

Health-Related Quality of Life in Patients with Permanent Pacemaker at the University of Santo Tomas Hospital: A Cross-sectional Correlational Study

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Abstract

Introduction: The evolution of cardiac pacing is expected to decrease the cardiovascular morbidity and mortality but this type of intervention might affect the health-related quality of life (HRQOL) and eventually the overall prognosis of the patient. This study assessed the HRQOL in patients with permanent pacemaker using Philippines (Tagalog) Short Form (SF)-36v2 health survey.

Methods: A cross-sectional correlation study was conducted. Philippines (Tagalog) SF-36v2 health survey was administered among patients with permanent pacemaker who had their pacemaker analysis at the University of Santo Tomas Hospital from October to December 2015. The higher the score the better HRQOL and many studies used a cut-off point of 50. Pearson Correlation and Non-Parametric Mann-Whitney Tests were used in this study.

Results: Forty-two patients were enrolled in this study. There were 24 male and 18 females with mean interval of age

71.48±12.3. Most of the HRQOL scores were lower than 50. The highest HRQOL scores were vitality and mental health aspect while the worst were role emotional and physical functional aspect. Age, educational attainment, type of permanent pacemaker, pacemaker dependency, NYHA (New York Heart Association) functional capacity and presence of co-morbidities particularly diabetes mellitus type 2 were significant factors for poor HRQOL.

Conclusion: This study showed that overall the HRQOL in patients with permanent pacemaker was below average. A comprehensive management in order to improve the HRQOL should be considered among patients with permanent pacemaker.

Keywords: health-related quality of life; HRQOL; permanent pacemaker; philippines (tagalog) SF-36v2 health survey; cross-sectional correlational study; pacemaker analysis

Introduction

Cardiac pacemaker has become a therapeutic tool used worldwide with more than 250,000 pacemaker insertion per year.¹ Following the advances in pacemaker technology, several studies have been done to assess the quality of life of patients since it can affect the overall prognosis. This consideration is important especially if the treatment such as permanent pacemaker can restrict their daily activities. Pacemaker insertion is often a difficult condition for the patient, considering the expensive cost of the pacemaker, the insertion procedure, the possible complication after the pacemaker insertion, and the awareness that the pacemaker can interfere with the patient's social environment. The quality of life can affect the outcome of patients with permanent pacemaker.^{2,3}

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The World Health Organization (WHO) defines quality of life as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. This definition emphasizes that the quality of life is subjective, includes both positive and negative facets of life and is multi-dimensional.⁴ Several instruments have been developed to assess the quality of life of the patient. The General Health Survey of the Medical Outcomes Study (MOS) by Stewart and colleagues developed the Short Form 36 (SF-36) health survey. It is a multi-purpose, short-form survey which contains 36 questions. It has demonstrated sensitivity to significant treatment effects in a variety of population. The International Quality of Life Assessment (IQOLA) Project was established in 1991 to translate the SF-36 health survey and to validate, norm, and document the translations as required for their use internationally.⁵ In 1996, version 2.0 of the SF-36 (SF-36v2) health survey was introduced which has simpler instructions and questionnaire items.⁶ The SF-36 health survey has been translated to over 140 languages.⁵ Philippines (Tagalog) SF-36v2 health survey was already validated in a study done by Castillo-Carandang NT et al.⁷

This study aimed to assess the HRQOL and its clinical correlation among patients with permanent pacemaker using the newest version of SF-36 in Tagalog language.

Methods

A cross-sectional correlation study was conducted. A total of 42 patients with permanent pacemaker who had their pacemaker analysis at the Cardiovascular Catheterization and Intervention unit of the University of Santo Tomas (UST) Hospital from October to December 2015 were included in this study. We utilized the Philippines (Tagalog) SF-36v2 health survey. After explaining the objective of the study and securing consent from the patients, a short interview was conducted by the investigator before the survey was self-administered.

Clinical profile of the patients was gathered using a case report form which included: socio-demographic data (age, sex, civil status, educational attainment, and employment status), rhythm disorder prior to the permanent pacemaker insertion, permanent pacemaker insertion time span, type of permanent pacemaker (single/dual chamber pacemaker), pacemaker dependency (pacemaker dependent/non-pacemaker dependent), ventricular lead placement (right ventricle septum/right ventricle apex), pacing rate (A and V pace), NYHA functional capacity and presence of co-morbidity disease/s. The clinical profile of the patients was then correlated with the HRQOL score.

During the self-administered survey, patients were asked to give mark sign (x) for each answer. The investigator offered assistance to the patient with a limitation in completing the survey, such as difficulty reading. The investigator encouraged the patient to choose answers based on symptoms they had experience and asked them to provide spontaneous answers without excessive reflection. After the patient finished answering the survey, the investigator checked the survey for the completeness. The interview took about five to 10 minutes and another 10-15 minutes for answering the survey.

The SF-36 health survey has no single overall score. It has eight subscales and two summary scores. The two summary scores are the Physical Health Score (PHS) and Mental Health Score (MHS). The PHS consists of four subscales as follows physical functioning, role-physical, bodily pain, and general health scores. The MHS also consists of four subscales as follows vitality, social functioning, role-emotional, and mental health. The physical functioning, role-physical, and bodily pain contribute most to the scoring of PHS while the social functioning, role-emotional, and mental health contribute most to the scoring of MHS. The HRQOL score range from zero to 100 with higher score representing better HRQOL status.^{5,7,8} The score of the survey was computed automatically by

the online SF-36v2 health survey calculator. This calculator is available free in the internet.⁹

Pearson correlation test was used to determine the correlation between the HRQOL score and the continuous variable (age, permanent pacemaker insertion time span, pacing rate and co-morbidity disease/s). Non-Parametric Mann-Whitney test was used for the categorical variables (gender, civil status, educational attainment, employment status, rhythm disorder prior to permanent pacemaker insertion, type of permanent pacemaker, pacemaker dependency, ventricular lead placement and NYHA functional capacity). We performed sub-analysis study among patients with co-morbid hypertension and or diabetes mellitus (DM) type 2. We also did sub-analysis for patients with pacing rate of >70% versus <70% and pacing rate of >50% versus <50%. If the *p*-value is <0.05, we conclude significance at 95% level of significance. We used SPSS software version 21 in computing the results.

Results

A total of 42 patients were enrolled in this study. Of these, 24 patients (57.14%) were male and 18 (42.86%) were female with gender ratio of 1.3:1. The mean interval of age was 71.48 ± 12.3 . Hypertension was the most common co-morbid found in this study (73.81%) followed by DM type 2 (33.13%). Table I described demographic characteristic of study population.

