The impact of drug related problems on health-related quality of life among hypertensive patients in Jordan

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Abstract
Background: Hypertension is a major cause of cardiovascular diseases with a high prevalence in Jordan. No previous studies have been carried out to determine the effect of the presence of drug-related problems (DRPs) on the health-related quality of life (HRQOL) among hypertensive patients.

Objectives: The purpose of this study was to identify the influence of different types of DRPs on the HRQOL of hypertensive patients.

Methods: A total of 200 hypertensive patients were recruited in this cross-sectional correlation study that was conducted across the cardiac outpatient clinic at Jordan University Hospital. Ethical approval was obtained and patients were recruited using convenience sampling technique. During the study period, patients’ data was used to evaluate their quality of life using RAND-12 scale and to identify DRPs utilizing a systematic evidence based approach.

Results: 200 hypertensive patients (mean age 59.7 years (SD=10.2)) were recruited in this study. Patients showed a poor quality of life on both the physical and mental domains of the RAND-12 scale. The average number of DRPs was 5.1 (SD=2.3). Multiple linear regression analysis showed that among DRPs categories, non-adherence to medications, non-adherence to non-pharmacological therapies and inadequate knowledge about medications were among the main predictors of the poor physical domain of the RAND-12 (Beta= -0.149, -0.226 and -0.230 respectively, p-value < 0.05 for all). On the other hand, only non-adherence to medication and non-adherence to non-pharmacological therapies were significantly associated with poor mental domain of the RAND-12 (Beta= -0.208 and -0.191 respectively, p-value < 0.05 for both).

Conclusion: Prevalence of DRPs among hypertensive patients is a concern that needs attention. These DRPs were associated with poor HRQOL on both the physical and mental domain of the RAND-12 scale. The pharmaceutical care service delivered by pharmacists is needed to identify, prevent and resolve DRPs, which may improve patients HRQOL.

Keywords
Hypertension; Quality of Life; Medication Errors; Patient Medication Knowledge; Medication Adherence; Risk Factors; Regression Analysis; Cross-Sectional Studies; Jordan

INTRODUCTION
Hypertension is a common disease that has been identified among the leading causes of cardiovascular diseases worldwide. In Jordan the prevalence of hypertension is very high approaching 32.3%, with 60.4% of those patients having uncontrolled blood pressure. This high rate of uncontrolled hypertension may be independently associated with worsened Health Related Quality of Life (HRQOL) in hypertensive patients compared to those with controlled blood pressure.

HRQOL is defined as “those aspects of self-perceived well-being that are related to or affected by the presence of disease or treatment.” Several tools have been used to evaluate HRQOL, among them is the RAND-12 Health Status Inventory (RAND-12). The RAND-12 contains 12 items that are identical to the Short Form-12 Health Survey (SF-12) which was originally developed in 1994. Those 12 items were derived from the Short Form-36 Health Survey (SF-36) a shorter alternative for studies in which a 36-item form was too long. The validity of the RAND-12 in measuring the quality of life in patient with chronic diseases was assessed by Feeny et al in 2005.

Many factors have been found to be significantly associated with poor HRQOL in hypertensive patients. Poor systolic and diastolic blood pressure, obesity, target organ complications, the number of hypertensive drugs used, and the presence of drug side-effects were among the clinical factors independently affecting the general quality of life in patients with hypertension. The influence of these factors on HRQOL is important since HRQOL may influence life quality and adherence to antihypertensive therapy.

Improving a patient’s HRQOL is among the main missions of the pharmacy profession. Through pharmaceutical care services, pharmacists cooperate with patients and other healthcare professionals in designing, implementing, and monitoring a care plan aimed at preventing and resolving drug related problems (DRPs). A DRP is an event or circumstance involving medication therapy that actually or potentially interferes with an optimum outcome for a specific patient and thus affecting patients quality of life. Patients with hypertension often receive multiple medications and have different co-morbid chronic diseases that can lead to the occurrence of DRPs. Numerous DRPs have been found amongst patients with hypertension. These DRPs were associated with poor blood pressure...
This necessitates the implementation of pharmaceutical care services for all patients with hypertension,20,22 designing continuous educational workshops for healthcare providers in Jordan, drawing attention to the most frequent DRPs among this population of patients.

