 1504-12. Available from: https://www.clinicalkey.com/#!/content/medline/2-s2.0-23965489. [Accessed Aug 28, 2015].
19. Cummings JH, Macfarlane GT. Gastrointestinal effects of prebiotics. Br J Nutr 2002 May; 87(2): S145-51. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12088511. [Accessed Aug 28, 2015].

Compliance of selected hospitals in the National Capital Region to the Department of Health functional indicators of safe hospitals in emergencies and disasters

Pura Jacobe T. Bascuña, Josue Antonio L. Baroña, Ann Lorraine M. Basilan, Arvinjay A. Bautista, Blessie C. Batac, Dana Gabrielle M. Arellano, Edshane L. Arevalo, Marie Grace A. Aseron, Beatrice April D. Austria, Mary Anne Claudine SP Avena

Abstract

Introduction This study determined the compliance of selected hospitals in the National Capital Region in 2015 to the Functional Indicators on Safe Hospitals in Emergencies and Disasters of the Department of Health.

Methods This study administered the DOH checklist to a knowledgeable representative from all 61 hospitals of Marikina, Pasig, Mandaluyong, Valenzuela, Quezon City and Malabon, which were randomly selected via cluster random sampling. Eighteen hospitals consented to participate. The median of the scores in the seven categories of functional indicators and in the overall score was used to set the standard of compliance.

Results Seven out of 18 hospitals were non-compliant to each of the functional indicators of the DOH checklist with compliance greatest for site and accessibility and monitoring and evaluation (83.3%), and least for hospital emergency preparedness and response and recovery plan (55.6%). Overall, 11 out of 18 of the hospitals were compliant to the DOH checklist.

Conclusion The respondent hospitals were not fully prepared for emergencies; there were indicators in which different hospitals had inadequate compliance.

Key words: Disaster preparedness, hospital emergency preparedness

The Philippines is one of the most vulnerable countries in the world in terms of sustaining damage brought about by natural calamities. Eight to nine tropical storms make landfall in the Philippines annually and another 10 enter Philippine waters, totaling about 19 tropical storms per year.[1] The most destructive earthquakes in the Philippines were the Moro Gulf Earthquake and 1990 Luzon earthquake which killed approximately 6,000 and 2,500 lives respectively. A study funded by the Japan International Cooperation Agency in 2004 showed that a magnitude 7.2 earthquake along the West Valley Fault would destroy 40% of structures and claim 34,000 lives in Metro Manila.[2] The potential

Correspondence:
Pura Jacobe T. Bascuña, Department of Preventive and Community Medicine, College of Medicine, University of the East Ramon Magsaysay Memorial Medical Center Inc., Aurora Boulevard, Barangay Doña Imelda, Quezon City 1113; E-mail: bascunapura@gmail.com; Telephone: 9998813786

for major damage and significant loss of lives from these natural calamities necessitate disaster preparedness at all times.

According to the World Health Organization, the health sector is "the foundation of any health response to be launched to save lives of people injured when their city is struck by a disaster."[3] Hospitals are an invaluable component and it is imperative that the hospital administrators and staff are resilient against disasters in order to provide emergency care during critical times and undertake post-disaster recovery measures.

This study determined the compliance of selected hospitals in the National Capital Region to the Department of Health (DOH) functional indicators of safe hospitals in emergencies and disasters to assess their capability to be functional and consequently to deliver medical care in times of emergencies and disasters. The results may help the health sector maintain the good practices that hospitals are already practicing, and to improve on specific areas which will enable them to effectively carry out their responsibilities to the community.

Methods

This was a descriptive cross-sectional study done in 2015 to estimate the level of compliance of selected level I and II, and level III[4] hospitals in the National Capital Region (NCR) to the functional indicators of emergency and disaster preparedness prescribed by the DOH. Hospitals were randomly selected and a key person was asked to answer an evaluation tool from the DOH.

Government and private level I to III hospitals in NCR operating for at least 10 years were recruited and selected by cluster random sampling. Two out of four districts in NCR were randomly chosen. From these, six cities or municipalities were randomly selected: Marikina, Pasig, Mandaluyong, Valenzuela, Quezon City and Malabon. The hospitals in these places were listed and classified based on level. A sample size of 39 was computed using the formula for estimating a population proportion with 36%[3] compliance, 95% reliability and 15% precision. Hospitals from each city were randomly selected based on a weight assigned to each city depending on the number of hospitals in each city. Each hospital was represented by the doctor, administrator, or head of the disaster response team, or anyone who was deemed most knowledgeable about the subject matter and designated by the medical director or hospital administrator. After obtaining an informed consent, the designated representative was asked to answer the survey tool. The survey was collected after completion, the responses tabulated and the scores for each category and overall score were computed.

The 2011 DOH Checklist on Safe Hospitals in Emergencies and Disasters was used to determine compliance to the functional indicators set by the department.[5] This checklist was previously pre-tested and used to survey the hospitals in NCR but results were not made available to the public. The checklist consisted of 78 and 92 items for levels I and II, and level III hospitals, respectively, and was answerable by yes or no with an optional remarks section beside each item.[4] Both sets had seven categories consisting of (1) site and accessibility, (2) internal circulation and inter-operability, (3) basic equipment and supplies, (4) hospital emergency preparedness, response, and recovery plan, (5) back-up system, (6) organization, management, and human resources, and (7) monitoring and evaluation. Site and accessibility (4 and 7 questions for level I-II and level III hospitals, respectively) asked about road emergency signs, ingress and egress routes, open spaces and directional signages. Internal circulation and inter-operability (5 and 10 questions) referred to ramps, stairways, corridors, hallways, well-ventilated spaces for conversion to mass casualty handling areas. Basic Equipment and supplies (7 questions for both) pertained to the capacity to provide available diagnostic and therapeutic equipment, medical supplies, and proper personal protective equipment. Hospital emergency preparedness, response and recovery plan (32 questions for both) pertained to the current preparations for emergency medical response to natural disasters which were approved, disseminated and tested by the administration. Backup system for supplies (8 questions for both) included supply of water, energy, gas, communication tools, and waste water treatment during emergency medical response to natural disasters. Organization, management and human resources (21 and 25 questions) included the central disaster command center and committees responsible for direction and order to several subordinate committees. Monitoring and evaluation (1 question for both) pertained to the evaluation of response after emergencies or disasters.

Each "yes" answer was given a score of 2 points and the "no" responses were scored 1 point. The

scores for each of the 7 indicators and the overall scores were computed. The median for each category was determined and served as the standard of compliance: hospitals scoring greater than or equal to the median were compliant, and those scoring less than the median were non-compliant in the particular category. To determine overall compliance, the score of each hospital in the whole checklist was calculated. The median of the overall scores of the hospitals under each group set the standard of compliance, such that hospitals scoring greater than or equal to the median was compliant, and those scoring less than the median were non-compliant. The scores were computed separately for the level I-II and level III hospitals based on their respective medians.

This study was approved by the Ethics Research Committee of the University of the East Ramon Magsaysay Memorial Medical Center, Inc.

Results

There were 61 hospitals in the six cities and municipalities in Districts II and III. Eighteen institutions consisting of 10 private and eight government hospitals were included, of which nine were level I or II and nine were level III.

As shown in Table 1, level I and II hospitals showed the greatest compliance to three functional indicators: site and accessibility; internal circulation and inter-operability; and monitoring and evaluation. On the other hand, hospital emergency preparedness, response and recovery plan, and back-up system had the lowest number of compliant hospitals. For the level III hospitals, four functional indicators - site and accessibility; basic equipment and supplies; backup system; and monitoring and evaluation had the highest number of compliant hospitals. On the other hand, the two categories with the lowest compliance were hospital emergency preparedness, response, and recovery plan; and organization, management and human resources. Overall compliance was seen in five level I-II and six level III hospitals.