The most common indication for pacemaker insertion was sick sinus syndrome in 24 patients (57.14%). Table II shows the baseline characteristics of the study population. Among 42 patients included in this study, 33 had their pacemaker insertion at the UST Hospital.

The overall mean scores for PHS and MHS were 40.96 ± 7.48 and 45.92 ± 9.49 . Analyzing the highest and lowest scores across all aspects assessed by the Philippines (Tagalog) SF-36v2 health survey, the highest HRQOL was vitality aspect (51.7 ± 8.32) followed by mental health aspect (47.86 ± 9.92) while the lowest HRQOL was role emotional aspect (35.66 ± 12.21) followed by physical functioning aspect (36.01 ± 11.28).

Among the socio-demographic factors, age and educational attainment were significantly correlated with the HRQOL score. (Table III and IV) Age was significantly correlated with the PHS and physical functioning score with *p*-value of 0.010 and 0.041, respectively. With *r* of -0.392 and -0.317, the older the patient, the lower the HRQOL related to PHS and physical functioning aspect. Those who had tertiary level of education had higher HRQOL than those with lower educational attainment when it came to the mental health aspect (*p*-value of 0.013).

Table I. Demographic characteristic of patients

| | No | Percentage |
|------------------------|-----------------|------------|
| Gender | | |
| Male | 24 | 57.14 |
| Female | 18 | 42.86 |
| Age | 71.48 ± 12.3 SD | |
| Civil status | | |
| Single | 5 | 11.90 |
| Married | 34 | 80.95 |
| Disrupted | 3 | 7.14 |
| Educational attainment | | |
| Non high school | 9 | 21.43 |
| High school | 4 | 9.52 |
| Technical | 10 | 23.81 |
| College | 19 | 45.24 |
| Employment status | | |
| Not working | 33 | 78.57 |
| Working | 9 | 21.43 |
| Co-morbidity disease | | |
| Hypertension | 31 | 73.81 |
| DM type 2 | 14 | 33.33 |
| COPD | 1 | 2.38 |
| CKD | 5 | 11.90 |
| Cancer | 3 | 7.14 |
| Bronchial asthma | 1 | 2.38 |

Table II. Baseline characteristics of patients

| | No | Percentage |
|----------------------------|----|------------|
| Rhythm disorder | | |
| Sick sinus syndrome | 24 | 57.14 |
| Complete heart block | 14 | 33.33 |
| High grade AV block | 4 | 9.52 |
| Type of pacemaker | | |
| Single chamber | 19 | 54.76 |
| Dual chamber | 23 | 45.24 |
| Ventricular lead placement | | |
| Right ventricle septum | 11 | 33.34 |
| Right ventricle apex | 22 | 66.66 |
| NYHA functional capacity | | |
| Class I | 15 | 35.71 |
| Class II | 24 | 57.14 |
| Class III | 3 | 7.14 |

Female patients had higher scores of the PHS and MHS but they were not significant compared to male patients (*p*-value of 0.492 and 0.360, respectively). Married and working patients had also higher scores of the PHS and MHS however there were no significant difference across

Table III. Correlation of age and HRQOL (n=42)

| | Pearson correlation coefficient | <i>P</i> -value |
|-----------------------|---------------------------------|-----------------|
| Physical functioning | -0.392 | 0.010 |
| Role-physical | -0.185 | 0.240 |
| Bodily-pain | 0.027 | 0.863 |
| General health | -0.200 | 0.204 |
| Physical health score | -0.317 | 0.041 |
| Vitality | -0.122 | 0.440 |
| Social functioning | -0.012 | 0.940 |
| Role emotional | -0.098 | 0.537 |
| Mental health | -0.091 | 0.566 |
| Mental health score | 0.002 | 0.992 |

Table IV. Correlation of educational attainment and HRQOL

| | College Level (n=19) | Others (n=23) | <i>P</i> -value |
|-----------------------|----------------------|---------------|-----------------|
| Physical functioning | 37.14 ± 7.93 | 35.07 ± 13.56 | 0.694 |
| Role-physical | 41.58 ± 6.19 | 36.96 ± 10.66 | 0.098 |
| Bodily-pain | 44.06 ± 8.65 | 44.19 ± 10.34 | 0.807 |
| General health | 47.97 ± 6.75 | 46.01 ± 8.3 | 0.274 |
| Physical health score | 40.99 ± 5.51 | 40.93 ± 8.92 | 0.456 |
| Vitality | 52.41 ± 8.83 | 51.13 ± 8.02 | 0.547 |
| Social functioning | 41.05 ± 7.47 | 40.95 ± 9.84 | 0.718 |
| Role emotional | 38.91 ± 9.53 | 32.99 ± 13.67 | 0.146 |
| Mental health | 52.08 ± 9.05 | 44.37 ± 9.39 | 0.013 |
| Mental health score | 48.97 ± 8.36 | 43.4 ± 9.8 | 0.063 |

Table V. Correlation of type of permanent pacemaker and HRQOL

| | Single (n=18) | Dual (n=24) | <i>P</i> -value |
|-----------------------|---------------|---------------|-----------------|
| Physical functioning | 33.81 ± 11.42 | 37.66 ± 11.14 | 0.366 |
| Role-physical | 37.01 ± 9.55 | 40.58 ± 8.67 | 0.299 |
| Bodily-pain | 41.7 ± 6.41 | 45.95 ± 11.06 | 0.267 |
| General health | 44.01 ± 6.89 | 49.07 ± 7.53 | 0.030 |
| Physical health score | 39.13 ± 7.48 | 42.33 ± 7.34 | 0.204 |
| Vitality | 48.25 ± 7.91 | 54.3 ± 7.79 | 0.011 |
| Social functioning | 38.35 ± 5.95 | 42.98 ± 10.03 | 0.068 |
| Role emotional | 33.21 ± 12.09 | 37.5 ± 12.22 | 0.293 |
| Mental health | 43.43 ± 10.64 | 51.18 ± 8.05 | 0.009 |
| Mental health score | 42.23 ± 10.16 | 48.68 ± 8.1 | 0.026 |

all aspects of the HRQOL score of the Philippines (Tagalog) SF-36v2 health survey (*p*-value of >0.05).