Despite the availability of several studies investigating the effect of different demographic and clinical factors on HRQOL amongst patients with hypertension,3,10,15 no previous studies have been carried out to determine the effect of the presence of DRPs on the HRQOL in this population of patients. Thus, the purpose of this study was to identify the impact of different types of DRPs on the HRQOL of hypertensive patients in Amman-Jordan, using a comprehensive classification system for DRPs.

**METHODS**

**Study design, subjects and data collection**

This study protocol adopted a cross-sectional correlation study design that was approved by the Institutional Review Board Committee at the Jordan University Hospital. The study was carried out across two outpatient’s cardiac clinics at Jordan University hospital in Amman-Jordan over 3 months’ period. According to the study protocol, patients were recruited if they were adult patients (≥18 years of age) with a diagnosis of primary hypertension for at least 6 months, receiving treatment for hypertension, able to read and write Arabic, had no apparent cognitive deficit, had an appointment at cardiac clinic in the study site, and willing to participate in the study. Patients were excluded if they had hypertensive crisis or diagnosed with secondary hypertension.

Once patients were approached and agreed to participate, data was collected from patients’ medical files which included: demographic information, clinical tests performed, diagnosed medical conditions, and prescription/over the counter used medications. Patients were interviewed to assess their knowledge and adherence about pharmacological and non-pharmacological therapies as well as to evaluate their quality of life.

**DRPs classification system**

AbuRuz et al. classification system was used in our study as a guide to identify the different DRPs.23 This tool is considered one of the validated tools for the identification of DRPs. However, this tool has several features that are new in the field of DRPs assessment and identifications. First; the presence of an assessment part which helps pharmacist to evaluate patient data for the presence of DRPs and probably increases the likelihood of detecting problems. Second, this system is considered a comprehensive clinically tested tool, where a new DRPs appear that have not been mentioned in other tools.23

In this classification, DRPs were divided into six main categories including 1) Indication, 2) Effectiveness, 3) Safety, 4) Knowledge, 5) Adherence, and 6) Miscellaneous.23 This system has been carefully explained and successfully applied in several studies.19,21

**RAND-12 Health Status Inventory (RAND-12)**

The RAND-12 contains 12 items that are identical to the SF-12; these 12 questions are used to measure eight concepts related to quality of life including: general health perceptions, physical functioning, limitations due to role-physical health, bodily pain, vitality, social functioning, limitations due to role-emotional problems, and general mental health.8

These eight domains may be further aggregated into two component scores: Physical Health Composite (PHC) and Mental Health Composite (MHC).24 The PHC includes physical functioning, role-physical, bodily pain, and general health scales while the MHC includes vitality, social functioning, role-emotional and mental health scales. RAND-12 was used to assess quality of life for the past 4 weeks. The questionnaire was translated to Arabic and validated in a previous study on diabetic patients.25

**Identification of DRPs**

DRPs were identified individually for each patient utilizing a systematic evidence based approach.26 For each of the patients’ documented diseases, treatment was evaluated using the appropriate updated evidence based treatment guidelines. On the other hand, the appropriateness of dosing regimen was checked by comparing doses with evidence-based guideline recommendations. The I-fact® (Facts and Comparison®) was used for identifying major drug-drug interactions.27

Patients’ knowledge was assessed based on ability to answer correctly the questions related to their medications and life style activities. As for medication knowledge, patients were asked about their medication doses, indications and timing. For each correct statement the patient gained 1 point with a total of 3 points for each medication. Patient was considered to have suboptimal knowledge if they obtain an average medication score of 2 or less.

Patients were considered to have a problem in their knowledge regarding self-care activities if they were not able to classify one out of the five issues regarding their self-care activities including (avoid alcohol drinking, avoid high salt diet, avoid high fat diet, avoid cigarette smoking and perform regular physical exercises).

