# ASSESSMENT OF RISK, KNOWLEDGE AND QUALITY OF LIFE OF PATIENTS ON STEROID THERAPY

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# **ABSTRACT**

Steroid therapy has been extensively utilized in the past decade by physicians. Long-term use of glucocorticoids is associated with a higher risk of steroid-induced osteoporosis. Our study aimed to assess the level of knowledge on risk factors of osteoporosis in patients on glucocorticoid therapy, assess the quality of life, and evaluate the impact of patient counselling in patients diagnosed with osteoporosis. A prospective study was conducted among 150 patients at a tertiary care hospital in central Kerala. Knowledge and Quality of life were assessed using a self-validated questionnaire. Patient education resulted in a significant improvement in knowledge from baseline  $3.73\pm1.591$  to 2nd review  $7.27\pm1.192$ . Risk factors like age, female sex, family history, smoking, and alcohol intake were also assessed during the study. Among A significant improvement in the QoL of GROUP II-(96.6%) was observed compared to GROUP I (43.6%). Patient education and osteoporosis awareness programs must be conducted at regular intervals to improve their understanding of the disease. Verbal counselling and Patient Information Leaflets contribute to an enhanced improvement in the Quality of Life of patients with steroid therapy.

KEYWORDS: Glucocorticoids, osteoporosis, Quality of life, PILs,

#### INTRODUCTION

Osteoporosis is a developing public health issue associated with significant morbidity, mortality, and reduced quality of life. As the disease progresses painlessly and without any signs or symptoms, it is also known as 'the silent disease' [1,2]. More than 200 million people are thought to be affected by osteoporosis around the world. In India, the prevalence of osteoporosis is

estimated to be around 41 million, of which women in the postmenopausal age and older men appear to be most exposed [3]. Certain risk factors can lead to the development of osteoporosis or can exacerbate the likelihood of developing the disease. The most common cause of secondary osteoporosis is long-term steroids, which is one of the risk factors of osteoporosis. Glucocorticoid-induced

osteoporosis (GIOP) contributes to fracture risk and bone loss in the long-term use of steroids [4]. The most basic necessity for managing any chronic health disorder starts with the evaluation of awareness about the disease among the patients. Despite having a thorough understanding of the condition may not be sufficient to bring about health-related changes, adequate knowledge is a prerequisite for the success of preventive efforts [5].

Osteoporosis, on a global level, causes approximately nine million fractures per year<sup>[6]</sup>. The lack of knowledge in the patient population regarding the risk factors, benefits of exercise, and the intake of calcium and vitamin-D-rich diet are key factors to be analyzed<sup>[7]</sup>. The knowledge and awareness regarding osteoporosis in patients is an essential aspect as it plays a major role in the implementation of various therapeutic prevention programs to manage osteoporosis<sup>[8]</sup>. Understanding knowledge and beliefs of the patients helps the physician to enhance awareness about osteoporosis and its health behaviors [9].

The World Health Organization (WHO) defines quality of life as an individual's perception of their life position in the context of various cultural and value systems by which they live. It also incorporates their goals, expectations, standards, and concerns<sup>[10]</sup>. The assessment of the quality of life has been an essential aspect as it plays an important role in the

social development of the patient. Modern developments in health care have brought about an elevated need for better life expectancy rates and improved quality of life. With an aging society, the percentage of individuals with chronic disease conditions has also increased<sup>[11]</sup>. The need of the hour has been shifted from mere survival to a much-improved quality of life for the patients. This includes the patient's physical, emotional, mental, and social well-being <sup>[12]</sup>.

The pharmacist plays an integral role in the management of osteoporosis as a part of a multidisciplinary approach. Pharmacists can assist in the process of screening the level of knowledge about the disease which is associated with improved patient compliance with treatment<sup>[13]</sup>. Pharmacists aid in the betterment of the quality of life in osteoporotic patients through recognition of symptoms and tracking progress in the condition<sup>[14]</sup>. This session will go over the multiple roles of clinical pharmacists in the management of osteoporosis. This study aims to assess the level of knowledge and impact of patient education on risk factors of osteoporosis in patients on glucocorticoid therapy and assess Quality of Life and evaluate the impact of patient counseling in patients diagnosed with osteoporosis.