In comparing the rhythm disorder prior to the permanent pacemaker insertion, patients with sick sinus syndrome had lower PHS and MHS. However, this was not statistically significant compared with other rhythm disorder as indication (*p*-value of 0.291 and 0.760, respectively). There was also

Table VI. Correlation of pacemaker dependency and HRQOL

| | Dependent (n=16) | Not dependent (n=26) | P-value |
|-----------------------|------------------|----------------------|---------|
| Physical functioning | 36.66 ± 10.97 | 35.61 ± 11.67 | 0.876 |
| Role-physical | 40.24 ± 10.16 | 38.32 ± 8.55 | 0.548 |
| Bodily-pain | 47.64 ± 10.73 | 41.97 ± 8.14 | 0.082 |
| General health | 49.34 ± 7.66 | 45.4 ± 7.32 | 0.109 |
| Physical health score | 42.72 ± 7.49 | 39.88 ± 7.42 | 0.260 |
| Vitality | 51.89 ± 9.3 | 51.59 ± 7.84 | 0.990 |
| Social functioning | 44.22 ± 9.06 | 39.01 ± 8.09 | 0.046 |
| Role emotional | 37.54 ± 13.31 | 34.51 ± 11.59 | 0.388 |
| Mental health | 49.49 ± 8.68 | 46.86 ± 10.65 | 0.334 |
| Mental health score | 47.76 ± 8.38 | 44.79 ± 10.1 | 0.430 |

Table VII. Correlation of NYHA Functional Capacity and HRQOL

| | Class I (n=15) | Others (n=27) | P-Value |
|-----------------------|----------------|---------------|---------|
| Physical functioning | 40.52 ± 11.16 | 33.5 ± 10.74 | 0.027 |
| Role-physical | 41.03 ± 8.98 | 37.95 ± 9.18 | 0.368 |
| Bodily-pain | 46.79 ± 10.76 | 42.65 ± 8.58 | 0.311 |
| General health | 49.57 ± 6.85 | 45.41 ± 7.72 | 0.059 |
| Physical health score | 44.23 ± 8.12 | 39.14 ± 6.58 | 0.019 |
| Vitality | 52.29 ± 8.31 | 51.38 ± 8.46 | 0.489 |
| Social functioning | 45.55 ± 8.36 | 38.46 ± 8.02 | 0.018 |
| Role emotional | 38.65 ± 10.71 | 34.01 ± 12.85 | 0.194 |
| Mental health | 49.45 ± 8.85 | 46.98 ± 10.52 | 0.397 |
| Mental health score | 47.77 ± 7.39 | 44.89 ± 10.47 | 0.237 |

Table VIII. Correlation of presence of co-morbidity disease/s and HRQOL

| No of Co-Morbidity Disease/s | Pearson Correlation Coefficient | P-Value |
|------------------------------|---------------------------------|---------|
| Physical Functioning | -.316 | .041 |
| Role-Physical | -.115 | .470 |
| Bodily-Pain | -.026 | .870 |
| General Health | .144 | .364 |
| Physical Health Score | -.287 | .066 |
| Vitality | .165 | .296 |
| Social Functioning | -.050 | .751 |
| Role Emotional | -.099 | .533 |
| Mental Health | -.305 | .049 |
| Mental Health Score | .222 | .158 |

no significant correlation across all aspects of the HRQOL compared with the time span of pacemaker insertion (p -value of >0.05).

In terms of the type of permanent pacemaker, patient with dual chamber pacemaker had significantly higher HRQOL scores of general health (p -value of 0.03), vitality (p -value of 0.011) and mental health aspect (p -value of 0.009) and also MHS (p -value of 0.026) compared to patient with single chamber pacemaker. (Table V)

As to the pacemaker dependency, there was significant difference in the HRQOL score of social functioning aspect with p -value of 0.046. Dependent pacemaker patients had higher HRQOL compared to non-dependent pacemaker patients in relation with social functioning aspect. (Table VI)

In comparing the pacing rate of the A and V pace, there was no significant correlation between the pacing rate and all aspects of the HRQOL score. We also did sub-analysis comparing patients with pacing rate of V pace of $>70\%$ versus $<70\%$; and comparing patients with pacing rate of V pace of $>50\%$ versus $<50\%$ which all showed no statistically significant difference in HRQOL scores.

As to the ventricular lead placement, patients with ventricular lead placement at the right ventricle apex had higher PHS and MHS compared to those with ventricular lead placement at the right ventricle septum. However, this was not statistically significant (p -value of 0.789 and p -value of 0.894).

In terms of the NYHA functional capacity, there was significant difference in the HRQOL scores of physical and social functioning aspects and also PHS. Patients with NYHA class I had higher HRQOL compared to NYHA class II and III in relation with physical and social functioning aspects (p -value of 0.027 and 0.018, respectively) and also PHS (p -value of 0.019). (Table VII)

The number of co-morbidity was significantly correlated to HRQOL score. The higher the number of co-morbidity the lower the HRQOL in terms of physical functioning (p -value of 0.041) and mental aspect (p -value of 0.049). (Table VIII) The sub-analysis study among patients with hypertension showed that there was no significant difference among patients with hypertension than those without hypertension across all aspects of the HRQOL score. However, those without DM type 2 showed significantly higher HRQOL scores of physical functioning (p -value of 0.028), general health (p -value of 0.027); vitality aspect (p -value of 0.04) and; PHS (p -value of 0.031) compared to those with DM type 2. (Table IX)

Discussion

The first artificial pacemaker was designed by Albert S. Hyman in 1932. He used a magneto generator to produce direct current voltage for supplying power to the electrodes. Since that time, there have been tremendous advances in the pacemaker technology which have improved the cardiovascular outcome.^{1,10} Pacemaker insertion may influence the quality of life of the patient considering the pacemaker itself can interfere with the patient's social environment and also the expensive cost of the pacemaker implantation.^{2,3,11}

Table IX. Sub-analysis study among patients with hypertension and DM type 2

| | Yes (n=31) | No (n=11) | P-Value |
|-----------------------|---------------|---------------|---------|
| Hypertension | | | |
| Physical functioning | 34.93 ± 11.82 | 39.05 ± 9.46 | 0.447 |
| Role-physical | 38.81 ± 10.05 | 39.73 ± 6.09 | 0.795 |
| Bodily-pain | 44.93 ± 10.03 | 41.87 ± 7.78 | 0.459 |
| General health | 47.56 ± 7.93 | 45.04 ± 6.62 | 0.454 |
| Physical health score | 40.62 ± 8.52 | 41.91 ± 3.27 | 0.647 |
| Vitality | 51.67 ± 9.08 | 51.79 ± 6.02 | 0.850 |
| Social functioning | 41.88 ± 9.33 | 38.5 ± 6.58 | 0.262 |
| Role emotional | 35.38 ± 13.04 | 36.47 ± 9.98 | 0.817 |
| Mental health | 48.83 ± 9.86 | 45.14 ± 10.02 | 0.273 |
| Mental health score | 46.69 ± 9.71 | 43.75 ± 8.91 | 0.367 |
| DM Type II | (n=14) | (n=28) | |
| Physical functioning | 30.74 ± 12.09 | 38.64 ± 10.07 | 0.028 |
| Role-physical | 36.81 ± 10.59 | 40.17 ± 8.27 | 0.476 |
| Bodily-pain | 42.08 ± 9.14 | 45.15 ± 9.67 | 0.278 |
| General health | 44.99 ± 7.11 | 50.71 ± 7.37 | 0.027 |
| Physical health score | 38.36 ± 7.68 | 42.26 ± 7.17 | 0.031 |
| Vitality | 49.63 ± 7.38 | 55.86 ± 8.77 | 0.040 |
| Social functioning | 41.26 ± 6.72 | 40.86 ± 9.72 | 0.817 |
| Role emotional | 31.73 ± 14.32 | 37.63 ± 10.74 | 0.170 |
| Mental health | 51.02 ± 10.52 | 46.28 ± 9.4 | 0.192 |
| Mental health score | 48.41 ± 10.59 | 44.67 ± 8.82 | 0.401 |