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**Table 1. Demographic and clinical characteristics of study sample (n=200)**

| Age, years, mean (SD) | 59.7 (10.2) |
|-----------------------|-------------|
| Male, n (%)           | 79 (39.5%)  |
| Marital status, n (%) |             |
| Single                | 2 (1%)      |
| Married               | 163 (81.5%) |
| Others                | 35 (17.5%)  |
| Education, n (%)      |             |
| Not educated          | 27 (13.5%)  |
| Primary               | 89 (44.5%)  |
| Secondary             | 12 (6%)     |
| High School           | 22 (11%)    |
| Control of hypertension, n (%) |         |
| Controlled            | 103 (51.5%) |
| Uncontrolled          | 97 (48.5%)  |
| Duration of hypertension, years, mean (SD) | 8.4 (6.4) |
Patients adherence to medications was assessed by a questionnaire developed and validated in Arabic by AbuRuz et al. Based on the scale developed previously by Morisky et al. The questionnaire contains five questions asking the patients how often during the last month they forgot to take their medications, skipped their medication, stopped their medication when they feel better, stopped their medication when they feel worse or stopped their medication when they experienced side effect. The questionnaire was scored at scale of 0 (never), 1 (rarely), 2 (sometimes), 3 (often) and 4 (always). Patients were considered non-adherent if they have a mean score ≥1.0 in the total adherence score.

On the other hand, adherence to self-care activities was assessed using six questions that was based on the summary of diabetes self-care activities measure. The instrument asks the patients to recall their self-care behaviors during the previous seven days. Patients were considered non-adherent if they could recall any inappropriate lifestyle behavior during the last week.

**Quality assurance**

DRPs were identified independently by the authors of the study. In the case of disagreement, the DRP was discussed until consensus is reached.

| Table 2. Percentages and examples of the various type of the identified DRPs |
|---------------------------------|---------------------------------|
| **DRPs categories**             | **Examples**                    |
| Indication drug related problems (12%) | Patient has osteoporosis and she receives only alendronate, she needs additional therapy to treat osteoporosis so add vitamin D and CaCO3 |
| Efficacy drug related problems (18%) | It is more effective to use fibrate (gemfibrozil) instead of statin, since patient has hypertriglyceridemia [LDL= 59 mg/dl while TG = 214 mg/dl] |
|                                   | The maximum recommended dose of atenolol that can be used in hypertension should not exceed 100 mg /day and the patient receives 150 mg /day, so reduce the dose of atenolol |
|                                   | The standard dose of gemfibrozil that should be used in patient with dyslipidemia should be 600 mg 1*2 not 600 mg 1*1 |
| Safety drug related problems (11%) | The dose of simvastatin that should be used in patient using fibrate should not exceed 10 mg 1*1 so reduce the dose of simvastatin from 20 mg to 10 mg 1*1 |
|                                   | Enalapril causes cough to the patient, so change to angiotensin receptor antagonist like candesartan |
| Inappropriate adherence to medications (11%) | Patient needs education to understand his medication |
| Inappropriate knowledge about medications (24%) | Patient needs education to understand non-pharmacological therapy |
|                                   | Patients does not adhere to medication |
|                                   | Patient needs education to adhere to self-care activities (reduce salt intake, make exercise). |
| Miscellaneous drug related problems (24%) | Lipid profile needs monitoring |

**Sample size calculation**

Based on Tabachnick and Fidell recommendation for sample size calculation in multiple linear regression analysis, 20 subjects per each predictor are suggested to be preferable, but the minimum required subject per predictor should be five. Based on the preferred number, and since we have eight predictors or independent variables in our study (eight classes of DRPs), a sample size of 160 was considered to be representative. So, in this study, a sample size of 200 was decided to be involved in order to have more generalizable results.

**Compliance with ethical standards**

The study was conducted following the ethical standards outlined in the World Medical Association Declaration of Helsinki guideline. Participant’s confidentiality was preserved by using anonymous data collection forms. Due to the anonymity of the study protocol, only verbal informed consents were obtained from all participants before the interview.

**Statistical analysis**

Data was analyzed using statistical package for social science (SPSS) version 22 (SPSS Inc., Chicago, IL, USA). The descriptive analysis was done using mean and SD for continuous variables and percentage for qualitative variables. Checking for normality was carried out using