Table 2 shows that private hospitals had the highest compliance to site and accessibility; basic equipment and supplies; backup system; and monitoring and evaluation while government hospitals had the highest compliance to site and accessibility; internal circulation and inter-operability; and monitoring and evaluation. Hospital emergency preparedness, response and recovery plan; and backup

Table 1. Compliance of level I-II and level III Hospitals to functional indicators of safe hospitals in emergencies and disasters.

Indicator	Level I-II (n = 9)	Level III (n = 9)
Site & accessibility	8 (88.9%)	7 (77.8%)
Internal circulation & inter-operability	8 (88.9%)	6 (66.7%)
Basic equipment & supplies	6 (66.7%)	7 (77.8%)
Hospital hospital emergency preparedness, response, & recovery plan	5 (55.6%)	5 (55.6%)
Back-up system	5 (55.6%)	7 (77.8%)
Organization, management & human resources	7 (77.8%)	5 (55.6%)
Monitoring & evaluation	8 (88.9%)	7 (77.8%)

Table 2. Compliance of private and government hospitals to functional indicators of safe hospitals in emergencies and disasters.

Indicator	Private (n = 10)	Government (n = 8)
Site & accessibility	8 (80%)	7 (87.5%)
Internal circulation & inter-operability	7 (70%)	7 (87.5%)
Basic equipment & supplies	8 (80%)	5 (62.5%)
Hospital hospital emergency preparedness, response, & recovery plan	5 (50%)	5 (62.5%)
Back-up system	8 (80%)	4 (50.0%)
Organization, management & human resources	7 (70%)	5 (62.5%)
Monitoring & evaluation	8 (80%)	7 (87.5%)

system had the lowest compliance among the private and government hospitals, respectively. None of the level I-II government hospitals was compliant to basic equipment and supplies, and backup system.

Discussion

Overall, 11 of the 18 hospitals that participated in the study were compliant to the functional indicators of the Department of Health. While most hospitals were compliant on individual functional indicators, there was still a significant proportion - 40% - that was not compliant. This could be alarming since this means that a considerable proportion of the respondent hospitals in NCR are not totally prepared for emergencies and disasters. Being prepared means taking measures before a disaster occurs to minimize loss of life. It is a protective process that enables governments, communities and individuals to respond rapidly to a disaster situation and cope with it effectively.[7] Thus, with hospitals not fully prepared, coping with post-disaster events could be difficult since health is one of the basic needs that need to be addressed.

Site and accessibility, and internal circulation and inter-operability were the two functional indicators which had the highest number of compliant hospitals regardless of type or level. The Government of India recognized the importance of this functional indicator in its Emergency and Disaster for Health Facilities Guidance Notes, which cited specific scenarios where site and accessibility could prove to be a crucial component to deliver efficient and effective health care.[6] For instance, according to this guide, the traffic of patients being brought in aside from relatives, bystanders and media during an emergency situation could block the routes to the hospital consequently delaying the transport of patients. It was also necessary for transportation to be available to bring patients from the site of a mass casualty incident to the hospital, or from the hospital to other health facilities if the hospital suffered from internal damage and was thus incapable of rendering service. The location of hospitals near proper roads with sufficient means of transportation was also highlighted by Bajow and Alkhalil as an important structural element that determined the overall safety of a hospital during disasters.[8] The World Health Organization also advised that, in order to prevent confusion and panic during an emergency which may cause stampedes of trapping of individuals in enclosed spaces, there should be signages inside the health facility that indicate the location of escape routes and firefighting equipment.[9]

In general, the hospitals that participated in this study reported to be located near accessible roads with adequate means of transportation and had measures to control the flow of patients, relatives, media, and health care workers within the hospital through properly labeled entrances and exits. They also ensured accessible emergency rooms and alternative areas where health services could be performed should there be a mass casualty.

The World Health Organization stressed the need for internal circulation and inter-operability so that in case of a surge of patients areas in the hospital could be vacated and converted to patient areas. Provision of adequate water supply, electricity, and medical gases was also vital in daily operations of hospitals and health facilities.[9] These basic needs were shown to be vital in disaster preparedness, thus it was just proper that all hospital levels in NCR should have these prepared. It was also stated by the American Hospital Association that being ready entailed investment in communications and emergency power systems, purchase personal protective gear, construction of decontamination units and stockpile medical supplies.[10] It is important to know that generally, the included hospitals showed good compliance in this category.

On the other hand, hospital emergency preparedness, response, and recovery plan was the indicator in which both level groups were least compliant. This is a crucial criterion since according to WHO: it is imperative that hospitals remain structurally sound and fully operational in times of disaster.[9] For emerging or less common emergency scenarios, standard operating procedures were important in achieving emergency preparedness while knowledge gained from training was the basis for familiar emergencies; thus, policy makers should identify the essential knowledge and skills and emphasize them in training programs.[11] It is also important that the administrators monitor and update their emergency operations plans regularly to maintain a constant state of preparedness and ensure appropriate response.[12] Early detection and identification of a public health emergency are important objectives for prompt and effective public health response to an emergency.[13] Since all hospitals experience threats, an emergency preparedness plan

must include a "hazard vulnerability analysis" to determine the most likely emergency scenarios to be addressed by the hospital.[14]

During the 2011 Great East Japan Earthquake and Tsunami (GEJET), hospitals learned first-hand the importance of adopting hospital disaster preparedness. After that incident, the Japanese saw the importance of conducting routine disaster drills, or exercises and training for various emergencies.[7] This category is of crucial importance to mobilize the health teams and ensure that they were knowledgeable and skilled to deliver health care to victims of emergencies and natural disasters. This area should be assessed and improved by the administrators of the select hospitals.

For level III hospitals, organization, management and human resources was the second criteria they were not compliant with. It was noted that only a few hospitals among those who participated in the study had a designated disaster team. Usually, it was just delegated to whoever was available and interested in the position. This practice was also seen in some hospitals in Manila. A study conducted in a major hospital in Manila showed low level of knowledge among the emergency medicine department staff on disaster planning and emergency preparedness. None of them even saw the disaster plan of this hospital.[15] A study conducted by the former National Association of Public Hospitals and Health Systems (NAPHHS), now called America's Essential Hospitals, stated that a hospital's response to an emergency depends on its internal readiness. All the members of the association are required to have an internal emergency preparedness planning committee that collects input from multiple departments about preparedness efforts within the facility and is in charge of discussing drills, updating the emergency response plan and prioritizing preparedness efforts. This type of organization may be beneficial in ensuring each hospital's preparedness.[14]

The Government of India acknowledged the importance of medical authorities especially disaster team leaders together with the chief medical directors in providing the emergency plans applicable to the hospital.[16] Moreover, hospitals need to communicate and cooperate with other local health agencies, to function as a networked public health provider. The lack of communication and coordination between hospital departments and inter-agency networks impede the availability and distribution of resources in a community and hinder public communication and effective handling of a public health emergency.[13] Healthcare executives should take part and be active in planning and creation of systems and processes to make sure that the plan can be effectively and efficiently executed as stated by American College of Healthcare Executives. Also, they should have clear and defined roles during the pre-disaster and disaster phase. During the pre-disaster phase, they should be the ones to assess the available medical resources within their area and to be able to share them to neighboring areas. For the disaster phase, they should play the leading role in medical treatment of the victims. The chief medical director should be in command and should set up a medical team that can work with the local government.[12]

