ASIAN JOURNAL OF PHARMACEUTICAL AND CLINICAL RESEARCH



# ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH FIBROADENOMA

## PRIYA RAJAM VIVEAN S\*, ASHOK KUMAR M, PRAVEEN D

Department of Pharmacy Practice, School of Pharmaceutical Sciences, VISTAS, Vels University, Chennai, Tamil Nadu, India. Email: priyasagayaraj16@gmail.com

## Received: 25 May 2016, Revised and Accepted: 27 May 2016

## ABSTRACT

**Objective:** Health problems can interfere with even the most basic aspects of daily living. Health-related quality of life (QoL) is an assessment of how the individual's well-being may be affected over time by a disease, disability, or disorder. Fibroadenomas of the breast are benign tumors composed of stromal and epithelial tissue.

**Methods:** The study will be carried out by the collection and documentation of general information of the patient including personal history, family background, clinical findings, investigations, and medical illness associated with fibroadenoma. Further, QoL will be documented using SF-12 questionnaire designed to assess the impact of fibroadenoma and their complications.

**Results and Discussion:** Out of 130 female patients, 112 patients (86%) were married and 18 patients (14%) were unmarried; the study confirms that married women are more affected with fibroadenoma than unmarried. The results indicate that physical component summary (PCS) does not improve significantly, but the mental component summary (MCS) improves significantly after counseling. PCS and MCS have been significantly improved in post-menopausal women. MCS is improved pre-menopausal women.

**Conclusion:** The study concludes that PCS does not improve significantly, but MCS improves significantly after counseling in pre- and post-menopausal women. Therefore, after counseling, patient's physical health, social relationships, and environment have been improved.

Keywords: Quality of life, Fibroadenoma, Counseling.

## INTRODUCTION

In general, quality of life (QoL) is the perceived quality of an individual's daily life that is assessment of their well-being or lack thereof. This includes all emotional, social, and physical aspects of the individual's life [1]. In health care, health-related QoL (HRQoL) is an assessment of how the individual's well-being may be affected over time by a disease, disability, or disorder [2].

Because health problems can interfere with even the most basic aspects of daily living (for example, breathing comfortably, quality of sleep, eliminating wastes, feeding oneself, dressing, and others), the healthcare professions have codified the concepts of activities of daily living (ADLs) and instrumental ADLs [3]. Such analysis and classification help to at least partially objectify QoL. It cannot eliminate all subjectivity, but it can help improve measurement and communication by quantifying and by reducing ineffability [4].

Fibroadenomas of the breast are benign tumors composed of stromal and epithelial tissue. Fibroadenomas are sometimes called breast mice or a breast mouse owing to their high mobility in the breast [5,6].

Fibroadenomas are the most common surgically treated breast masses in adolescents, accounting for 44-94% of biopsied breast lesions. They are assumed to be aberration of normal breast development or the product of hyperplastic processes, rather than true neoplasms [7].

Fibroadenomas present as firm, on tender, clearly demarcated masses usually 2-3 cm in size, though they may range from <1 to >10 cm. They are most commonly found in the upper quadrant of the breast. These benign masses may enlarge slowly without associated pain or nipple and skin changes, but fluctuations in size may occur with the menstrual cycle; when symptoms are present, they last on average of 5 months [8-10].

Multiple fibroadenomas occur in 10-25% of cases. In adolescents, the mass regresses completely between 10% and 40% of the time [11].

Fibroadenomas are a stromal and epithelial proliferation arising from the terminal duct lobular unit [12].

## Pathology

Fibroadenomas arise in the terminal duct lobular unit of the breast. Fibroadenomas usually form during menarche (15-25 years of age), a time at which lobular structures are added to the ductal system of the breast. Hyperplastic lobules are common at that time and may be regarded as a normal phase of breast development [13,14].

The preferred treatment of multiple fibroadenomas is complete excision. However, this approach can lead to undesirable scarring or to extensive ductal damage if all the fibroadenomas are excised through one incision [15].