| Table 3. RAND-12 physical and Mental Health Composite scores among the study hypertensive patients (n= 200) |
|-------------------------------------------------|-------------------------------------------------|
| **Mental health composite (MHC)**                | **Physical health composite (PHC)**              |
| Mean                                            | Mean                                            |
| 60.5                                            | 58.3                                            |
| SD                                              | SD                                              |
| 22.9                                            | 29.9                                            |
| Median                                          | Median                                          |
| 66.7                                            | 70.8                                            |
| IQR                                             | IQR                                             |
| 47.7-76.7                                       | 29.2-87.5                                       |
| Actual DRPs                                     | Actual DRPs                                     |
| r = -0.278, p-value <0.05                       | r = -0.375, p-value <0.05                       |
| SD: standard deviation, IQR: interquartile range, r: Pearson correlation coefficient |
A relation coefficient was used to evaluate the proportion of hypertension in Jordan (mean=6.31, SD=2.63, range 0–15), among them 1020 were considered actual DRPs (mean=5.1, SD=2.3, range=0–14). Examples of the different identified DRPs are presented in Table 2, showing also the percentage of the different identified actual DRPs categories. Inappropriate knowledge and miscellaneous DRPs (mainly need additional monitoring) were the most frequently identified DRPs among the study sample, approximating for 24%, followed by efficacy related DRPs (18%).

The demographic and clinical characteristics of the sample are shown in Table 1. The mean age of patients was around 59.7 years (SD=10.2); males accounted for 39.5% of all the patients recruited. The mean duration of hypertension amongst the study participants was 8.4 (SD 6.4) years, from which about half of them (51.5%) had controlled hypertension.

The total number of identified DRPs was 1261 (mean=6.31, SD 2.63, range 0–15), among them 1020 were considered actual DRPs (mean=5.1, SD=2.3, range=0–14). Examples of the different identified DRPs are presented in Table 2, showing also the percentage of the different identified actual DRPs categories. Inappropriate knowledge and miscellaneous DRPs (mainly need additional monitoring) were the most frequently identified DRPs among the study sample, approximating for 24%, followed by efficacy related DRPs (18%).

Table 4. Simple linear regression analysis for actual DRPs affecting MHC of the RAND-12 quality of life

| Actual DRPs category | B Estimate | SE | Beta | R² (%) | p-value* |
|----------------------|------------|----|------|--------|---------|
| Indication drug related problems | -0.632 | 3.245 | -0.014 | 0.00% | 0.846 |
| Efficacy drug related problems | -0.629 | 3.326 | -0.013 | 0.00% | 0.850 |
| Safety drug related problems | -8.873 | 3.207 | -0.193 | 3.70% | 0.006* |
| Inappropriate adherence to medications | -11.305 | 3.182 | -0.245 | 6.00% | 0.006* |
| Inappropriate adherence to non-pharmacological therapy | -12.83 | 3.914 | -0.227 | 5.10% | 0.001* |
| Inappropriate knowledge about medications | -4.986 | 3.231 | -0.109 | 1.20% | 0.124 |
| Inappropriate knowledge about non-pharmacological therapy | -7.209 | 4.239 | -0.120 | 1.40% | 0.091 |
| Miscellaneous drug related problems | -4.315 | 3.786 | -0.081 | 0.70% | 0.256 |

*Simple linear regression analysis *Significant at 0.05 level. ** MHC: Mental Health Composite

Table 5. Multiple linear regression analysis of the actual DRPs affecting MHC of the RAND-12 quality of life

| Variables | B estimate | SE | Beta | R² (%) | p-value* |
|-----------|------------|----|------|--------|---------|
| Indication drug related problems | 0.213 | 3.256 | 0.005 | 0.0% | 0.948 |
| Efficacy drug related problems | 0.158 | 3.177 | 0.003 | 0.0% | 0.96 |
| Safety drug related problems | -6.097 | 3.19 | -0.133 | 1.8% | 0.057 |
| Inappropriate adherence to medications | -9.626 | 3.268 | -0.208 | 4.3% | 0.004* |
| Inappropriate adherence to non-pharmacological therapy | -10.793 | 3.922 | -0.191 | 3.6% | 0.006* |
| Inappropriate knowledge about medications | -1.988 | 3.318 | -0.043 | 0.2% | 0.55 |
| Inappropriate knowledge about non-pharmacological therapy | -1.506 | 4.355 | -0.025 | 0.1% | 0.73 |
| Miscellaneous drug related problems | -5.546 | 3.95 | -0.104 | 1.1% | 0.162 |
| Model | R^2=0.369; R^2=13.6%; adjusted R^2=10.0% | <0.05 |

*Multiple linear regression analysis * Significant at 0.05 level. ** MHC: Mental Health Composite
A simple linear regression analysis was applied to determine which classes of DRPs significantly affect MHC of the RAND-12. Table 4 shows that three classes of actual DRPs were significantly associated with poor MHC of quality of life (p-value<0.05). These were: safety DRPs, non-adherence to medication, and non-adherence to non-pharmacological therapy.