Several studies showed that the quality of life of patients with a permanent pacemaker can affect the overall outcome of the patient. Those studies assessed quality of life relating it to gender, age, civil status and pacemaker implantation time span. In addition, this study also compared HRQOL with educational attainment, type of permanent pacemaker, pacemaker dependency, NYHA functional capacity and co-morbidities which showed significant correlation with quality of life.^{2,3,11}

Among the current instruments used to assess quality of life of pacemaker patients, SF-35 appeared to be the best among generic questionnaires because of its psychometric characteristics and experience of use.¹¹ The SF-36 health survey is easy to administer and one of the most widely used generic measures of health-related quality of life.⁸ It is a structured, self-report questionnaire that patient can generally complete with little or no intervention from an interviewer.^{8,13,14}

This study showed the overall mean scores for PHS and MHS were 40.96±7.48 and 45.92±9.49. Although there was no single overall score for SF-36 health survey, the higher the score represents better HRQOL status and many literatures and studies used a cut-off point of 50 (average score) to determine the best and worst aspects since the final score

ranges from zero to 100.^{3,12,13} In this study, most of the HRQOL scores obtained scored lower than 50, indicating that HRQOL of patients with permanent pacemaker was below average. Analyzing the highest and lowest scores across the aspects of the Philippines (Tagalog) SF-36v2 health survey; the highest HRQOL score referred to vitality aspect followed by mental health aspect while the lowest HRQOL referred to role emotional aspect followed by physical functioning aspect. Since vitality and mental health aspects had the highest scores, most of the patients felt full of pep and energy, peaceful, happy and calm all of the time. While the lowest scores referred to role emotional and physical functioning aspects. Most of the patients had problem with work or other daily activities as a result of emotional problem and they were very limited in performing most physical activities. In terms of socio-demographic factors, age and educational attainment were significantly correlated with the HRQOL score. Age had negative correlation with the PHS and physical functioning score. The older patients experienced more difficulty performing physical activities affecting the HRQOL. Those who had tertiary level education had higher HRQOL in term of mental health aspect while patients with lower educational attainment felt more nervous and depressed.

Patients with dual chamber pacemaker had higher HRQOL in relation with general health, vitality and mental health aspect and also MHS. They evaluated their personal health as excellent, felt full of energy, peaceful and calm most of the time. They had frequent positive affect and absence of psychological distress and limitations in usual social or role activities due to emotional problems.

Dependent pacemaker patients had better HRQOL in terms of social functioning aspect. They performed most all types of physical activities without limitation due to health. Patients with NYHA class I had higher HRQOL in relation with physical and social functioning aspects and in PHS. They were able to perform normal social activities without interference due to physical or emotional problems and most all types of physical activities without limitation due to health.

The presence of co-morbidity was also a significant factor. The higher the number of co-morbidities the lower the HRQOL in terms of physical functioning aspect and PHS. They had more limitation in self-care, physical, social and role activities. The sub-analysis study among diabetic patients showed that having diabetes was a significant factor for HRQOL in term of physical functioning, general health, vitality aspects and PHS.

Conclusion

The overall HRQOL scores of patients with permanent pacemaker included in this study was below the average.

The HRQOL was worse in terms of role-emotional and physical functioning aspect and better in terms of vitality and general health aspect. Thus, a comprehensive management should be given in patients with permanent pacemaker particularly strategies that can improve the HRQOL since it can affect the overall outcome and prognosis of the patients.

This study is not without limitation. We recommend a bigger population for future studies to confirm the results of this study. In this study, we used the Non-Parametric Mann-Whitney Test in the data analysis for the categorical variables due to limitation of the sample size. We also recommend future studies that assess the HRQOL in patients before and after the permanent pacemaker insertion, so we will be able to determine if there is any improvement in the HRQOL of those patients after the pacemaker insertion. Further research could also be proposed on HRQOL assessment over a longer period after the pacemaker insertion which could show the effectiveness and patients' tolerance to the treatment.

References

1. **Haddad Sandro AP, Houben Richard PM, Serdijn Wouter A;** The Evolution of Pacemakers. *IEEE Engineering in Medicine and Biology Magazine*, 38-48, May/Juns 2006
2. **Kurucova R, Ziakova K, Gurkova E, et al;** Quality of Life of Patients with a Permanent Pacemaker. *Osetrovatelstvi a Porodni Asistence*, 5(1):15-20, 2014.
3. **De Barros RT, de Carvalho SMB, Borges JBC, et al;** Evaluation of Patients' Quality of Life Aspects after Cardiac Pacemaker Implantation. *Rev Bras Cir Cardiovasc*, 29(1):37-44, 2014.
4. **The World Health Organization Quality of Life Assessment (WHOQOL) Group.** The WHOQOL: Position Paper from the World Health Organization. *Soc. Sci. Med*, 41(10):1403-09, 1995.
5. **Ware JE Jr, Gandek B;** Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project. *J Clin Epidemiol*, 51(11):903-12, 1998.
6. **Ware JE Jr;** SF-36 Health Survey Update. *Spine*, 25(24):3130-9, 2000.
7. **Castillo-Carandang NT, Sison OT, Grefal ML, et al;** A Community-Based Validation Study of the Short-Form 36 Version 2 Phillipines (Tagalog) in Two Cities in the Philippines. *Plos One* December 8(12):1-9, 2013.
8. **Health Status Questionnaire SF-36 (serial online).** Available from: URL: [http://www.nationalmssociety.org/For-Professionals/Researchers/Resources-for-Researchers/Clinical-Study-Measures/Health-Status-Questionnaire-\(SF-36\)](http://www.nationalmssociety.org/For-Professionals/Researchers/Resources-for-Researchers/Clinical-Study-Measures/Health-Status-Questionnaire-(SF-36)).
9. **SF-36v2 (serial online).** Available from: URL: <http://www.SF-36.org/demos/SF-36v2.html>
10. **Mittal T.** Pacemakers-A Journey through the Years; *Indian Journal of Thoracic and Cardiovascular Surgery*, 21: 236-49, 2005.
11. **Stofmeel MA, Post MW, Kelder JC, et al;** Quality of Life of Pacemaker Patients: A Reappraisal of Current Instruments. *Pacing Clin Electrophysiol*, 23(6):946-52, Jun 2000.
12. **Servelhere KR, Fernandes YB, Ramina R, et al;** Aplicação da Escala SF-36 em Pacientes Operados de Tumores da Base do Crânio (Application of SF-36 Scale in Patients Operated on Skull Base Tumors). *Arq Bras Neurocir*, 30(2):69-75, 2011.
13. **Gandek B.** Interpreting the SF-36 Health Survey. *Canadian Association of Cardiac Rehabilitation*, 2002.