Another functional indicator where level I and II hospitals were least compliant was on the back-up system. During the Great Earthquake in Japan, the most affected installations in the hospitals that were affected were water and electricity supply. Hospitals in Tohoku region responded that they could provide electricity, food, and water supply for a range of 3-14 days during a disaster. Enough stocks of critical supplies likely supported hospital preparedness. In terms of communication, having alternative communication devices as backup than reliance on one communication method was a good indicator of hospital preparedness.[7] A combination of communication tools in an emergency can be used to establish redundancy which may ensure coverage in case one system fails.[14] In a study on the reliability of telecommunication systems in Miyagi, Japan, satellite mobile phones and multi-channel access wireless systems were more reliable than ordinary systems during major disasters. It was pointed out that it was essential to distribute reliable disaster communication equipment to hospitals and plan for situations in which hospital telecommunications systems do not function.[17]

For levels I and II private hospitals, the six hospitals involved were compliant with all of the parameters except for hospital emergency preparedness, response, and recovery plan. It was found that only half of six hospitals had sites for temporary placement of dead bodies for forensic medicine. Managing dead bodies was one of the basic activities that local authorities should concentrate immediately following a disaster.[18] The proper handling of dead bodies was important for public

hygiene, cultural and religious implications, and for forensic work. Correct identification of the dead was significant for legalities of inheritance and insurance that has major effect on families and communities.[19]

The three public hospitals from level I and II category showed no compliance on basic equipment and supplies, and available back-up system. Under basic equipment and supplies, only one hospital has available material safety data sheets. The material safety data sheet or "MSDS" is a document in the laboratory that contains information on potential hazards, such as in health, fire, reactivity, and environment. It also contains guidelines on how to handle safely the chemical product. Its importance had been shown in every laboratories or institutions, which houses dangerous chemicals. Chemicals, if not handled properly, may have detrimental effects on health and environment.[20] Availability of a back-up system was also deemed important as mass casualties result in higher demands for basic human needs such as water. Most of the hospitals involved in this category showed lack in services such as source of drinking water, fuel reserves, and solid waste treatment. In order for these hospitals to sustain a number of people in the institution in cases of emergencies, these services must be fulfilled, or there should be an external source that can provide these services.

For level III, the four private hospitals were found to be least compliant with hospital emergency preparedness, response, and recovery. Subcategories found to have least compliance includes, psychological support to all personnel, handling of volunteers during disasters, and waste management program during disasters. According to the WHO, extreme stressors brought about by disasters cause social and mental health problems among victims and health personnel. It was therefore recommended to ensure mental health in primary health care and community care services to meet basic health needs. Psychological support for all volunteers should also be implemented, as they were working long hours, risking their lives under stressful conditions.[21] They serve as the first responders in managing victims, making them vulnerable to depression or exhaustion. Aside from these, volunteers should be encouraged and promoted, and recognized. Recognition may come in a simple gesture, a speech at public gathering, free pubic transport, new uniforms, or scholarships to public universities. Insurance was another issue that concerns majority of volunteers, as they are the ones who always face danger, and it was only right that they should be provided with free medical assistance or compensation in case of his or her death.[22]

Another subcategory lacking compliance was waste management program during disasters. There were health hazards involved in wastes not properly disposed. Every hospital must have a mode of collection and disposal of wastes. Personnel working on waste management must be protected through the provision of masks, gloves, boots, and vaccination.[23] Five public hospitals from level III were least compliant with organization, management, and human resources. Under this, public education campaign was seen as having one of the least compliance among the subcategories. Public education campaigns in hospitals were designed to inform an audience about a disaster preparedness and emergencies. These mainly included IEC (information, education, and communication) materials. This was important as this targeted change in behavior, and social awareness among patients, and health workers.[24]

Another subcategory seen to have least compliance was capability of building of personnel and managers trained in hospital emergency incident command system (HEICS) and hospital emergency response training (HERT). These two subcategories primarily correspond to the training, drills, and exercises among personnel in preparation for a disaster. Personnel and staff training included basic life support (BLS) and cardiopulmonary resuscitation (CPR) training, standard first aid, advanced cardiac life support (ACLS) and pediatric advanced cardiac life support (PACLS), personnel trained as emergency medical technicians (EMT), in incident command system (ICS), mass casualty incident (MCI), and earthquake drills. A hospital that was capable of responding to disasters were composed of trained personnel that could handle the surge of patients during a disaster.[25]

This study only covered the functional indicators section of the DOH checklist on disaster preparedness. The researchers thus recommend covering the structural and non-structural parameters of hospital disaster preparedness. It is recommended also that given the time and resources, extensive data validation can be done to further evaluate the hospitals. This can include photographs and gathering of legal

documents to support each answer by the point person in the hospital.

In this study, hospital preparedness came last in terms of the criteria for functional indicators. Part of this criterion involves training of personnel for emergency preparedness. The researchers then recommend a random survey to the actual workforce of hospitals which include nurses, doctors, medical technologists, etc. to further validate the answers in this study which were answered only by the hospital engineer, medical director, or any persons knowledgeable in their respective hospitals. Once extensive validations such as these are performed, this study can be further used as a baseline data for further improvement of hospitals involved in this study. Likewise, data from this study can be used as reference by the other hospitals inside and outside NCR, especially those which are located in highly vulnerable locations.

Under Section 9 of RA 4226 "Hospital Licensure Act," hospitals must procure a license to operate from the Bureau of Health Facilities and Services from the Department of Health. Based on the requirements set by the DOH, the only disaster which the hospitals are required to be prepared for is for fire. Though other requirements include photographs of the exterior and interior of the facility and an inspection by the Director of the Center for Health Development, these may not be deemed sufficient to check for disaster preparedness. In line with the research and its results, it is recommended that disaster preparedness for any kind of disaster such as fire, floods and earthquakes be made part of the requirements for the registration and application for a license to operate.

It is recommended to locate and trace hospital's geographical setting whether it is within the fault line or flood prone area. This will enable the determination of whether hospitals are part of the "core hospitals'' that will provide immediate primary care during disasters. It is also recommended that that the results of this study can be used by an independent body or organization to recognize formally those hospitals which are compliant to DOH criteria for disaster preparedness and tag those which can serve as proper emergency centers during disasters. This could eventually be used as a requirement by the DOH for licensing hospitals to get their accreditation. For the Department of Health, the researchers recommend revisions for hospital accreditation, i.e. inclusion of hospital's compliance to disaster preparedness. In line with this, it is also recommended that stricter granting of accreditations be in place, especially that higher tier hospitals are expected to have higher standards with regards to patient's welfare and safety.

For the hospitals, to ensure compliance of the hospital to the DOH checklist, a special committee must be made who shall oversee functional and structural factors relating to hospital and patient safety during disasters. This committee should report to the DOH, and the DOH, in turn, must publicize to inform the public which hospitals are disaster-ready.

With only 11 out of 18 of the selected hospitals compliant with the functional indicators by the Department of Health, improvements must be made to the health sector since they will be one of the frontrunners during disaster events and post-disaster responses. Communities turn to hospitals in times of disaster, not only to care for the ill and injured, but also to provide food and shelter and most importantly, to coordinate recovery. Having a health sector that is unprepared means that disaster response in a municipality, city, or region would be very slow, and as such, recovery will be vastly delayed.

Taking the individual functional indicators by DOH into consideration, hospitals of all levels complied best to site and accessibility, and internal circulation and inter-operability, which are steps towards a more compliant health sector. However, it is in hospital emergency preparedness, response and recovery plan where both level groups are least compliant with. Hospital emergency preparedness is very important since it ensures appropriate response and recovery within short possible time frames. It is also in this aspect where integration with other organizations and appropriate agencies at the local, regional and national levels start. This facilitates a more efficient recovery process and most importantly, it ensures that advancing community health is a fully integrated strategic priority. However, this does not mean that it is only in this criteria of functional indicators by DOH needs to be improved. Based on the results, 7 of the 18 select hospitals are still non-compliant, and thus the need for improvement for all functional indicators.

Acknowledgements

The authors would like to thank their advisers Dr. Georgina Paredes, Dr. Ma. Penafrancia

Adversario and Dr. Lino Santiago Pabillo for their guidance and advice.