All classes of actual DRPs from Table 4 were entered into a multiple linear regression to identify the most important predictors of MHC of the RAND-12 quality of life. The result of the multiple linear regression showed that only two of these variables were significantly associated with poor MHC of quality of life (p-value<0.05) (Table 5). These variables were: non-adherence to medication, and non-adherence to non-pharmacological therapy.

The R for the regression was significantly different from zero. The highest correlation between independent variables was -0.278 indicating absence of multicollinearity.

On the other hand, a simple linear regression analysis was applied to determine which classes of DRPs significantly affect PHC of the RAND-12. Table 6 shows that five classes of actual DRPs were significantly associated with poor PHC of quality of life (p-value<0.05). These were: inadequate knowledge about medication, inadequate knowledge about non-pharmacological therapy, non-adherence to medication, non-adherence to non-pharmacological therapy and miscellaneous (mainly need additional monitoring).

All classes of actual DRPs from Table 6 were entered into a multiple linear regression to identify the most important predictors of PHC of the RAND-12 quality of life. The result of the multiple linear regression analysis showed that only three of these variables were significantly associated with PHC of quality of life (p-value<0.05) (Table 7). These variables were: non-adherence to medication, non-adherence to non-pharmacological therapy and inadequate knowledge about medication.

The R for the regression was significantly different from zero. The highest correlation between independent variables was -0.278 indicating absence of multicollinearity.

**DISCUSSION**

Improving HRQOL is increasingly become one of the most important responsibilities for healthcare professionals including pharmacists. In order to do so, factors affecting table:

| Table 6. Simple linear regression analysis for actual DRPs affecting PHC of the RAND-12 quality of life |
|---|---|---|---|---|
| Actual drug related problem category | Dependent variable: PHC** | B Estimate | SE | Beta  | R2 % | p-value* |
| Indication drug related problems |  | -4.864 | 4.223 | -0.082 | 0.70% | 0.251 |
| Efficacy drug related problems |  | -7.493 | 4.31 | -0.123 | 1.50% | 0.084 |
| Safety drug related problems |  | -6.906 | 4.239 | -0.115 | 3.10% | 0.105 |
| Inappropriate adherence to medications |  | -11.438 | 4.207 | -0.19 | 3.60% | 0.007* |
| Inappropriate adherence to non-pharmacological therapy |  | -19.321 | 5.065 | -0.262 | 6.80% | 0.000* |
| Inappropriate knowledge about medications |  | -18.204 | 4.042 | -0.305 | 9.30% | 0.000* |
| Inappropriate knowledge about non-pharmacological therapy |  | -13.113 | 5.497 | -0.167 | 2.80% | 0.018* |
| Miscellaneous drug related problems |  | -11.556 | 4.892 | -0.166 | 2.70% | 0.019* |

*Simple linear regression analysis *Significant at 0.05 level. **PHC: Physical Health Composite

| Table 7. Multiple linear regression analysis of the actual DRPs affecting PHC of the RAND-12 quality of life |
|---|---|---|---|---|
| Variables | Dependent variable: PHC** | B estimate | SE | Beta | R2 (%) | p-value* |
| Indication drug related problems |  | -2.078 | 4.087 | -0.035 | 0.12% | 0.612 |
| Efficacy drug related problems |  | -5.359 | 3.988 | -0.088 | 0.77% | 0.181 |
| Safety drug related problems |  | -3.916 | 4.004 | -0.065 | 0.42% | 0.329 |
| Inappropriate adherence to medications |  | -8.973 | 4.102 | -0.149 | 2.22% | 0.030* |
| Inappropriate adherence to non-pharmacological therapy |  | -16.652 | 4.923 | -0.226 | 5.11% | 0.001* |
| Inappropriate knowledge about medications |  | -13.707 | 4.165 | -0.23 | 5.29% | 0.001* |
| Inappropriate knowledge about non-pharmacological therapy |  | -1.16 | 5.466 | -0.015 | 0.02% | 0.832 |
| Miscellaneous drug related problems |  | -8.717 | 4.958 | -0.125 | 1.56% | 0.08 |
| Model |  | R=0.449; R²=0.20.2%, adjusted R²=16.8% | <0.05 |

* Multiple linear regression analysis * Significant at 0.05 level. **PHC: Physical Health Composite
HRQOL must be identified. To our knowledge, the effect of DRPs on HRQOL among hypertensive patients was not previously investigated in the literature. So, this study is the first one to evaluate the influence of DRPs on the HRQOL in hypertensive patients using RAND-12 quality of life scale.