Giant fibroadenomas tend to shrink after cessation of lactation, so their removal should be delayed until the patient's hormonal status returns to normal, and a smaller excision can be performed. It may be very disfiguring to excise juvenile fibroadenomas because of their larger sizes [16,17].

Some fibroadenomas respond to treatment with ormeloxifene [18].

Fibroadenomas have not been shown to recur following complete excision or transform into phyllodes tumors following partial or incomplete excision [19,20].

There are also natural treatments being touted to diminish fibroadenomas, such as fibrosolve, but no definite studies have been made as to prove their effectiveness [21].

Kowalski *et al.*, 2007 conducted a study on "QoL assessment in women with breast cancer: Benefits, acceptability, and utilization." The study

found out that QOL assessment tools, including written assessments and computer assessments, have several advantages and are beneficial for breast cancer patients. The implementation of QOL assessments into clinical practice for breast cancer treatment has a high potential to benefit patients. HRQoL has increasingly been an important factor to consider in the holistic treatment of breast cancer patients, and by providing accurate insights into QOL through self-reported questionnaires, physicians will be better able to make treatment decisions [22,23].

The main aim is to assess the QOL of women suffering from breast fibroadenoma including physiological, general perception, and social role among patients with fibroadenoma.

The main objective of the study is to:

- To assess the HRQoL in patients with fibroadenoma using SF-12 Questionnaire
- To improve the QoL in fibroadenoma patients through patient counseling and reducing the complications.

#### METHODS

It is a prospective interventional study, conducted in 130 post-operative fibroadenoma patients for a period of 9-month (August 2015-April 2016).

#### Patient inclusion criteria

- Study involves female group of fibroadenoma
- Willing to participate in completing the case pro forma
- Patients of age group 18-60 years
- Post-operative patients.

#### **Exclusion criteria**

- Patients of age above >60 years
- Pregnant women
- Patients with psychiatry complications.

#### Source of data

- Patient informed consent form
- Patient profile form
- SF-12 questionnaire.

#### Statistical analysis

The values obtained were averaged for analysis. The collected data were analyzed using mean, standard deviation, and Student's t-test.

Patients were selected based on the inclusion and exclusion criteria in the Surgery Department ESI Hospital.

This method involves prospective analysis of QoL in women with fibroadenoma. The study will be carried out by the collection and documentation of general information of the patient including personal history, family background, clinical findings, investigations, and medical illness associated with fibroadenoma. Further, QoL will be documented using SF-12 questionnaire designed to assess the impact of fibroadenoma and their complications.

SF-12 questionnaire: The SF-12<sup>®</sup> health survey includes 12 questions from the SF-36<sup>®</sup> health survey (version 1). These include: 2 questions concerning physical functioning; 2 questions on role limitations because of physical health problems; 1 question on bodily pain; 1 question on general health perceptions; 1 question on vitality (energy/fatigue); 1 question on social functioning; 2 questions on role limitations because of emotional problems; 2 questions on general mental health (psychological distress and psychological well-being). Finally, the documented questionnaire will be evaluated for the outcome.

## RESULTS

Out of selected 130 female patients, 37 patients (28%) were in the age group of 18-25 years, 48 patients (37%) were in the age group of

25-35 years, 31 patients (24%) were in the age group of 35-50, and 14 patients (11%) in the age group of 50-60 years are affected with fibroadenoma. Hence, in this study, it indicates that more number of people in the age group 25-35 years is affected with fibroadenoma which is depicted in table 1.

Table 2 shows that out of 130 female patients, 112 patients (86%) were married and 18 patients (14%) were unmarried; the study confirms that married women are more affected with fibroadenoma.

Table 3 shows that out of selected 130 female patients, 27 patients (21%) were qualified with  $10^{\rm th}$  std, 45 patients (35%) were qualified with  $12^{\rm th}$  std, 41 patients (32%) were qualified with college degree, 10 patients (7%) are studying currently, and 7 patients (5%) are uneducated.

Table 4 shows that out of 130 selected female patients, 47 patients (36%) were government employees, 7 patients (5%) were tailors, 17 patients (13%) were students, 40 patients (31%) were housewives, and 19 patients (15%) were not working.