References

1. Time: Current & Breaking News. The Philippines is the most storm-exposed country on earth. 11 Nov 2013. Retrieved from: http://world.time.com/2013/11/11/the-philippines-is-the-most-storm-exposed-country-on-earth/. [Accessed Sept 17, 2014].
2. Japan International Coordination Agency. Earthquake Impact Reduction Study for Metropolitan Manila, Republic of the Philippines. Manila: Metropolitan Manila Development Agency and Philippine Institute of Volcanology and Seismology; 2004. Retrieved from: http://ndrrmc.gov.ph/attachments/article/1472/Earthquake_Impact_Reduction_Study_Volume_1.PDF. [Accessed Sept 2014].
3. World Health Organization. Protecting Hospitals and Health Centres before Disas-ters Saves Lives. Geneva: World Health Organization; 2010. Retrieved from: http://www.who.int/mediacentre/news/notes/2010/disaster_reduction_20101013/en/ [Accessed Sept 17, 2014].
4. Department of Budget and Management. Revised Organizational Structure and Staffing Standards for Government Hospitals. Manila: Department of Budget and Management and Department of Health; 2013. Retrieved from: http://www.dbm.gov.ph/?page_id=5894. [Accessed July 2015].
5. Department of Health. Safe Hospitals in Emergencies and Disasters: Philippine in-dicators for Level 1 to 4 hospitals. Manila: Department of Health; 2011. Retrieved from: http://hems.doh.gov.ph/uploads/publication_attachments/1c93ee7879774fea1ec32f87bbf80716a4ec39db.pdf. [Accessed Aug 14, 2014].
6. Oreta AW. Emergency and Disaster Preparedness for Health Facilities. Guidance Notes. New Delhi: Government of India; 2010. Retrieved from: http://www.unisdr-apps.net/confluence/download/attachments/4554883/1MSSH_GuideNotes_Hospital-Preparedness_060210.pdf. [Accessed Aug 14, 2014].
7. Mulyasari F, Inoue S, Prashar S, Isayama K, Basu M, Srivastava N, Shaw R. Disas-ter preparedness: looking through the lens of hospitals in Japan. International Jour-nal on Disaster Risk Sciences 2013; 4(2): 89-100. Retrieved from: http://link.springer.com/article/10.1007%2Fs13753-013-0010-1. [Accessed Aug 14, 2014].
8. Bajow N, Alkhalil S. Evaluation and analysis of hospital disaster preparedness in Jeddah. Health 2014; 6(19): 2668-87. Retrieved from: http://www.scirp.org/journal/PaperInformation.aspx?paperID=51588#.VbEfTfmqqko. [Accessed July 5, 2015].
9. World Health Organization Regional Office for the Western Pacific. Safe Hospitals in Emergencies and Disasters, Structural, Non-Structural and Functional Indicators. WHO Western Pacific Region; 2010. Retrieved from: http://www.wpro.who.int/emergencies_disasters/documents/SafeHospitalsinEmergenciesandDisasterswebоptimized.pdf. [Accessed July 5, 2015].
10. American Hospital Association. Hospital Emergency Preparedness and Response; 2014. Retrieved from: http://www.aha.org/content/14/ip-hospemerprepared.pdf. [Accessed July 5, 2015].
11. Adini B, Goldberg A, Cohen R, Laor D, Bar-Dayan Y. Evidence-based support for the all-hazards approach to emergency preparedness. Isr J Health Policy Res 2012; 1(40). Retrieved from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3494498/. [Accessed July 5, 2015].
12. American College of Healthcare Executives. Healthcare Executives' Role in Emer-gency Preparedness; 2013. Retrieved from: http://www.ache.org/policy/emergency_preparedness.cfm. [Accessed July 5, 2015].
13. Li X, Huang J, Zhang H. An analysis of hospital preparedness capacity for public health emergency in four regions of China: Beijing, Shandong, Guangxi, and Hainan. BMC Public Health 2008; 8(319). Retrieved from: http://www.biomedcentral.com/content/pdf/1471-2458-8-319.pdf. [Accessed July 5, 2015].
14. Spieler SS, Singer MP, Cummings L. Emergency preparedness in public hospitals. Washington DC: National Association of Public Hospitals and Health Systems; 2008. Retrieved from: http://essentialhospitals.org/wp-content/uploads/2014/02/EP-Study.pdf. [Accessed July 5, 2015].
15. Gundran CP. Knowledge, attitudes, and practices of the Department of Emergency Medicine employees regarding disaster planning and preparedness at UP-Philippine General Hospital. Research Gate 2014. Retrieved from: http://www.researchgate.net/publication/260312271. [Accessed July 5, 2015].
16. Government of India. Guidelines of hospital emergency preparedness planning. New Delhi: Government of India; 2008. Retrieved from: http://www.preventionweb.net/files/15007_doc18033contenido.pdf. [Accessed July 10, 2015].
17. Kudo D, Furukawa H, Nakagawa A, Abe Y, Washio T, Arafune T, et al. Reliability of telecommunications systems following a major disaster: Survey of secondary and tertiary emergency institutions in Miyagi Prefecture during the acute phase of the 2011 Great East Japan Earthquake. Prehosp Disaster Med 2014; 29(2): 204-8. Re-trieved from: http://www.ncbi.nlm.nih.gov/pubmed/24555870. [Accessed July 10, 2015].
18. World Health Organization. Management of Dead Bodies in Disaster Situations. Ge-neva: World Health Organization; 2015. Retrieved from: http://www.who.int/hac/techguidance/management_of_dead_bodies.pdf. [Accessed Sept 26, 2015].
19. Morgan O. Management of Dead Bodies after Disasters. International Federation of Red Cross and Red Crescent Societies. 2015. Retrieved from: https://www.icrc.org/eng/assets/files/other/icrc-002-0880.pdf. [Accessed Sept 25, 2015].
20. University of Toronto Environmental Health and Safety. Material Safety Data Sheets (MSDS). 2015. Retrieved from: http://www.ehs.utoronto.ca/resources/whmis/whmis11.htm. [Accessed Sept 25, 2015].
21. World Health Organization. Disaster Risk Management for Health: Mental health and Psychosocial Support. 2015. Retrieved from: http://www.who.int/hac/events/drm_fact_sheet_mental_health.pdf. [Accessed Sept 26, 2015].

22. International Federation of Red Cross and Red Crescent Societies. Volunteering in Emergencies. 2015. Retrieved from: https://www.ifrc.org/PageFiles/41321/Volunteering%20in%20emergency_EN-LR.pdf. [Accessed Sept 26, 2015].
23. World Health Organization. Solid Waste Management in Emergencies. 2015. Re-trieved from: http://www.who.int/water_sanitation_health/publications/2011/tn7_waste_mangt_en.pdf. [Accessed Sept 26, 2015].
24. California Department of Pesticide Regulation. A Public Education Campaign. 2015. Retrieved from: http://www.cdpr.ca.gov/docs/specproj/h2o/workbook/section1/page5.html. [Accessed Sept 26, 2015].
25. Gage L. Hospital staffing and surge capacity during a disaster event. Research Brief. 2015. Retrieved from: http://essentialhospitals.org/wp-content/uploads/2014/10/May2007_Research_Brief.pdf. [Accessed Sept 26, 2015].

A randomized double-blind placebo-controlled trial on the effects of Capsicum annum as an adjunct for reducing blood pressure among hypertensive patients

Fidela Anne P. Salvador; Carmela A. Salvaña; Alexandra S. Sedano; Franklin John C. Yap; Loraine Alexis G. Yap; Maria Dawn Rosary B. Yap; Angelica Mae G. Yee, RPh; Carol Angeline G. Yu; Paulino Nathaniel H. Zamesa III, RN; Rachel Ann N. Zapanta, RN; Jose Ronilo G. Juangco, MD MPH FPSVI (Adviser) and Maribeth T. Delos Santos, MD, FPCP (Content Adviser)

Abstract

Introduction This study aimed to determine the efficacy and safety of capsaicin capsules from Capsicum annum as an adjunct to medications in controlling hypertension.