# MATERIALS AND METHODS

This prospective observational study was conducted for a duration of 6 months from January 2022 to June 2022. From a total of 250 patients screened,150 patients were included in this study as per inclusion and exclusion criteria. Patients aged between 40-80 years who are on therapy with glucocorticoids (at least 5mg/day) for more than 3 months and are willing to answer the questionnaire by

providing written informed consent were included in the study. Pregnant and lactating women and patients with mental disorders were excluded from the study.

self-validated Osteoporosis knowledge assessment questionnaire was used to assess the knowledge of patients on factors of osteoporosis. This questionnaire consists of 10 items associated with risk factors, family history of osteoporosis, calcium, and vitamin intake, knowledge about steroid-induced osteoporosis, and osteoporosis prevention methods[15]. A value of 1 was given for each right answer and 0 for each wrong answer. If the score obtained by the subject was greater than 7 indicates a good level of knowledge, between 5 to 7 indicates a medium level of knowledge, and below 5 indicates poor knowledge of osteoporosis [16]. Participants were educated about the awareness of risk factors of osteoporosis and its preventive measures. Then, they interviewed with the were same questionnaire once in 30 days for two times. The risk of osteoporosis among patients who are part of the study population and not diagnosed with osteoporosis also was analyzed in the study.

**Patients** diagnosed with osteoporosis were evaluated and given counseling to improve their quality of life. Quality of life was assessed by a selfvalidated Osteoporosis Quality of Life Ouestionnaire which includes domains: Physical function (difficulties with components of activities of daily living) 2 items; Emotional function (affective components associated with osteoporosis)2 items; Symptoms (physical experiences associated with osteoporosis which proved primarily associated with pain)2 items; Leisure (recreational activities), and Daily activity (self-care,

housework, etc.) [17]. The questionnaire incorporated a total of 10 items of which each domain represents two items. Each item was associated with a four-point scale in which a rating of 4 represents the best possible function and a rating of 1 the worst possible function<sup>[18]</sup>.

The study participants who had osteoporosis were further divided into two groups, each group containing 75 participants. The first group included patients provided with verbal counseling and the second group included patients who received verbal counseling plus Patient Information Leaflets (PILs). The first follow-up of the study was done after 1 month and 2<sup>nd</sup> follow-up after 2 months from the baseline. Every participant was interviewed with the same questionnaire.

The data were entered and analyzed using SPSS version 21. The categorized variables were presented as frequency and percentage and the continuous variables were reported using mean and standard deviation. A paired student 't' test was used to compare the means. The correlation was determined by using Pearson's correlation. The P value <0.05 at the Confidence interval of 95% was considered statistically significant.

# **RESULTS**

A total of 150 patients were prescribed steroids among them 49 (32.66%) participants aged between 51 and 60 years. There were 105 female respondents comprising 70% of the study sample. Majority of the study participants 17(52%) had a high school education and

13 (8.66%) were illiterate. Out of all participants, 63 (42%) were housewives and 72 (48%) patients had a family history of osteoporosis. Among the study participants, 60 (40%) were diagnosed with osteoporosis.

Table 1: Baseline Demographics (n=150)

| S. No Demographics | Frequency | Percentage |
|--------------------|-----------|------------|
|--------------------|-----------|------------|

| 1.  | Sex                       |     |       |
|-----|---------------------------|-----|-------|
| 2.  | Male                      | 45  | 30.00 |
| 3.  | Female                    | 105 | 70.00 |
| 4.  | Age (years)               |     |       |
| 5.  | 40-50                     | 35  | 23.33 |
| 6.  | 51-60                     | 49  | 32.67 |
| 7.  | 61-70                     | 66  | 44.00 |
| 8.  | <b>Educational Status</b> |     |       |
| 9.  | Illiterate                | 13  | 08.67 |
| 10. | Primary school            | 18  | 12.00 |
| 11. | Middle school             | 14  | 09.33 |
| 12. | High school               | 78  | 52.00 |
| 13. | Graduate                  | 19  | 12.67 |
| 14. | Professional Degree       | 8   | 05.33 |
| 15. | <b>Employment Status</b>  |     |       |
| 16. | Housewife                 | 63  | 42.00 |
| 17. | Industrial Workers        | 32  | 21.33 |
| 18. | Health Care Workers       | 29  | 19.33 |
| 19. | Educational Sector        | 17  | 11.33 |
| 20. | Others                    | 9   | 06.00 |

A comparison of knowledge on risk factors of osteoporosis between baseline and reviews is given in Table 2. There is a statistically significant improvement in the

knowledge assessment on risk factors of osteoporosis at baseline and in 1<sup>st</sup> and 2 <sup>nd</sup> reviews.