Table 5 shows that out of 130 selected female patients, 110 patients (85%) were pre-menopausal women and 20 patients (15%) were post-menopausal; and the study confirms that pre-menopausal women were more affected than post-menopausal women.

Table 6 shows that out of 130 selected female patients, 20 patients (15%) were not having child, and patients having one child were 43 patients (33%), patients having two children were 46 patients (36%), and patients having more than two children were 21 patients (16%).

Table 7 out of selected 130 female patients, 28 patients (22%) were having diabetes, 14 patients (11%) were having hypothyroidism, 25 patients (20%) were having hypertension, 22 patients (15%) were having anemia, and 12 patients (7%) were having cellulitis and 29 patients (23%) with no comorbidities.

The results from Table 8 and 9 clearly indicate that physical component summary (PCS) does not improve significantly, but the mental component summary (MCS) improves significantly after counseling.

There is no variation in pre- and post-menopausal women. PCS and MCS have been significantly improved in post-menopausal women. MCS is improved pre-menopausal women.

#### DISCUSSION

This study was designed to find out the QoL among fibroadenoma patients and to create awareness about fibroadenoma disease. In this study, total 130 students were included. The patients who were all suffering from fibroadenoma are included in this study. It is an interventional study conducted in fibroadenoma patients.

Using pro forma, the patient's demographics, patient medical history, lab investigations, and other reports were monitored. Assessment is done using SF-12 questionnaire, which consists of 12 questions about the physical and mental components summaries, respectively.

Patient counseling was provided at the initial level, and the patient knowledge about fibroadenoma, cause, risk, management, treatment, and lifestyle modifications was assessed during the pre-counseling phase and post-counseling phase.

Out of selected 130 female patients, 37 patients (28%) were in the age group of 18-25 years, 48 patients (37%) were in the age group of 25-35 years, 31 patients (24%) were in the age group of 35-50, and 14 patients (11%) in the age group of 50-60 years are affected with fibroadenoma. Hence, in this study, it indicates that more number of people in the age group 25-35 years is affected with fibroadenoma compared to other age groups.

Out of 130 female patients, 112 patients (86%) were married and 18 patients (14%) were unmarried; the study confirms that married women are more affected with fibroadenoma than unmarried.

Out of selected 130 female patients, 27 patients (21%) were qualified with  $10^{\rm th}$  std, 45 patients (35%) were qualified with  $12^{\rm th}$  std, 41 patients (32%) were qualified with college degree, 10 patients (7%) are studying currently, and 7 patients (5%) are uneducated.

Out of 130 selected female patients, 47 patients (36%) were government employees, 7 patients (5%) were tailors, 17 patients (13%) were students, 40 patients (31%) were housewives, and 19 patients (15%) were not working.

Out of 130 selected female patients, 110 patients (85%) were premenopausal women and 20 patients (15%) were post-menopausal; and the study confirms that pre-menopausal women were more affected than post-menopausal women.

Out of 130 selected female patients, 20 patients (15%) were not having child, patients having one child were 43 patients (33%), patients having two children were 46 patients (36%), and patients having more than two children were 21 patients (16%).

Out of selected 130 female patients, 28 patients (22%) were having diabetes, 14 patients (11%) were having hypothyroidism, 25 patients (20%) were having hypertension, 22 patients (15%) were having

Table 1: Age-wise distribution

Age in years	Number of patients (%) (n=130	
18-25	37 (28)	
25-35	48 (37)	
35-50	31 (24)	
50-60	14 (11)	

## Table 2: Distribution based on marital status

Number of patients (%) (n=130)
112 (86)
18 (14)

#### Table 3: Distribution based on educational qualification

Educational qualification	Number of patients (%) (n=130)
10 <sup>th</sup> std	27 (21)
12 <sup>th</sup> std	45 (35)
College degree	41 (32)
Studying present	10 (7)
No education	7 (5)

#### Table 4: Distribution based on occupation

Occupation	Number of patients (%) (n=130)	
Government employee	47 (36)	
Tailor	7 (5)	
Student	17 (13)	
Housewife	40 (31)	
Not working	19 (15)	

#### Table 5: Distribution based on characteristics of patients

Characteristics of patients	Number of patients (%) (n=130)
Pre-menopausal women	110 (85)
Post-menopausal women	20 (15)

anemia, and 12 patients (7%) were having cellulitis and 29 patients (23%) with no comorbidities.