Methods Forty adults with stage I or II hypertension were randomized to receive either 500 mg capsaicin or placebo capsules on top of their maintenance medications for four weeks. Post-intervention blood pressure was compared the baseline within and between groups. Treatment success and side effects were also determined.

Results There was a statistically significant decrease in the AM diastolic and AM systolic blood pressures of the capsaicin and placebo groups after four weeks. However, intergroup analysis showed no significant difference between capsicum and placebo. The capsaicin group had a higher risk of developing local GI irritation symptoms (RR = 4.75) than the placebo group.

Conclusion Capsaicin, at the dose and frequency used in the study, is not effective as an adjunct to medications in the management of hypertensive patients.

Key words: Capsaicin, hypertension, blood pressure

Hypertension is one of the risk factors for cardiovascular disease in the Philippines and worldwide.[1] According to the 8th National Nutrition Survey of 2013, 22.3% of Filipinos were considered hypertensive.[2] Clinical practice guidelines recommend diet and lifestyle modification as well as medications for the control of hypertension.[3] The Presyon 3 Report of the Council on Hypertension says that awareness, treatment, and compliance in the Philippines are low but this could be addressed. Poor control rates are observed among the hypertensive patients who are aware and are taking maintenance medications.[4]

There are many drugs, maintenance medications, and interventions for hypertension.[5] Chili pepper *Capsicum annum*, locally known as *siling labuyo*, is a

Correspondence:
Fidela Anne P. Salvador, Department of Preventive and Community Medicine, College of Medicine, University of the East Ramon Magsaysay Memorial Medical Center Inc., Aurora Boulevard, Barangay Doña Imelda, Quezon City 1113; E-mail: fidesalva@yahoo.com; Telephone: 9175727075

plant that is affordable and widely available in the Philippines. Its principal ingredient is capsaicin.[6] It has folkloric health benefits: swallowing whole pieces of *siling labuyo* is said to decrease blood pressure. This study aimed to determine the efficacy and safety of *Capsicum annum* capsules containing capsaicin, as an adjunct to current antihypertensive medications in controlling hypertension.

Methods

This was a 4-week randomized double blind, placebo-controlled clinical trial comparing the efficacy and safety of capsaicin capsules with placebo as an adjunct to medications in controlling blood pressure among adult hypertensive patients from San Juan City. The treatment and control groups were given *Capsicum annum* and placebo capsules, respectively, in addition to their usual antihypertensive medications. The difference in blood pressure from the baseline within and between groups was determined after the intervention period. The Ethics Review Committee approved the study.

Subjects were recruited through interview and selected based on the following criteria: (1) previously diagnosed with stage I or II hypertension by a physician; (2) on antihypertensive maintenance prescription medications for at least one year with strict compliance and adherence; (3) age 35 to 75 years; (4) resident of Barangay San Perfecto, San Juan City for the past 5 years; and (5) signed the Informed Consent Agreement prior to enrollment in the study. The exclusion criteria were: (1) terminal illness, (2) hypersensitivity to capsaicin capsules, (3) pregnancy, and (4) cognitive impairment affecting the subject's ability to give consent. The computed sample size was 20 subjects per group for a total of 40 subjects for both capsaicin and placebo groups based on the following parameters: confidence level of 95%, standard deviation of 14.63[9] and a difference of 10.

The treatment and control groups were given *Capsicum annum* and placebo capsules, respectively, on top of their current antihypertensive medications and monitored for four weeks.[7] Strict compliance and adherence was ensured by direct observation. The blood pressures (BP) of subjects from the capsaicin and placebo groups were compared for significant differences. A decrease in the systolic blood pressure of at least 10 mm Hg was considered significant. The occurrence of side effects of *Capsicum annum* capsules was noted.

The data collection had four phases: (1) obtaining a list of persons with hypertension in Brgy. San Perfecto, (2) obtaining the demographic profile of the subjects and baseline blood pressure, (3) blood pressure measurements of the patients taken twice a day during the observation period, and (4) collecting data pertaining to the adverse reactions of capsaicin capsules.

The researchers determined the baseline blood pressure by computing the mean of six measurements taken in the morning and evening of three consecutive days prior to the experiment proper.[3, 11-13] The researchers ensured adequate preparation of the environment and patient for blood pressure determination using a standard apparatus (Welch Allyn and Baxtel) and procedure. Subjects should not have smoked or ingested caffeine 30 minutes prior to measurement.[14] The palpatory BP was determined before the auscultatory BP. The cuff was inflated 30mmHg higher than the palpatory reading and deflated at 2-3 mm Hg per second for measurement of the auscultatory BP. Readings were taken twice after an interval of 10 minutes. If the difference between the two readings was more than 5 mm Hg, a third reading was taken; the average of the three determinations was then computed and recorded.

The researchers requested *Capsicum annum* and placebo capsules from Mount Halcon Organics, through New Yenyin Trading, and Interchemex, respectively. The subjects were asked to take one 500 mg capsaicin or placebo capsule every morning in front of the researcher assigned to measure the blood pressure, while still continuing their current maintenance medications. This was done to limit possible adverse effects that may be experienced by the subjects and to ensure strict compliance and adherence of the subjects to their maintenance and capsaicin or placebo drug medications. The researchers measured blood pressure twice a day: every morning and late afternoon for 4 weeks.

Pearson's chi-square and Fisher's exact test were used to determine significant differences in nominal variables. An independent t-test was used for the blood pressure and other continuous data. A dependent samples t-test was used to compare the post-hoc and baseline BP in each group. Missing data was imputed before the baseline and weekly blood pressure readings for each treatment and were

compared using factorial repeated measures analysis of variance (ANOVA). Significance was computed using a post-hoc Bonferroni adjustment for multiple comparisons. The relative risk for treatment success was computed and significance was determined using Fisher's exact test. Treatment success was defined as a decrease in BP of at least 10 mm Hg. Alpha was set at 0.05 for 2-tailed tests. The researchers also computed hazard ratios and number needed to treat for the adverse reactions. IBM SPSS 19 was used for statistical computations.

Results

The capsaicin and placebo groups initially consisted of 20 subjects each. There were four dropouts in the capsaicin group and one in the placebo group. Both groups were comparable in terms of sex ratio, age mean, BMI, number of diabetics and smokers, as shown in Table 1. Most subjects from both groups were on monotherapy, the most common being a calcium channel blocker. The baseline blood pressures at different times of the day were similar except for the PM systolic blood pressure, which was significantly higher in the capsaicin group.

As shown in Figure 1, the daily AM and PM systolic and diastolic blood pressure readings of the two groups were similar. There was a significant decrease in the post intervention AM diastolic and AM systolic blood pressures of the capsaicin and placebo groups, respectively (Table 2). When the change in blood pressure between the two groups was compared, the difference was not significant (Table 3). Determination of treatment success did not favor the capsaicin group as shown in Table 4.

Half of the subjects in the capsaicin group experienced gastrointestinal side effects including heartburn, feeling of warmth in the stomach, hyperacidity, and spicy sensation when burping. Those taking capsaicin capsules were almost five times more prone to develop gastrointestinal side effects compared with the placebo group (p = 0.02)

Table 1. Comparison of baseline characteristics of capsaicin and placebo groups.