Appendices

Appendix A: Short Form-36 Health Survey version 2

Your Health and Well-Being

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an in the one box that best describes your answer.

1. In general, would you say your health is:

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Excellent | Very good | Good | Fair | Poor |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

2. Compared to one year ago, how would you rate your health in general now?

| | | | | |
|-----------------------------------|---------------------------------------|--------------------------------|--------------------------------------|----------------------------------|
| Much better now than one year ago | Somewhat better now than one year ago | About the same as one year ago | Somewhat worse now than one year ago | Much worse now than one year ago |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

SF-36v2™ Health Survey © 1992, 2006 Health Assessment Lab, Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-36® is a registered trademark of Medical Outcomes Trust. (DQOLA SF-36v2 Standard, Philippines (English))

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

| | | | |
|---|--------------------------|--------------------------|--------------------------|
| | Yes, limited a lot | Yes, limited a little | No, not limited at all |
| 1. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Moderate activities, such as moving a table, sweeping the floor, swimming, or cycling | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Lifting or carrying groceries | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Climbing several flights of stairs | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Climbing one flight of stairs | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Bending, kneeling, or stooping | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Walking more than a kilometre | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Walking several hundred metres | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Walking one hundred metres | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Bathing or dressing yourself | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

| | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
| 1. Cut down on the amount of time you spent on work or other activities | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Accomplished less than you would like | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Were limited in the kind of work or other activities | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Had difficulty performing the work or other activities (for example, it took extra effort) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

| | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
| 1. Cut down on the amount of time you spent on work or other activities | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Accomplished less than you would like | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Did work or other activities less carefully than usual | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

| | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | Not at all | Slightly | Moderately | Quite a bit | Extremely |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

7. How much bodily pain have you had during the past 4 weeks?

| | | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | None | Very mild | Mild | Moderate | Severe | Very severe |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

| | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | Not at all | A little bit | Moderately | Quite a bit | Extremely |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Did you feel full of life? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Have you been very nervous? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Have you felt so sad and low in mood that nothing could cheer you up? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Have you felt calm and peaceful? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Did you have a lot of energy? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Have you felt downhearted and depressed? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Did you feel worn out? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Have you been happy? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Did you feel tired? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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11. How TRUE or FALSE is each of the following statements for you?

| | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| I seem to get sick a little easier than other people | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I am as healthy as anybody I know | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| I expect my health to get worse | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| My health is excellent | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Thank you for completing these questions!

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Appendix B: Philippines (Tagalog) Short Form-36 Health Survey Version 2

ANG IYONG KALUSUGAN AT KAGALINGAN

Ang kuwestiyonaryong ito ay nagtatanong ukol sa iyong mga pananaw tungkol sa iyong kalusugan. Ang impormasyong ito ay tutulong na i-rekord ang iyong nararamdaman at kung gaano ksgaling mo nagagawa ang iyong mga regular na aktibidad. *Salamat sa pagkumpleto sa kuwestiyonaryong ito!*

Sa bawat isa sa mga sumusunod na tanong, markahan ng ang isang kahon na pinaka-naglalarawan ng iyong sagot.

1. Sa kabuuan, masasabi mo bang ang kalusugan mo ay:

| Lubhang napakabuti | Napakabuti | Mabuti | Hindi masyadong mabuti | Masama |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

2. Kumpara nung nakatipas na isang taon, ano ang masasabi mo tungkol sa iyong kalusugan sa kabuuan ngayon?

| Lubhang mas mabuti ngayon kumpara nung nakatipas na isang taon | Medyo mas mabuti ngayon, kumpara nung nakatipas na isang taon | Halos pareho lamang kumpara nung nakatipas na isang taon | Medyo mas masama ngayon kumpara nung nakatipas na isang taon | Lubhang mas masama ngayon kumpara nung nakatipas na isang taon |
|--|---|--|--|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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3. Ang mga sumusunod na katanungan ay tungkol sa mga aktibidad na maaari mong gawin sa karaniwang araw. Nalilimitahan ka ba ng kasalukuyang kalagayan ng iyong kalusugan sa mga aktibidad na ito? Kung oo, gaano?

| | Oo, lubhang nalilimitahan | Oo, medyo nalilimitahan | Hindi, hindi nalilimitahan kahit kaunti |
|---|---------------------------|--------------------------|---|
| Nakakapagod na mga aktibidad, tulad ng pagtakbo, pagbuhat ng mga mabibigat na bagay, pagsali sa mga nakakapagod na laro | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Katamtamang mga aktibidad, tulad ng paggalaw ng mesa, pagwawalis, pag-bowling, o katamtamtang pagbibisekleta | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Pagbuhat o pagdala ng mga pinamili | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Pag-akyat sa <u>ilang</u> hagdanan | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Pag-akyat sa <u>isang</u> hagdanan | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Pagbaluktot, pagluhod, o pagyuko | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Paglakad ng <u>mahigit isang kilometro</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Paglakad ng <u>ilang daang metro</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Paglakad ng <u>isang daang metro</u> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Pagpaligo o pagbihis sa iyong sarili | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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4. Sa **nakaraang 4 na linggo**, gaano kadalas na nagkaroon ka ng alin man sa mga sumusunod na problema sa iyong gawain o iba pang regular na pang-araw-araw na aktibidad **sanhi ng iyong pisikal na kalusugan?**

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Lahat ng oras ▼ | Karamihan ng oras ▼ | Minsan-minsan ▼ | Bihira ▼ | Hindi kahit minsan ▼ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

- Bawesan ang **dami ng oras** na ginamit sa trabaho o iba pang mga aktibidad..... 1, 2, 3, 4, 5,
- Nakatapos ng mas kaunti** sa iyong ninanais..... 1, 2, 3, 4, 5,
- Nalimitahan sa **uri ng gawain** o iba pang mga aktibidad..... 1, 2, 3, 4, 5,
- Nahirapan sa **paggawa ng** trabaho o iba pang mga aktibidad (halimbawa, nangailangan ite ng dagdag na pagsisikap)..... 1, 2, 3, 4, 5,

5. Sa **nakaraang 4 na linggo**, gaano kadalas na nagkaroon ka ng alin man sa mga sumusunod na problema sa iyong gawain o iba pang regular na pang-araw-araw na mga aktibidad **sanhi ng ano mang emosyonal na mga problema** (gaya ng katatimlayan o pagkabalisa)?