**Table 2: Knowledge Assessment** 

| S. No | Reviews                | Knowledge Score | Mean<br>Difference | T -Value |
|-------|------------------------|-----------------|--------------------|----------|
| 1.    | Baseline               | 3.73±1.591      |                    | 28.446   |
| 2.    | 1st Review             | 5.57±1.195      | 1.707*             | 12.710   |
| 3.    | 2 <sup>nd</sup> Review | 7.27±1.192      | 3.570*             | 26.767   |

<sup>\*</sup>*p*<0.05

Out of 90 patients who were not diagnosed with osteoporosis, their risk of osteoporosis was assessed using the Osteoporosis Self-Assessment Tool (OST) and found that 63.3% of respondents were at low risk, 28.8% were at moderate risk and 13.3% were at high risk for osteoporosis. <sup>15</sup>

In the study of patients who were not diagnosed with osteoporosis (90), it was found that 42.2% of the patients were smokers and 62.2% were alcoholics. 48.8% of the patients had a family history of osteoporosis. 57.7% were passive. 54.4% of the respondents in this study were females.

Table 3: Comparison of total Quality of Life

| S. No | Reviews  | Group-I    | Group-II   |  |
|-------|----------|------------|------------|--|
| 1.    | Baseline | 17.73±4.16 | 17.53±4.52 |  |

| 2. | 1st Review             | 19.57±3.83* | 24.03±4.43* |
|----|------------------------|-------------|-------------|
| 3. | 2 <sup>nd</sup> Review | 20.87±3.58* | 28.63±4.23* |

<sup>\*</sup>p<0.05

Table 4. Comparison of quality of life in each domain.

| S. No | Domains                   | Group 1 | Group 2 |  |  |  |  |
|-------|---------------------------|---------|---------|--|--|--|--|
| 1.    | Physical Function         |         |         |  |  |  |  |
| 2.    | Baseline                  | 3.76    | 3.60    |  |  |  |  |
| 3.    | 1st Review                | 3.86    | 4.50    |  |  |  |  |
| 4.    | 2 <sup>nd</sup> Review    | 3.96    | 4.86    |  |  |  |  |
| 5.    | <b>Emotional Function</b> |         |         |  |  |  |  |
| 6.    | Baseline                  | 3.76    | 3.70    |  |  |  |  |
| 7.    | 1st Review                | 4.16    | 5.40    |  |  |  |  |
| 8.    | 2 <sup>nd</sup> Review    | 4.60    | 6.46    |  |  |  |  |
| 9.    | Symptoms                  |         |         |  |  |  |  |
| 10.   | Baseline                  | 3.03    | 3.20    |  |  |  |  |
| 11.   | 1st Review                | 3.26    | 4.46    |  |  |  |  |
| 12.   | 2 <sup>nd</sup> Review    | 3.56    | 5.30    |  |  |  |  |
| 13.   | Daily Activities          |         |         |  |  |  |  |
| 14.   | Baseline                  | 3.50    | 4.36    |  |  |  |  |
| 15.   | 1st Review                | 4.26    | 5.80    |  |  |  |  |
| 16.   | 2 <sup>nd</sup> Review    | 4.66    | 6.73    |  |  |  |  |
| 17.   | Leisure                   |         |         |  |  |  |  |
| 18.   | Baseline                  | 3.70    | 3.36    |  |  |  |  |
| 19.   | 1st Review                | 4.03    | 4.46    |  |  |  |  |
| 20.   | 2 <sup>nd</sup> Review    | 4.13    | 5.56    |  |  |  |  |

PIL- Patient Information Leaflet

Results shown in Table 5 reveal a positive correlation between all the variables. Statistically, there was a strong positive correlation between total quality of life and its physical function (r=0.708), emotional function (r=0.857), symptoms (r=0.793), and daily activity (r=0.676).

Knowledge was found to have a significant positive correlation between the quality of life (r=0.364) and its physical function, emotional function except for symptoms (r=0.238) and daily activity (r=0.143).