	Placebo (n=20)	Capsaicin (n=20)	p-value
Sex: female	14	11	0.51++
Age	58.4 ± 11.89	59.5 ± 12.08	0.77+
BMI	25.8 ± 4.69	27.3 ± 5.82	0.39+
Diabetic	4	4	1.00++
Smoker	3	5	0.70++
Type of therapy			0.60+++
Monotherapy	19	18	
Dual therapy	1	1	
Triple therapy	-	1	
Drugs used++++			0.73+++
ARB	4	5	
Beta blocker	3	5	
CCB	13	12	
ACEi	1	-	
Alpha agonist	-	1	
Baseline BP			
AM systole	135.3 ± 9.79	137.4 ± 16.31	0.63+
AM diastole	81.8 ± 9.66	81.1 ± 11.54	0.84+
PM systole	130.2 ± 11.96	139.6 ± 15.63	0.04+,*
PM diastole	78.6 ± 10.09	80.1 ± 10.56	0.65+

Alpha = 0.05, 2-tailed
* significant difference
+ Independent samples t-test
++ Fisher's exact test
+++ Pearson's chi-square
++++ Drugs used: ARB - Angiotensin receptor blocker, CCB - Calcium channel blocker, ACEi - Angiotensin converting enzyme inhibitor

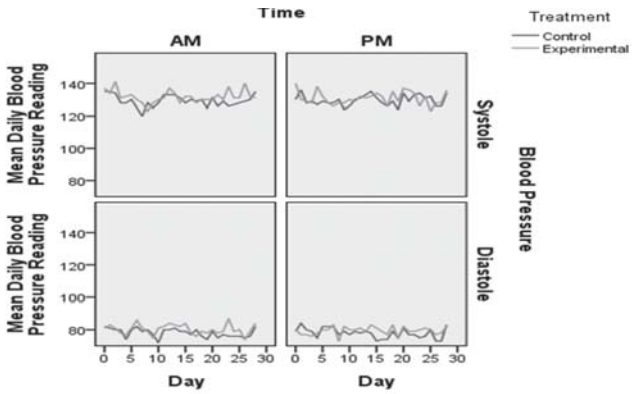

Figure 1. Mean daily blood pressure readings for the control and experimental groups by time of BP measurement.

as shown in Table 5. The placebo group was generally spared of side effects.

Discussion

The objective of this study was to determine the effectiveness of *Capsicum annum* capsules as an adjunct to current medications in controlling hypertension. The results suggest that *Capsicum annum* capsules are not different from placebo when used as an adjunct to medications in the management of hypertension.

Yang reported that capsaicin lowers blood pressure by activating TRPV1, a receptor that allows the transient influx of cations especially Ca^{2+}, on

Table 2. Mean post-study blood pressure reading and the p-value when compared to the baseline using dependent samples t-test employing ITT.

	Baseline		Post-study reading		Difference (95% CI)		p-value	
	Placebo	Capsaicin	Placebo	Capsaicin	Placebo	Capsaicin	Placebo	Capsaicin
AM systolic	135.3 ± 9.79	137.4 ± 16.31	130.5 ± 9.63	137.4 ± 19.48	4.8 (0.91, 8.69)	0 (-6.72, 6.72)	0.02*	1.00
AM diastolic	81.8 ± 9.66	81.1 ± 11.54	78.8 ± 11.24	75.6 ± 13.60	3.05 (-0.11, 6.21)	5.53 (0.75, 10.30)	0.06	0.03*
PM systolic	130.2 ± 11.96	139.6 ± 15.63	127.9 ± 9.85	135.4 ± 14.70	2.26 (-1.29, 5.82)	4.2 (-0.41, 8.81)	0.20	0.07
PM diastolic	78.6 ± 10.09	80.1 ± 10.56	76.2 ± 10.31	77.8 ± 11.35	2.42 (-0.01, 4.85)	2.3 (-1.65, 6.25)	0.05	0.24

Table 3. Comparison of change in blood pressure reading for the capsaicin and placebo groups at different times of day.

	Placebo	Capsaicin	Difference (95 % CI)	p-value
AM systole	-4.95 ± 1.91	-0.10 ± 3.06	- 4.85 ± 3.60 (-2.45, 12.15)	0.19
AM diastole	-3.10 ± 1.54	-5.35 ± 2.20	-2.25 ± 2.68 (-7.69, 3.19)	0.41
PM systole	-2.30 ± 1.64	-4.20 ± 2.20	-1.90 ± 2.74 (-7.46, 3.66)	0.49
PM diastole	-2.35 ± 1.12	-2.30 ± 1.89	0.05 ± 2.20 (-4.40, 4.50)	0.98

Table 4. Relative risk for treatment success for each BP measurement.

	Treatment success	Treatment failure	Relative risk for treatment success (95% CI)	p-value[a]
AM systole			0.43	
Capsaicin	3	17	(0.13, 1.43)	0.27
Placebo	7	13		
AM diastole			0.67	
Capsaicin	2	18	(0.12, 3.57)	1.00
Placebo	3	17		
PM systole			0.80	
Capsaicin	4	16	(0.25, 2.55)	1.00
Placebo	5	15		
PM diastole			3.00	
Capsaicin	3	17	(0.34, 26.46)	0.61
Placebo	1	19		

[a] Fisher's exact test, alpha = 0.05, 2-tailed

Table 5. Side effects reported, hazard ratio, and number needed to harm.

	With side effects	No side effects	Hazard ratio (95% CI)	Number needed to harm (95% CI)	p-value[a]
Local GIT					
Capsaicin	8	8	4.75	2.53	
Placebo	2	17	(1.17, 19.25)	(1.59, 10.93)	0.02[b]
General warm feeling					
Capsaicin	1	15	0.59	23.38	
Placebo	2	17	(0.06, 5.96)	(-3.88, 5.24)	1.00
Blurring of vision					
Capsaicin	1	15	Undefined	16	
Placebo	0	19	(0.31,^{oo})	(-9.92, 3.53)	0.46
Nausea					
Capsaicin	1	15	Undefined	16	
Placebo	0	19	(0.31,^{oo})	(-9.92, 3.53)	0.46

[a] Fisher's exact test, alpha = 0.05, 2-tailed
[b] Significant difference

endothelium channels.[16] This receptor can only be activated through heat, acid, vanilloids, gingerol, and endocannabinoids. Capsaicin, the major component in *siling labuyo*, contains a vanillyl group that helps activate TRPV1 on the peripheral neurons. Activation of TRPV1 increases Ca^{2+} influx and subsequently elevates the phosphorylation of PKA and eNOS in the endothelial channels and plasma nitric oxide (NO) concentrations. NO is an important protective molecule in the vasculature by dilating blood vessels through stimulation of guanylyl cyclase and cGMP in the smooth muscle. As a result, capsaicin induces a NO-dependent vasodilatation in mesenteric arteries and lowers arterial pressure in subjects with hypertension.

The blood pressure readings appear to have decreased from the baseline to the end of the experimental period for both treatment and control groups but a comparison of these decreases did not yield any significant difference between the two treatment groups. Even the baseline and post-study blood pressure readings, when compared statistically,

did not yield significant differences except for the AM systolic BP reading for the control group and the AM diastolic reading for the experimental group. The insignificance of the results may be due to the inadequate time of administration of the capsaicin capsules. This result is similar to the study by Yang.[16] Due to the limited amount of time to conduct the experiment proper and the lack of published studies on human subjects to determine the adequate treatment duration, the four-week intervention was adopted from a trial by Yamamoto.[7] A more evident decrease in blood pressure may have been observed if the treatment was administered for a longer time.[16]

Another problem encountered in the study was the uncertainty of the pharmacodynamic aspects of the drug because there are no studies on human subjects taking capsaicin for hypertension. According to the Open Heart Society, the clinically tolerable dosing of capsaicin in human hypertension has not been etablished.[17] In this study, 500 mg of capsaicin was used since this is the general marketed dose of capsaicin in the Philippines. It is possible that capsaicin will be effective if the dose or the frequency of administration is increased.