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Lahat ng oras ▼ | Karamihan ng oras ▼ | Minsan-minsan ▼ | Bihira ▼ | Hindi kahit minsan ▼ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

- Bawasan ang **dami ng oras** na ginamit sa trabaho o iba pang mga aktibidad..... 1, 2, 3, 4, 5,
- Nakatapos ng mas kaunti** sa iyong ninanais..... 1, 2, 3, 4, 5,
- Ginawa ang gawain o iba pang mga aktibidad na **kakaunti ang pag-lingat gaya ng karaniwan**..... 1, 2, 3, 4, 5,

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9. Ang mga tanong na ito ay tungkol sa kung ano ang iyong pakiramdam at ano ang iyong naging kalagayan sa **nakaraang 4 na linggo**. Sa bawat tanong, ibigay ang isang sagot na pinaka-akma sa iyong nararamdaman. Gaano kadalas sa **nakaraang 4 na linggo**...

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Lahat ng oras ▼ | Karamihan ng oras ▼ | Minsan-minsan ▼ | Bihira ▼ | Hindi kahit minsan ▼ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

- Naramdaman mo bang punung-purol ka ng buhay?..... 1, 2, 3, 4, 5,
- Ikaw ba ay naging napakaterbiyoso?..... 1, 2, 3, 4, 5,
- Nakaramdam ka ba na sukodulan ang iyong katatimlayan na walang makapagpasya sa iyo?..... 1, 2, 3, 4, 5,
- Nakaramdam ka ba na ikaw ay kalmado at mapayapa?..... 1, 2, 3, 4, 5,
- Nagkaroon ka ba ng maraming lakas na pisikal at mental?..... 1, 2, 3, 4, 5,
- Nakaramdam ka ba na ikaw ay nasiraan ng loob at matamlay?..... 1, 2, 3, 4, 5,
- Naramdaman mo bang ikaw ay naubusan ng lakas?..... 1, 2, 3, 4, 5,
- Naging masaya ka ba?..... 1, 2, 3, 4, 5,
- Naramdaman mo bang pagod ka?..... 1, 2, 3, 4, 5,

10. Sa **nakaraang 4 na linggo**, gaano kadalas nakasagabal ang iyong pisikal na kalusugan o mga problemang emosyonal sa iyong mga panlipunang aktibidad (gaya ng pagbisita sa mga kaibigan, kamag-anak, atbp.)?

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Lahat ng oras ▼ | Karamihan ng oras ▼ | Minsan-minsan ▼ | Bihira ▼ | Hindi kahit minsan ▼ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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6. Sa **nakaraang 4 na linggo**, gaano nakasagabal ang iyong mga problemang pisikal o emosyonal sa iyong mga normal na panlipunang aktibidad kasama ng iyong pamilya, mga kaibigan, mga kapitbahay, o mga grupo?

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Hindi kahit kaunti ▼ | Medyo ▼ | Katamtaman ▼ | Malaki ▼ | Sukodulan ▼ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

7. Gaano ang naging pananakit ng iyong **katawan sa nakaraang 4 na linggo?**

| | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Wala ▼ | Kaunting-kaunti ▼ | Kaunti ▼ | Katamtaman ▼ | Matindi ▼ | Napakatindi ▼ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

8. Sa **nakaraang 4 na linggo**, gaano nakasagabal ang **pananakit** sa iyong normal na gawain (kabilang ang gawain sa labas ng bahay at gawaing bahay)?

| | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Hindi kahit kaunti ▼ | Medyo ▼ | Katamtaman ▼ | Malaki ▼ | Sukodulan ▼ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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11. Gaano KA-TOTOO o HINDI TOTOO ang **hawak isa** sa mga sumusunod na pahayag para sa iyo?

| | | | | |
|---------------------|-------------------------|-----------------|-------------------------------|---------------------------|
| Tiyak na totoo ▼ | Karamihan ay totoo ▼ | Hindi alam ▼ | Karamihan ay hindi totoo ▼ | Tiyak na hindi totoo ▼ |
|---------------------|-------------------------|-----------------|-------------------------------|---------------------------|

- Parang medyo mas madali akong magkaskit kumpara sa ibang tao..... 1, 2, 3, 4, 5,
- Ako ay kasing lusog ng sinumang taong kilala ko..... 1, 2, 3, 4, 5,
- Inaasehan ko na ang aking kalusugan ay lalala..... 1, 2, 3, 4, 5,
- Ang aking kalusugan ay luhang napakabuti..... 1, 2, 3, 4, 5,

Salamat sa pagkumpleto sa mga katanungang ito!

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Appendix C

Case Report Form

Name: (Optional) _____ Patient #: _____

| | | |
|-----|-----|--|
| Age | Sex | Civil Status: 0-single 0-married 0-widow/ separated |
|-----|-----|--|

Address

Provincial add: _____

City add: _____

Educational
Attainment:

- non-high school grad high school grad
- vocational/technical college graduate

Occupation:

- not working
- working as _____

Rhythm disorder prior to permanent pacemaker insertion :

- Sick Sinus Syndrome
- Complete heart block
- 2:1 AV Block
- High grade AV Block
- Symptomatic sinus bradycardia

Date of permanent pacemaker insertion: _____

Type of permanent pacemaker:

- Single chamber pacemaker
- Dual chamber pacemaker

New York Heart Association (NYHA) functional capacity:

- Functional capacity class I
- Functional capacity class II
- Functional capacity class III
- Functional capacity class IV

Pacemaker dependency:

- Pacemaker dependent
- Not pacemaker dependent

Please mark (X) to corresponding answer (present/absent)

| Co morbidity disease: | Present | Absent | Duration (years) | Medications/Chemotherapy/ Radiotherapy |
|--|---------|--------|------------------|---|
| Diabetes Mellitus | | | | |
| Hypertension | | | | |
| Pneumonia | | | | |
| Chronic obstructive pulmonary disease | | | | |
| Bronchial asthma | | | | |
| Pre dialytic chronic kidney disease | | | | |
| Chronic kidney disease in maintenance dialysis | | | | |
| Carcinomatosis | | | | |
| Cerebrovascular accident | | | | |
| Others | | | | |