Results of this study revealed a high number of DRPs in hypertensive patients. The average number of actual DRPs was 5.1 per patient. This number was almost twice the number detected by another study which was conducted on hypertensive patients from East Ethiopia (mean=2.9 DRPs per patient). The most frequent DRPs identified in our study were inappropriate knowledge, needs additional monitoring and efficacy related problems. Our obtained results are not consistent with previously obtained results where drug interaction, followed by non-adherence and adverse drug interaction were the most common type of identified DRPs among hypertensive patients.

There were several previous studies investigating factors affecting quality of life in patient with hypertension. None of these studies investigated the influence of DRPs on HRQOL. Therefore, this is considered a new finding, as DRPs were found to have a significant influence on both the physical and mental components of RAND-12 quality of life scale in hypertensive patients, with the higher number of DRPs being associated with poorer quality of life.

The most identified DRPs affecting the mental domain of the RAND-12 were non-adherence to medication and non-adherence to non-pharmacological therapies. These two predictors explained around 14% of the variation in the mental domain of the RAND-12 scale. In a similar way, non-adherence to medication, non-adherence to non-pharmacological therapies and inadequate knowledge about medications were able to explain 20% of the variation of the physical domain of the RAND-12.

Non-adherence to medications and lifestyle changes demonstrated significant impact on both MHC and PHC of the RAND-12 scale; where patients with lower adherence tend to have poorer quality of life. This association was proved previously by Hanus et al., where hypertensive subjects with high medication adherence presented the higher quality of life scores compared to those with lower adherence.

The mutual interaction between non-adherence and quality of life can be explained through the effect of non-adherence on blood pressure control among hypertensive patients. Non-adherence to medications was found previously to be one of the main independent predictors of poor blood pressure control among hypertensive patients. This poor blood pressure control may hamper patients from maintaining better quality of life.

In addition to non-adherence, inadequate knowledge about medications was found to have an influence on the physical domain of the RAND-12 but not the mental domain. No previous studies have investigated the direct influence of knowledge about medications on HRQOL of hypertensive patients. On the other hand, one preceding study highlighted that knowledge about hypertension is weakly associated with HRQOL. This finding is in agreement with our results, where knowledge about hypertension and its related non-pharmacological treatment was not found to have any influence on both the physical or mental domains of the RAND-12 scale.

The investigation of the relationship between adherence to treatment and knowledge about medications on the HRQOL in hypertensive patients necessitates the development of strategies to incorporate patients into educational programs about the current management of hypertension, aiming to improve the adherence to and knowledge about medications and consequently improving disease control and achieving better quality of life of these individuals.

**Limitations**

It is worth mentioning the main limitations of this study, 1) this study was conducted only in one center, it therefore may not be representative to the whole patients’ population. 2) The severity of DRPs, the proportion of self-medication and use of alternative and complementary medicines were not assessed. 3) Since this study utilized a convenience sampling approach rather than random sampling, the results may not be representative of all hypertensive patients attending the Jordan University Hospital, and 4) we did not make suggestions for resolving the issue of the detected DRPs with the responsible physician to evaluate the impact of resolving such problems on HRQOL.

**CONCLUSIONS**

This is the first study to evaluate the influence of DRPs on hypertensive patients HRQOL. The prevalence of DRPs among hypertensive patients is a concern that needs attention. These DRPs were associated with poor quality of life on both the mental and physical domains of the RAND-12 scale. Pharmaceutical care services are strongly recommended to identify, resolve and prevent DRPs for all patients with hypertension. Non-adherence and inadequate knowledge DRPs should be given the highest priority. A future randomized controlled study is needed to investigate the impact of such service in improving HRQOL among this population.

**CONFLICT OF INTEREST**

None of the authors have any conflict of interest..

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