Another possible explanation for the results is its mechanism of action in combination to the current medication of the patient. As previously discussed, capsaicin induces a NO-dependent vasodilation to lower blood pressure in subjects with hypertension. Thus, when given as an adjunct to the current anti-hypertensive drug of the patient, most of which work to block vasoconstriction, it yielded an additive type of synergism wherein the final effect is similar to the magnitude of the effect of the individual drugs.

Among the problems encountered by the subjects was difficulty in tolerating the side effects of the drug. Most notable of these side effects were the local gastrointestinal symptoms. Gipetti,[18] Leung[19] and O' Neill[20] found that phosphatidylinositol 4,5-piphosphate (PIP_2), a membrane phospholipid required for a number of intracellular signaling pathways, is associated with TRPV1 in the plasma membrane. These receptors interact through C-fibers. PIP_2 was required for normal sensing of noxious heat. Thus, PIP_2 also produces a response once a TRPV1 receptor is stimulated by capsaicin. PIP_2 stimulation manifests as enhanced thermosensation and increased thermal hypersensitivity.[20] C-fibers, which are capable of sensing painful stimuli, are stimulated and the patient perceives pain. This also explains the warm sensation experienced by the patients after ingestion of capsaicin.

A patient with an untreated cataract experienced blurring of vision. Similarly, a number of patients also complained of syncope after intake of capsaicin capsules. These adverse reactions were the reason why some subjects dropped out. There were no studies showing the association of capsaicin with vision-related side effects.

An intention-to-treat analysis,[21] which reduces type I error and increases type II error, did not alter the interpretation of the results. The researchers conclude that capsaicin, at the dose and frequency used in the study, is not effective as an adjunct to medications in the management of hypertensive patients.

Acknowledgements

The authors would like to thank Kagawads Natividad Gruta and Neneng Madayag for accommodating them and assisting them in looking for participants in their community, Barangay San Perfecto, San Juan. They would also like to thank Ms. Martina Ysabel Sales for her major contributions in the research proposal. They also would like to thank Dr. Maribeth T. Santos, their content adviser, for imparting her expertise and their adviser, Dr. Jose Ronilo Juangco, for his guidance.

References

1. Agron E. Prevalence of hypertension among Filipinos increasing - PHS 2012 May; Available from: http://www.pchrd.dost.gov.ph/index.php/2012-05-23-07-46-36/2012-05-24-00-01-11/5047-prevalence-of-hypertension-among-filipinos-increasing-pshhttp://www.pchrd.dost.gov.ph/index.php/2012-05-23-07-46-36/2012-05-24-00-01-11/5047-prevalence-of-hypertension-among-filipinos-increasing-psh. [Accessed Sept 17, 2014].
2. Food and Nutrition Research Institute Department of Science and Technology. Burden of selected risk factors to noncommunicable disease among Filipino adults. Taguig, Philippines: Food and Nutrition Research Institute Department of Science and Technology; 2013. Available from: http://obesity.org.ph/v4/wp-content/uploads/2013/04/8thNNSResultsNCD.pdf. [Accessed Aug 5, 2015].
3. Rosendorff C, Black H, et al. Treatment of hypertension in the prevention and management of ischemic heart disease. American Heart Association 2007; 50: e28-e55. Available from: http://hyper.ahajournals.org/content/50/2/e28.full. [Accessed Aug 12, 2014].
4. Sison JA, Yape I, et al. Presyon 3: Report of the Council on Hypertension. Philippine Heart Association; 2013. Available from: http://www.philheart.org/44/images/sison.pdf. [Accessed Aug 28, 2015].

5. Katzung B, Masters S, Trevor A (editors). Basic and Clinical Pharmacology. 12th ed. New York: The McGraw-Hill Companies Inc; 2012.
6. Surh Y. More than spice: capsaicin in hot chili peppers make tumor cells commit suicide. Journal of the National Cancer Institute 2002; 94(17): 1263-5. Available from: http://jnci.oxfordjournals.org/content/94/17/1263.long. [Accessed Aug 12, 2014].
7. Wu H, Zhang Y, Huang J, et al. Clinical trial of arotinolol in the treatment of hypertension: dippers vs. non dippers. Jap Soc Hypertens 2001; 24(5): 605-10.
8. World Health Organization. Prevention of Cardiovascular Disease: Guidelines for Assessment and Management of Cardiovascular Risk; Geneva: World Health Organization; 2007; Available from: http://apps.who.int/iris/bitstream/10665/43786/1/9789241547253_eng.pdf?ua=1. [Accessed May 27, 2015].
9. Ongtenco I, Morales D, Sanderson J, et al., Persistence of the antihypertensive efficacy of amlodipine and nifedipine GITS after two 'missed doses': A randomised, double-blind comparative trial in Asian patients. J Hum Hypertens 2002; 16: 805–13. Available from: http://www.nature.com/jhh/journal/v16/n11/pdf/1001485a.pdf. [Accessed May 27, 2015].
10. British Society of Hypertension. Blood Pressure Measurement Recommendations on the 2007 DVD 2007; Available from: http://www.bhsoc.org/files/5413/3483/0433/DVD_script.pdf. [Accessed May 29, 2015].
11. Philippine Society of Hypertension. Philippine Clinical Practice Guidelines on the Detection and Management of Hypertension 2011 (also known as the 140/90 Report); Pasig, Philippines; 2011. Available from: http://www.thefilipinodoctor.com/cpm_pdf/CPM15th%20HYPERTENSION%20(PSH).pdf. [Accessed May 28, 2015].
12. Mancia G, Fagard R, Narkiewicz K, et al. ESH/ESC Guidelines for the management of arterial hypertension. European Heart Journal 2013; 34(28): 2108-9. Available from: http://eurheartj.oxfordjournals.org/content/ehj/34/28/2159.full.pdf. [Accessed May 29, 2015].
13. O'Briena E, Atkinsb N, Stergiouc G, et al. European Society of Hypertension International Protocol Revision 2010 for the Validation of Blood Pressure Measuring Devices in Adults 2010. Available from: http://www.dableducational.org/pdfs/ESH-IP%202010%20Protocol.pdf. [Accessed May 29, 2015].
14. Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals. Hypertension 2004; 45: 142-61. Available from: http://hyper.ahajournals.org/content/45/1/142.full.pdf+html. [Accessed May 29, 2015].
15. Sogut O, Kaya H, Gokdemir T, Sezen Y. Acute myocardial infarction and coronary vasospasm associated with the ingestion of cayenne pepper pills in a 25-year old male. International Journal of Emergency Medicine 2012; 5: 5. Available from http://link.springer.com/article/10.1186/1865-1380-5-5. [Accessed Aug 2015].
16. Yang D, Lou Z, Ma S, et al. Activation of TRPV1 by dietary capsaicin improves endothelium-dependent vasorelaxation and prevents hypertension. Cell Metabolism 2010; 12(2): 130-41. Available from: http://www.ncbi.nlm.nih.gov/pubmed/?term=Activation+of+TRPV1+by+dietary+capsaicin+improves+endothelium-dependent+vasorelaxation+and+prevents+hypertension. [Accessed Sept 11, 2015].
17. McCarty MF, DiNicolantonio JJ, O'Keefe JH. Capsaicin may have important potential for promoting vascular and metabolic health. Open Heart 2015 June; 2(1): e000262. Available from: http://openheart.bmj.com/content/2/1/e000262.full. [Accessed Aug 12, 2015].
18. Gipetti P, Holzer P. Neurogenic Inflammation. CRC Press; 1996.
19. Leung FW. Capsaicin as an anti-obesity drug. Prog Drug Res 2014; 68: 171-9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24941669. [Accessed Aug 12, 2015].
20. O' Neill J, Brock C, et al. Unravelling the mystery of capsaicin: A toll to understand and treat pain. ASPET Journals 2012; 64(94): 939-71. Available from: http://pharmrev.aspetjournals.org/content/64/4/939.full. [Accessed Aug 5, 2015].
21. Olivo SA, Warren S, Magee DJ. Intention to treat analysis, compliance, drop-outs and how to deal with missing data in clinical research: A review. Physical Therapy Reviews 2009; 14(1): 36-49.

