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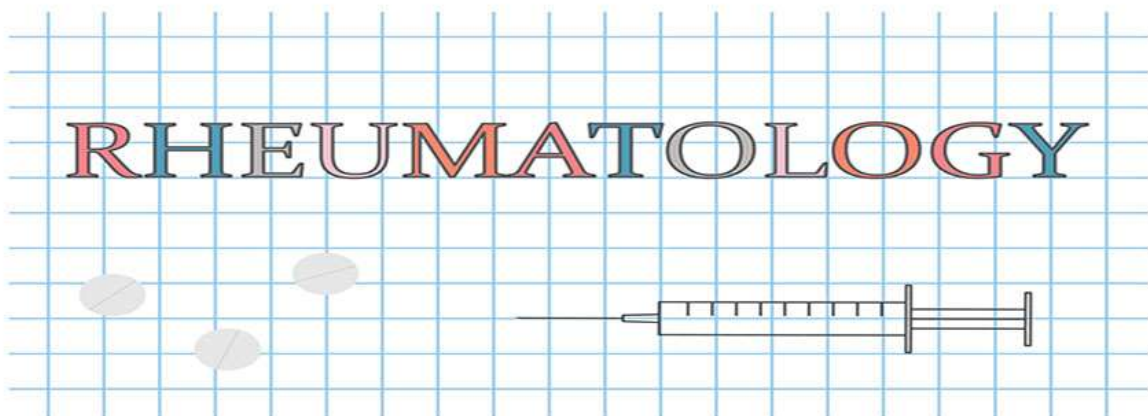


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Pharmaceutical care aspects in systemic lupus erythematosus

teaser

A study carried out at the Rheumatology Clinic, Mater Dei Hospital, Malta, suggests that the intervention of the clinical pharmacist is essential to support patients with systemic lupus erythematosus

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Systemic lupus erythematosus is traditionally considered to be a disease that has a great impact on all aspects of health status, be it physical or mental. These two dimensions are highly correlated since it is likely that suffering from an organic illness reduces mental wellbeing. It is thus important to evaluate both the severity of the disease as well as the influence of the physical symptoms on the patients'everyday life.[1]

Systemic lupus erythematosus brings about a change in the health-related quality of life of affected patients. Health-related quality of life refers to the physical, psychological, mental expectations. The concept of healthrelated quality of life is understood differently by each individual patient, and therefore it follows that the

same amount of damage affects different individuals to a different extent.

During the active phase of the disease, there is an increase in the physical limitation of the patient. This often brings about depressive feelings and psychological distress. Throughout the active phase of the disease, the patient is living in a state of uncertainty, since the outcome of the disease is unknown and unpredictable.[2]

Lupus patients may experience psychological symptoms such as depression and anxiety either through direct involvement of the central nervous system, or indirectly following adjustment of the patient to the chronic illness. Other mediators that may lead to this psychological distress include: reduced social support, lower self-efficacy and a sense of helplessness.[3]

A very common consequence of systemic lupus erythematosus is fatigue, and this is one of the major causes of reduced quality of life, since such patients will experience limited physical activity and a reduced ability to perform day-to-day "normal" chores. Fatigue can be of two types, both observed in patients suffering from systemic lupus erythematosus: peripheral (associated with pain and inflammation) and central (associated with coexisting psychological anxiety, depression, etc.).[4] This fatigue could also be related to disease activity and lack of sleep (due to pain). Hypothyroidism, anaemia, cardiovascular problems, poor sleep, mood disorders and lack of aerobic fitness, which are factors other than the activity of the disease, could also be related.[5]

Apart from the psychological distress and fatigue, the following factors may be contributing in decreasing the quality of life of lupus patients: musculoskeletal manifestations, photosensitivity and thus the consequence of avoiding sunlight, the necessity of regular visits to specialists, and the submission to various tests that monitor disease activity, osteoporosis risk and any other relevant tests.

A study was carried out in Malta at the Rheumatology Clinic, Mater Dei Hospital, to investigate the impact of the intervention of the clinical pharmacist during outpatients' visits on the quality of life of patients suffering from systemic lupus erythematosus. The objective was to investigate the impact of the interventions carried out by the clinical pharmacist on the quality of life of lupus patients.

Methods

The study was carried out in the Rheumatology Clinic of Mater Dei Hospital in Birkirkara. This clinic is run every Friday. Patients attending the Rheumatology Out-Patient Clinic benefit from the team approach and expertise of a multidisciplinary team. This multidisciplinary team consists of four consultants and one senior registrar with a speciality in rheumatology, a clinical pharmacist, a rheumatology specialist nurse, a physiotherapist, an occupational therapist and a podologist.

Two questionnaires were used to study the patients' change in quality of life. The Short-Form 36 (SF-36) questionnaire is a generic, multipurpose questionnaire consisting of 36 short, multiple-choice questions.[6] The second questionnaire used is the Systemic Lupus Erythematosus Quality Of Life (SLEQOL) questionnaire, [7] which consists of 40 short questions specific to systemic lupus erythematosus.

The inclusion criteria for this study were: patients had to be 18 years or older, medical diagnosis of systemic lupus erythematosus, attendance at the Rheumatology Out Patient Clinic, patients' ability to understand English or Maltese, and patients had to be free from any mental impairment. Medical files of patients eligible for the study were seen at the clinic on the day of their appointment, so as to record demographic data, date of diagnosis, any co-morbidities and medication history. Whilst waiting for their visit to the consultant or senior registrars the patients were approached and were asked whether they were interested in taking part in the study. Patients were given a patient information sheet describing the study, and patients willing to participate signed a consent form. Ethics approval was granted for the study by the Research Ethics Committee of the University of Malta.