Appendix D: Informed Consent Form (English Version)

Department of Internal Medicine, Section of Cardiology
 UNIVERSITY OF SANTO TOMAS HOSPITAL
 Espana, Manila

CONSENT TO ACT AS A RESEARCH SUBJECT

Health-Related Quality of Life in
 Patients with Permanent Pacemaker:
 A Prospective, Cross-Sectional Study

You are invited to participate in this study. Please take time to read through the information provided in this sheet. The study will also be explained to you and you will be given the chance to ask questions. After you are satisfied that you understand this study, and wish to take part in the study, please sign this informed consent form. You will be given a copy of this informed consent form to take home with you. This study aims to determine the health-related quality of life in patients with permanent pacemaker. There will be a total of 36 participants from University of Santo Tomas Hospital.

STUDY PROCEDURES

First, the investigator/s will explain this study to you and ask you to read and sign this informed consent as evidence of your willingness to participate in this study.

If you agree to take part in this study:

- a. We will give you a short questionnaire, named Short Form 36 version 2.0 (SF-36v2). This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Please mark the box (with mark sign (x) for each answer of the questionnaire.
- b. You will not spend for any additional laboratory examination/s.

Your participation will last for about 15-20 minutes. No additional visits will be required.

BENEFITS AND RISKS

Your participation in this study may add to the medical knowledge about health-related quality of life in patients with permanent pacemaker insertion. No blood testing or other procedures will be done.

SUBJECT'S RESPONSIBILITIES

It is important that you disclose all relevant medical history to the study doctor. You must carefully follow any instructions given to you concerning the study. By participating in this study, you will contribute significantly to the medical care of the community.

COSTS AND PAYMENTS IF PARTICIPATING IN THE STUDY

The cost of the data sheets that will be used in this study will be shouldered by the investigators. You will not be paid any money for participating in this study.

STUDY PARTICIPATION AND WITHDRAWAL

Your participation in the study is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or jeopardy to the medical care to which you are entitled. You may be removed from this study by the investigator without your consent if you do not follow the study procedures or if in the opinion of the study doctor, it is in your best interest. Dr. Muljadi has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Muljadi at 09339577269.

CONFIDENTIALITY

All information obtained during this study, including hospital records, personal data and research data will be kept confidential. However, this information may be inspected by the appropriate governmental agencies and/or the Institutional Review Board of the University of Santo Tomas Hospital in accordance with the legislation in force. By signing written informed consent, you agree with these possible actions. This study was approved by the Institutional Review Board of the University of Santo Tomas Hospital.

If you desire or want any further information regarding your rights as a research patient, you may contact dr. Wilson Tan-De Guzman, the chairman of Institutional Review Board of the University of Santo Tomas Hospital at the 6th Floor Clinical Division Building with contact numbers 731-3001 at local 2610. A copy of this informed consent document will be given to you.

CONSENT STATEMENT:

- You will be received a copy of this consent document to keep.
- You agree to participate in this research study.

| | | |
|---|---|---------------|
| _____ Name of Patient (Print) | _____ Signature of Patient | _____ Date |
| _____ Name of Investigator/ Person administering (Print) | _____ Signature of Investigator/ Person administering | _____ Date |
| _____ Name of Legally Acceptable Representative (LAC) (Print) | _____ Signature of LAC | _____ Date |
| _____ Name of Witness (Print) | _____ Signature of Witness | _____ Date |
| _____ Name of Attending Physician (Print) | _____ Signature of Witness | _____ Date |

Appendix E: Informed Consent Form (Tagalog Version)

Department of Internal Medicine, Section of Cardiology
UNIVERSITY OF SANTO TOMAS HOSPITAL
España, Manila

Pahintulot sa Pagsali sa Isang Pagsasaliksik

Health-Related Quality of Life in
Patients with Permanent Pacemaker:
A Prospective, Cross-Sectional Study

Inaanyayahan kayong lumahok sa pag-aaral na ito. Maari po lamang na basahin ang impormasyong nakasaad sa talaang ito. Ipapaliwanag din sa inyo ang pag-aaral na ito at mabibigyan kayo ng pagkakataong magtanong. Kapag naintindihan nyo na ang pag-aaral at nais ninyong sumali, maari po lamang na pirmahan ang katibayan ng pagpapayag sa hulihan. Upang matukoy ang kalidad ng kalusugan-kaugnay ng buhay sa mga pasyente na may permanenteng pacemaker. Magkakaroon ng 36 na kalahok mula sa University of Santo Tomas Hospital.

PARAAN NG PAGSISIYASAT

Una sa lahat, ipapaliwanag ng imbestigador ang pag-aaral sa inyo at tatanungin kayo na basahin at pirmahan ang informed consent bilang ebidensya na kusang-loob kayong sumali sa pag-aaral na ito. Kung kayo ay papayag na lumahok sa pag-aaral:

- Bibigyan namin kayo ng maikling questionnaire, ang Tagalog Short Form 36 version 2 (SF-36v2). Ang kuwestiyonaryong ito ay nagtatanong ukol sa iyong mga pananaw tungkol sa iyong kalusugan. Ang impormasyong ito ay tutulon na i-rekord ang iyong nararamdaman at kung gaano kagaling mo nagagawa ang iyong mga regular aktibidad. Sa bawat isa sa mga tanong ng kuwestiyonaryo, markahan ng (X) ang isang kahon na pinaka-naglalarawan ng inyong sagot.
- Hindi ninyo kailangan magbayad para sa karagdagang laboratory exam.
Ang inyong partisipasyon ay aabot laman sa mga 10-15 na minuto. Hindi na kakailanganin ng karagdagang pagbisita.

MGA BENEPISYO AT PANGANIB O PELIGRO

Ang paglahok niyo sa pagaaral na ito ay makakatulong sa pagpapalawak ng medisina. Kayo ay tatanungin, eeksaminin, at sasagot ng isang questionnaire lamang. Hindi na kakailanganin ng karagdagang pagsusuri sa dugo o iba pang procedure.

MGA RESPONSABILIDAD NG KASAPI

Importante na iyong mailahad ang lahat ng impormasyong nauukol at kailangan sa pagsisiyasat na ito. Ikaw ay kailangang sumunod sa mga patakaran at pamamaraan ng pag-aaral na ito. Ang iyong pagsali sa pag-aaral na ito, ikaw ay makakapagbigay ng karagdagang kaalaman at suporta sa larangan ng medisina.