Instructions to Authors

Aim and Scope

The UERMMMCI Health Sciences Journal is a peer-reviewed journal published twice a year by the University of the East Ramon Magsaysay Memorial Medical Center Research Institute for Health Sciences. It publishes original articles, reviews, and editorials written by the faculty, trainees, students and personnel of the Medical Center.

Style of Papers

All contributions should be written in English. Papers should be written so as to be intelligible to the professional reader who is not a specialist in the field. The editor and his staff reserve the right to modify manuscripts to eliminate ambiguity and repetitions, and to improve communication between author and reader. If extensive alterations are required, the manuscripts will be returned to the author for revision. Therefore, to minimize delay in publication, manuscripts should be submitted in accordance with the instructions detailed herein. The author may refer to the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals available at www.icmje.org for additional guidance. The editor will not be held responsible for views expressed in this journal.

Submission of Manuscript

A copy of the manuscript, including tables and figures, should be submitted to the editor. The manuscript should be typed on short bond paper, in a single column, double-spaced all throughout, using Times New Roman or Arial 12. Tables, figures and illustrations should be in separate sheets (not embedded in the text). This should be accompanied by a cover letter containing the following: (1) corresponding author with complete contact details; (2) signed declaration by all authors of their involvement and willingness to take public responsibility for the paper's contents; (3) ethics approval when applicable; (4) declaration that the paper has not been published and is not under consideration for publication in another journal; (5) declaration of support/ funding when applicable; and (6) declaration of conflict of interest. To facilitate revision of the manuscript, the editor requires submission of an electronic copy in Microsoft Word.

All pages of the typed manuscript should be numbered, including those containing acknowledgments, references, tables, and figures. The manuscript should be arranged as follows: (1) title and list of authors, (2) abstract, (3) key words, (4) introduction, (5) methods, (6) results, (7) discussion, (8) acknowledgments, (9) support/funding, (10) conflict of interest declaration, (11) references, (12) tables, (13) figure legends, and (14) figures.

Title

The title should be as concise and informative as possible and should contain all key words to facilitate indexing and information retrieval. This should be followed by the list of authors' names to be written as follows: first name, middle initial, family name and highest academic degree. The sequence of names should be agreed upon by the authors. The department or institution of each of the authors should also be provided. Only those qualified based on the *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* should be listed as authors. The contact details of the corresponding author should be provided.

Abstract

This should be a concise structured summary consisting of the Introduction, Methods, Results and Conclusion. It should be no more than 200 words and include the purpose, basic procedures, main findings and principal

conclusions of the investigation. New and important information should be emphasized.

Key Words

Two to ten key words or phrases should be provided, which will assist in cross-indexing the article.

Introduction

This should contain a summary of the rationale and objectives of the study and provide an outline of pertinent background material. It should not contain either results or conclusions.

Methods

This should adequately describe the study design, population, selection process, randomization, blinding, study procedures, data collected and statistical methods used in data analysis.

Results

This should be presented in logical sequence in the text, tables, and figures avoiding repetitive presentation of the same data. Measurements should be in International System (SI) units. This section should not include material appropriately belonging to the discussion. Results must be statistically analyzed when appropriate.

Discussion

Data mentioned in the results should be explained in relation to any hypothesis advanced in the introduction. This may also include an evaluation of the methodology and the relationship of new information to previously gathered data. Conclusions should be incorporated in the final paragraph and should be commensurate with and completely supported by data gathered in the study.

Acknowledgments

Only persons who have made genuine contributions and who endorse the data and conclusions should be acknowledged. Authors are responsible for obtaining written permission to utilize any copyrighted text and/or illustrations.

References

References cited in the test shall be written as Arabic numerals in superscript in the order in which they appear in the text. Use the format in the *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* which is available at www.icmje.org. Titles of journals should be abbreviated in the reference list according to the style used in Index Medicus. Unpublished observations and personal communications may not be used as references. Examples of the correct manner of listing references are illustrated below:

Standard journal article
(List all authors when six or less; when seven or more, list only the first three then add et al.)

Francis D, Hadler SC, Thompson S, et al. The prevention of hepatitis B with vaccine: Report of the Centers for Disease Control multi-center efficacy trial among homosexual men. Ann Intern Med 1982; 97: 362-6.

Krugman S, Overby LR, Mushahwar IK, et al. Viral hepatitis type B: studies on the natural history and prevention reexamined. N Engl J Med 1979; 300: 101-6.

Nyland LJ, Grimmer KA. Is undergraduate physiotherapy study a risk factor for low back pain? A prevalence study of LBP in physiotherapy students. Retrieved from: http://www.Biomed-central.com/1471-2474/4/22. 2003. [Accessed August 27, 2011].

Rankin J, Tennant PW, Stothard KJ, et al. Maternal body mass index and congenital anomaly risk: A cohort study. Int J Obes 2010; 34(9): 1371-80. Available from: http://ncbi.nlm.nih.gov/pubmed/20368710. [Accessed August 27, 2011].

Books and other monographs

Personal authors

Adams RD, Victor M. Principles of Neurology. New York: McGraw-Hill; 1981.

Chapter in a book

Corbett S. Systemic Response to Injury and Metabolic Support. In: Brunicardi FC (editor). Schwartz's Principles of Surgery. 10th ed. New York: McGraw-Hill; 2015: p13-50.

Tables

These should be typed on a separate sheet (NOT EMBEDDED IN THE TEXT), numbered with Arabic numerals and accompanied by a title and an explanatory caption at the top. Each table must be referred to in the text and an indication of the preferred position in the text should be given. Other explanatory materials should be placed in footnotes below the tables. All non-standard abbreviations should be explained in the footnotes. Vertical and horizontal rules between entries should be omitted.

Figure legends

All illustrations require legends, typed on a separate sheet (NOT EMBEDDED IN THE TEXT). When symbols, arrows, numbers, and letters are used to identify parts of illustrations, each one should be identified and explained in the legend.

Figures

Illustrations should be sharp, glossy, black and white prints. Letters, numbers and symbols must be clear and of sufficient size to retain legibility when reduced. Titles and detailed explanations should be confined to figure legends and not included in illustrations. Each figure should be identified clearly on the back with its number and author. Photographs of persons must be retouched to make the subject unidentifiable or be accompanied by written permission from the subject to use the photograph. Figures should be numbered in Arabic numerals and accompanied by a title and an explanatory caption at the bottom.

For inquiries and concerns please contact:
UERMMMCI Health Sciences Journal
Research Institute for Health Sciences
2/F Jose M. Cuyegkeng Building
University of the East Ramon Magsaysay Memorial Medical Center, Inc.
Aurora Boulevard, Barangay Doña Imelda, Quezon City 1113
Secretary: Mr. Jayson P. Barasona
Telefax: (632) 7161843
(632) 7150861 to 69 local 358
E-mail: research@uerm.edu.ph
jdquebral@uerm.edu.ph

UERM
Memorial Medical Center, Inc.
Research Institute
for Health Sciences

Research Institute for Health Sciences
2/F Jose M. Cuyegkeng Building
University of the East Ramon Magsaysay Memorial Medical Center
Aurora Boulevard, Brgy. Doña Imelda, Quezon City 1113
Telefax (02) 716-1843; Trunk Line (02) 715-0861 loc. 358
Email: research@uerm.edu.ph