Table 5: Correlation of Quality of Life Domines and Knowledge

| S.<br>No | Variables             | Total<br>QoL | Physical Function | Emotional<br>Function | Symptoms | Daily<br>Activity | Knowledge |
|----------|-----------------------|--------------|-------------------|-----------------------|----------|-------------------|-----------|
| 1.       | Total QoL             | 1            | 0.708*            | 0.857*                | 0.793*   | 0.676*            | 0.364*    |
| 2.       | Physical<br>Function  |              | 1                 | 0.570*                | 0.562*   | 0.238             | 0.434*    |
| 3.       | Emotional<br>Function |              |                   | 1                     | 0.682*   | 0.572*            | 0.406*    |
| 4.       | Symptoms              |              |                   |                       | 1        | 0.424*            | 0.238     |

| 5. | Daily<br>Activity | <br> | <br> | 1 | 0.143 |
|----|-------------------|------|------|---|-------|
| 6. | Knowledge         | <br> | <br> |   | 1     |

\*p<0.05, QoL- Quality of Life

#### **DISCUSSION**

Osteoporosis is a serious health concern that affects thousands of people in the Indian population. As life expectancy continues to increase through demographic transition, osteoporosis is becoming a major global health issue with clinical, economic, and social impacts<sup>[19]</sup>. Assessing the level of awareness about the risk factors of osteoporosis is sufficient to bring about changes in health-related behaviors<sup>[20]</sup>.In India, awareness osteoporosis is low, since there has been relatively minimal attempt to publicize the illness. Although few surveys indicate that awareness about the disease in the urban population is inadequate, there are no largescale surveys undertaken to assess the depth of awareness and understanding of osteoporosis in the general population<sup>[21,22]</sup>. The selection of the general population as study subjects is justified by the fact that they are understudied and may have knowledge gaps which, if addressed, would facilitate better prevention policies<sup>[23]</sup>.

The study aimed to assess the knowledge associated with the development of risk factors of osteoporosis in patients taking steroids and assess the quality of life and evaluate the impact of patient counseling in patients diagnosed with osteoporosis. Patient education intervention is an important strategy as there is an increasing rate of chronic diseases like osteoporosis in India [24]. Our results showed knowledge of risk factors of osteoporosis can be improved in patients on structured steroids with properly pharmacist interventions. Based on our study, there was a significant difference between the baseline, first review, and

second review of the questionnaire scores after the patient education.

During the study, patient education related to the knowledge on risk factors of osteoporosis provided a significant improvement from 66% of poor level knowledge to 4.66% of poor level knowledge, which is to an Indian study result obtained by Manickavasagam Senthilraja et al [5] that found poor level of knowledge in postmenopausal women using an OKAT questionnaire. This proves that the clinical pharmacist plays a better role in the understanding of osteoporosis and its risk factors which is low in the present cohort of Indian men and women

Progression of osteoporosis generally affects the normal daily activities of the patient as well as their quality of life. Older age hurts the QoL of patients as observed in the results of a study by Yasar Keskin et al [26] using OUALEFFO measurement. Assessing QoL has been considered essential for the clinical evolution of patients with osteoporosis. Patients have poor QoL at baseline in both groups. Table no:2 represents the QoL questionnaire score in GROUP I after the second follow-up showed significant improvement in QoL than in GROUP II by providing the structured pharmacist-led intervention. Verbal counseling and Patient Leaflet Information (PILs) contributes to an enhanced improvement in the QoL of the patients with proper intervention by clinical pharmacist<sup>[27]</sup>.

QoL had a strong positive correlation with all its physical functions, emotional functions, symptoms, leisure,

and daily activities. Physical function was significantly correlated with all domains except daily activity. Likewise, knowledge was found to have a positive correlation between the quality of life and its domains except for symptoms and daily activities. A study by D.J. Cook et al [18] showed a correlation between domains and other instruments with an observation of excellent reliability and responsiveness of all five domains.

The outcomes of our study indicate the influence of pharmacist intervention in the improvement of knowledge and quality of life of the patients. Osteoporosis awareness programs must be conducted at regular intervals to improve the understanding of the disease<sup>[28]</sup>. Osteoporosis prevention measures should commence during the early phase of life.

#### **CONCLUSION**

Our study evaluates the knowledge and impact of patient counseling on risk factors of osteoporosis in patients taking steroids as well as their quality of life. Both the knowledge assessment and quality of life were significantly improved from the baseline to the second follow-up after giving proper counseling. The study clearly showed the effectiveness of verbal

# CONFLICT OF INTEREST

The authors have no conflicts of interest regarding this investigation.

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counselling and implementation of PILs in improving Health-related quality of life in patients diagnosed with osteoporosis. This study could serve as a stimulant for clinical pharmacists to provide education and awareness about osteoporosis among patients on steroids.

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