Avis Ne *et al.*, concluded that the younger breast cancer survivors are at risk for impaired QOL up to several years after diagnosis. Younger women, especially those at high risk for lower QOL, may need interventions that specifically targeted their needs as in my study after counseling, the MCS has been improved in pre- and post-menopausal women.

Bloon *et al.*, concluded that young breast cancer survivors who remained cancer-free enjoyed good health and improved QOL. Nonetheless, physical, social, and psychological concerns must be addressed so that young breast cancer survivors will continue to the resilient as they age, so in my study, the MCS has been improved significantly in both preand post-menopausal women as they will be more aware of the disease.

Ganz *et al.*, study concluded that breast cancer survivors appeared to attain maximum recovery from the physical and psychological trauma of cancer treatment by 1 year after surgery. A number of aspects QL and rehabilitation problems worsen after that time. Nevertheless, breast cancer survivors rate their QL more favorably that outpatients with other common medical conditions, and they identify many positive aspects from the cancer experience. Hence, in my study, the outpatients

#### Table 6: Distribution based on childbirth nature of patients

Number of patients (%) (n=130)
20 (15)
43 (33)
46 (36)
21 (16)

Table 7: Distribution based on comorbidities

Comorbidities	Number of patients (%) (n=130)
Diabetes mellitus	28 (22)
Hypothyroidism	14 (11)
Hypertension	25 (20)
Anemia	22 (15)
Cellulitis	12 (9)
No comorbidities	29 (23)

#### **Table 8: PCS and MCS**

Parameters	Pre-counseling	Post-counseling	p value
PCS	41.36±2.42	49.86±3.17	>0.05
MCS	32.49±1.93	47.52±2.11	<0.01**

\*\*: indicates extremely significant, PCS: Physical component summary, MCS: Mental component summary

### Table 9: Comparison of PCS and MCS between pre- and postmenopausal women

Parameters	Pre-menopausal women	Post-menopausal women	p value
PCS			
Pre-counseling	42.41±3.16	40.02±1.84	>0.05
Post-counseling	48.42±3.22	51.06±2.10	>0.05
p value	>0.05	< 0.05*	
MCS			
Pre-counseling	29.38±1.94	34.16±2.73	>0.05
Post-counseling	45.42±2.99	49.76±1.84	>0.05
p value	< 0.001**	< 0.001**	

\*Indicates significant, \*\*Indicates extremely significant. PCS: Physical component summary, MCS: Mental component summary

attained maximum recovery by patient counseling which improves both the PCS and MCS in post-menopausal women and MCS in premenopausal women.

#### CONCLUSION

The study concludes that incidence rate of female patients in the age group of 25-35 years is affected with fibroadenoma compared to other age groups, and 86% of married women are affected with fibroadenoma.

The QoL of fibroadenoma patients was assessed using SF-12 questionnaire which includes PCS and MCS in pre- and post-menopausal women by providing counseling.

As a result, there was a significant improvement in MCS in pre- women and post-menopausal women.

The study concludes that PCS does not improve significantly, but MCS improves significantly after counseling in pre- and post-menopausal women.

Therefore, after counseling, patient's physical health, social relationships, and environment have been improved.

Clinical pharmacist plays a major role in improving patients' knowledge and adherence by patient education, developing maintenance of diet, and exercise improved the patient's enjoyment. Further improvement in QOL can be made using counseling aids such as patient information leaflet, pamphlets, patient education tool, dietary chart, and visual aids. Larger studies may reveal better outcomes.