The interview consisted in asking the patient to complete the two questionnaires. Also, during the interview information on demographic data, medical treatment and drug therapy problems was compiled. The drug therapy problems reported by the patients were classified into classes, namely: unnecessary drug therapy, wrong drug, the dose of the drug being too low or too high, any adverse drug reactions, inappropriate compliance and the need for additional drug therapy. This classification was adopted from Currie et al.[8]

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Following this part of the study, a pharmacist's intervention took place. This was carried out while the patients were waiting for their consultation visit. During the pharmacist intervention, the medications the patient was prescribed were reviewed with the patient – for example, confirming that patients were prescribed and were taking calcium and/or vitamin D supplements together with the corticosteroid therapy. The pharmacist also assessed patient monitoring – for example, confirming that patients have regular bone mineral density (BMD) tests and advising the patients about the importance of attending for this test, ensuring that patients on hydroxychloroquine attend for regular visits at the ophthalmology department since side-effects affecting the eye could occur, and advising patients on proper drug administration – for example, correct administration of potassium supplements to avoid the development of oesophageal ulcers. The pharmacist also discussed with the patients any problems, including patient access to collect their medications from the Out-Patient pharmacy of the hospital. Patients were also asked whether they apply sun protection factor as required, to prevent any photosensitivity reactions, and whether they needed a prescription so that they can obtain it for free.

The patients who participated in the study were contacted again by the investigator (LC) 14 weeks after. During the second meeting, the investigator asked the patients to complete the same questionnaires.

SPSS for Windows® version 15.0 was used to analyse the scores obtained with the questionnaires. The Kolmogorov–Smirnov test was used to test whether the means of the questionnaires before and after the intervention were normally distributed. In the case of the means not being normally distributed, the Wilcoxon signed ranks test was used to determine any statistical significance between the mean score before the intervention and the mean score after the intervention. In the case of the means being normally distributed, the paired sample t-test was used to compare the means or mean rate scores of the two related samples (ie, the scores of the questionnaires before and after the pharmacist's intervention). These tests were used for both the SF-36 and the SLEQOL questionnaires. A mean increase for the SF-36 questionnaire suggests an improvement in the quality of life, while for the SLEQOL questionnaire an improvement in the quality of life is shown by a decrease in the means.

As part of this study, guidelines regarding five common drugs used in systemic lupus erythematosus were developed. These guidelines review pharmacological and pharmacokinetic aspects together with drug profiles and the associated pharmaceutical care issues. The drugs considered were: prednisolone, azathioprine, hydroxychloroquine, cyclophosphamide and NSAIDs. These guidelines were validated by an expert panel group consisting of health professionals from the Rheumatology Department, namely four consultants, one senior registrar and one clinical pharmacist.

[[Fig 2]]

Results

A total of 30 patients were approached and interviewed at the Rheumatology Clinic. All 30 patients agreed to complete the questionnaires a second time, 14 weeks after the first encounter, thus resulting in a response rate of

100%. Two of the patients were male (6.7%), whilst the remaining 28 patients were female (93.3%). Their ages range from 22 to 64 years, with a mean age of 43.4 years and a median of 40.5 years.

With regard to the SLEQOL questionnaire, not all of the six subsections showed a mean decrease after the 14 weeks, thus the quality of life of the patients has not improved in all the subsections following the pharmacist's intervention. For those subsections showing a decrease in the mean, this decrease was not shown to be statistically significant (p -value <0.05). Therefore, none of the subsections of the SLEQOL questionnaire showed a statistically significant improvement in the quality of life of the patients following the pharmacist's intervention. The graph in Figure 1 shows the difference in the mean values before and after the pharmacist's intervention for the various subsections of the SLEQOL questionnaire.

For the SF-36 questionnaire all eight domains showed that the quality of life of the patients has improved; however, not all were statistically significant. In six out of the eight domains of the SF-36 questionnaire, a statistically significant improvement was shown in the quality of life of the patients following the pharmacist's intervention. Table 1 shows which domains of the SF-36 questionnaire showed statistically significant improvement in quality of life, and their respective p -value.

Discussion

A statistically significant improvement is seen in the physical aspect of health, in the interaction with friends and family, and on how the patients feel, as shown by the results of the SF-36 questionnaire. However, there was no significant improvement regarding the outlook of the patients on their life and condition (general health domain) and on the influence of emotions, such as anxiety and depression on normal day activities ("role functioning, emotional" domain). The fact that the SLEQOL questionnaire did not show any statistical significance could lead to the conclusion that the clinical pharmacist has a positive impact on the general quality of life of the patients, as opposed to the patients' quality of life where the lupus per se is involved.

During the interview it could be seen that, on the whole, the quality of life of the lupus patients interviewed was quite good, and symptoms specific to their condition were well controlled. Credit has to be given to the care, expertise and attention that these patients receive at the Rheumatology Clinic from the multidisciplinary team. This posed a limit to how much improved. This could be one reason why not all the SF-36 domains and the SLEQOL questionnaire showed a statistically significant improvement in quality of life following the pharmacist's intervention. Furthermore, the population of patients suffering from systemic lupus erythematosus in Malta is quite small, and the number of lupus patients attending the Rheumatology Clinic is even smaller. This small sample population could also be a reason why not all domains and questionnaires showed statistical significance. Thirty-six questions making up the SF-36 questionnaire were divided into eight domains, while the 40 questions included in the SLEQOL questionnaire were divided into six subsections. The smaller the number of questions and the greater the number of domains or subsections in a questionnaire, the easier it is to determine statistical significance. It was therefore easier to prove statistical significance using the SF-36 questionnaire since it is composed of a smaller domains.

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