KABAYARAN SA PAGLAHOK

Ang bayad para sa mga data sheet na gagamitin sa pagaaral na ito ay sasagutin ng mga tagapagsiyasat. Hindi kayo bibigyan ng kahit anong pera para lumahok sa pag-aaral na ito.

PAGSASALI AT PAGTANGGI SA PAGSASALIKSIK

Ang pagsali mo sa pagsisiyasat na ito ay mula sa iyong kusang loob. Ikaw ay maaaring tumanggi at tumigil ng walang naaayong kaparusahan. Ikaw ay maaaring ding tanggalin ng mga tagapagsiyasat kung ikaw ay hindi sumusunod sa mga patakaran at alituntunin ng pagsisiyasat na ito. Naipaliwanag sa iyo ng lubos ang pagsisiyasat na ito at nasagot ang iyong mga katanungan ni Dr. Muljadi. Kung ikaw ay mayroon pang karagdagang katanungan o mga problemang may kaugnayan sa pagsusuring ito, maaaring tawagan at ipagbigay-alam kay Dr. Muljadi sa telepono bilang 09339577269.

MANANATILING LIHIM

Lahat ng impormasyon ng pagsisiyasat na ito, kasama na ang dokumento sa ospital, personal at sa pag-aaral na ito ay mananatiling lihim. Subalit, anumang impormasyon ay pwedeng masuri ng mga taga-suporta ng pagsisiyasat na ito, ahensya ng gobyerno at Institutional Review Board ng University of Santo Tomas Hospital. Ang iyong pagpirma sa nakalaang kasulatang pahintulot na ito ay nagpapahiwatig ng iyong pagsang-ayon sa mga nasabing pamamaraan. Ang apgsisiyasat na ito ay inaprobahan ng Institutional Review Board ng University of Santo Tomas Hospital.

Kung nais mo ng karagdagang impormasyon tungkol sa iyong karapatan bilang kasali sa pagsisiyasat na ito, puwede mong lapitan dr. Wilson Tan-De Guzman, ang punong-tagapamahala ng Institutional Review Board ng University of Santo Tomas Hospital sa 6th Floor Clinical Division Building at sa numerong 731-3001 sa local 2610.

KASULATANG MAGPAPATOTOO SA IYONG PAHINTULOT SUMALI

- Ikaw ay makakatanggap ng sarili mong kopya ng dokumentong ito para sa iyong pag-iingat.
- Malaya mong ibinibigay ang iyong pahintulot para makalahok sa pagsisiyasat na ito.

| | | |
|---|--|-------|
| _____ | _____ | _____ |
| Pangalan ng Pasyente | Lagda ng Pasyente | Petsa |
| _____ | _____ | _____ |
| Pangalan ng Tagapagsaliksik/ Tagapagsuri | Lagda ng Tagapagsaliksik/ Tagapagsuri | Petsa |
| _____ | _____ | _____ |
| Pangalan ng Lehitimong Kumakatawan sa Pasyente | Lagda ng Lehitimong Kumakatawan sa Pasyente | Petsa |
| _____ | _____ | _____ |
| Pangalan ng Saksi | Lagda ng Saksi | Petsa |
| _____ | _____ | _____ |
| Pangalan ng pangunahing doktor (Print) | Lagda ng pangunahing doktor | Petsa |

Appendix F: Summary of Information about SF-36 Scales and Physical and Mental Component Summary Measures

Overview of the SF-36 Health Survey and the IQOLA Project

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TABLE 2. Summary of information about SF-36 scales and physical and mental component summary measures

| Scales | Correlations ^a | | Number of ^b | | Mean ^c | SD ^c | Reliability ^a | CI ^c | Definition (% observed) | |
|----------------------------------|---------------------------|-----|------------------------|------------------|-------------------|-----------------|--------------------------|-----------------|---|--|
| | PCS | MCS | Items | Levels | | | | | Lowest possible score (floor) ^d | Highest possible score (ceiling) ^d |
| Physical Functioning (PF) | .85 | .12 | 10 | 21 | 84.2 | 23.3 | .93 | 12.3 | Very limited in performing all physical activities including bathing or dressing (0.8%) | Performs all types of physical activities including the most vigorous without limitations due to health (38.8%) |
| Role-Physical (RP) | .81 | .27 | 4 | 5 | 80.9 | 34.0 | .89 | 22.6 | Problems with work or other daily activities as a result of physical health (10.3%) | No problems with work or other daily activities (70.9%) |
| Bodily Pain (BP) | .76 | .28 | 2 | 11 | 75.2 | 23.7 | .90 | 15.0 | Very severe and extremely limiting pain (0.6%) | No pain or limitations due to pain (31.9%) |
| General Health (GH) | .69 | .37 | 5 | 21 | 71.9 | 20.3 | .81 | 17.6 | Evaluates personal health as poor and believes it likely to get worse (0.0%) | Evaluates personal health as excellent (7.4%) |
| Vitality (VT) | .47 | .65 | 4 | 21 | 60.9 | 20.9 | .86 | 15.6 | Feels tired and worn out all of the time (0.5%) | Feels full of pep and energy all of the time (1.5%) |
| Social Functioning (SF) | .42 | .67 | 2 | 9 | 83.3 | 22.7 | .68 | 25.7 | Extreme and frequent interference with normal social activities due to physical and emotional problems (0.6%) | Performs normal social activities without interference due to physical or emotional problems (52.3%) |
| Role-Emotional (RE) | .16 | .78 | 3 | 4 | 81.3 | 33.0 | .82 | 28.0 | Problems with work or other daily activities as a result of emotional problems (9.6%) | No problems with work or other daily activities (71.0%) |
| Mental Health (MH) | .17 | .87 | 5 | 26 | 74.7 | 18.1 | .84 | 14.0 | Feelings of nervousness and depression all of the time (0.0%) | Feels peaceful, happy, and calm all of the time (0.2%) |
| Physical Component Summary (PCS) | | | 35 | 567 ^b | 50.0 | 10.0 | .92 | 5.7 | Limitations in self-care, physical, social, and role activities, severe bodily pain, frequent tiredness, health rated "poor" (0.0%) | No physical limitations, disabilities, or decrements in well-being, high energy level, health rated "excellent" (0.0%) |
| Mental Component Summary (MCS) | | | 35 | 493 ^b | 50.0 | 10.0 | .88 | 6.3 | Frequent psychological distress, social and role disability due to emotional problems, health rated "poor" (0.0%) | Frequent positive affect, absence of psychological distress and limitations in usual social/role activities due to emotional problems, health rated "excellent" (0.0%) |