#### REFERENCES

- Bottomley A, Flechtner H, Efficace F, Vanvoorden V, Coens C, Therasse P, *et al.* Health related quality of life outcomes in cancer clinical trials. Eur J Cancer 2005;41(12):1697-709.
- Koller M, Kantzer V, Mear I, Zarzar K, Martin M, Greimel E, *et al.* The process of reconciliation: Evaluation of guidelines for translating quality-of-life questionnaires. Expert Rev Pharmacoecon Outcomes Res 2012;12(2):189-97.
- Scott-Conner CE, Dirbas FM. Breast Surgery Office Management and Surgical Techniques. New York: Springer; 2010. p. 71.
- Jayasinghe Y, Simmons PS. Fibroadenomas in adolescence. Curr Opin Obstet Gynecol 2009;21(5):402-6.
- Turbey WJ, Buntain WL, Dudgeon DL. The surgical management of pediatric breast masses. Pediatrics 1975;56(5):736-9.
- 6. Wilkinson S, Forrest AP. Fibroadenoma of the breast. Br J Surg

1985;72:835-8.

- Diehl T, Kaplan DW. Breast masses in adolescent females. J Adolesc Health Care 1985;6(5):353-7.
- Divasta AD, Weldon C, Labow BI. The breast: Examination and lesions. In: Emans SJ, Laufer MR, editors. Pediatric and Adolescent Gynecology. 6<sup>th</sup> ed. Philadelphia, PA: Lippincott, Williams & Wilkins; 2012. p. 405-20.
- Neinstein LS, Atkinson J, Diament M. Prevalence and longitudinal study of breast masses in adolescents. J Adolesc Health 1993;14(4):277-81.
- Chung EM, Cube R, Hall GJ, González C, Stocker JT, Glassman LM. From the archives of the AFIP: Breast masses in children and adolescents: Radiologic-pathologic correlation. Radiographics 2009;29(3):907-31.
- Pettinato G, Manivel JC, Kelly DR, Wold LE, Dehner LP. Lesions of the breast in children exclusive of typical fibroadenoma and gynecomastia. A clinicopathologic study of 113 cases. Pathol Annu 1989;24:296-328.
- Demay M. Practical Principles of Cytopathology. Revised Edition. Chicago, IL: ASCP Press; 2007.
- Nelson ZC, Ray RM, Wu C, Stalsberg H, Porter P, Lampe JW, *et al.* Fruit and vegetable intakes are associated with lower risk of breast fibroadenomas in Chinese women. J Nutr 2010;140(7):1294-301.
- Pike AM, Oberman HA. Juvenile (cellular) adenofibromas. A clinicopathologic study. Am J Surg Pathol 1985;9:730-6.
- Wilkinson S, Anderson TJ, Rifkind E, Chetty U, Forrest AP. Fibroadenoma of the breast: A follow-up of conservative management. Br J Surg 1989;76:390-1.
- Cant PJ, Learmonth GM, Dent DM. When can fibroadenoma be managed conservatively. Br J Clin Pract 1988;42 Suppl 56:62-6.
- Jackson VP, Rothschild PA, Kreipke DL, Mal DL. The spectrum of sonographic finding of fibroadenoma of the breast. Invest Radiol 1986;21:34-9.
- Hughes LE, Mansel RE, Webster DJ. Aberration of normal development and involution: A new perspective on pathogenesis and nomenclature of benign breast disorders. Lancet 1987;11:1316-9.
- Van Agthoven T, Timmerans M, Foelcens JA, Dorssers LC. Differential expression of estrogen, progesterone and epidermal growth factor receptors in normal, benign and malignant human breast tissues using dual staining immune histochemistry. Am J Pathol 1994;144(6):1238-46.
- Williamson ME, Lyons K, Hyghes LE. Multiple fibroadenoma of the breast a problem of uncertain incidence and management. Ann R Coll Surg Engl 1993;75:161-3.
- Noguchi S, Motomura K, Inaji H, Imaoka S, Koyama H. Clonal analysis of fibroadenoma and phyllodes tumor of the breast. Cancer Res 1993;53(17):4071-4.
- Bottles K, Chan JS, Holly EA, Chiu SH, Miller TR. Cytologic criteria for fibroadenoma. A step-wise logistic regression analysis. Am J Clin Pathol 1988;89:707-13.
- Narayanasingh V, Raju GC. Familial bilateral fibroadenoma of the breast. Postgrad Med J 1985;64:430-40.