



Patient education: Improving health outcomes in rheumatoid arthritis

Éducation thérapeutique patient : Efficacité au cours de la polyarthrite rhumatoïde.

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ABSTRACT

Introduction: Rheumatoid arthritis is a disabling disease leading to an impaired quality of life. To avoid joint damage, innovative strategies such "educational" medical procedures are developing, involving the patient in the management of his illness.

Aim: The objective of our study was to assess the effectiveness of patient education (PE) program on quality of life and adherence in the short and medium term.

Methods: A prospective study including RA patients. The intervention consisted of sessions that lasted half a day including four workshops. The parameters studied included the quality of life evaluated by the HAQ, adherence to treatment according to Girerd's questionnaire, fatigue evaluated by the MAF psychological state evaluated according to the HAD. We compared these results at baseline, then after 3 and 6 months of follow-up.

Results: Fifty-one patients participated in the PE program. At the end of the intervention, HAQ remained stable through the different controls with a slight improvement at 6 months. The percentage of patients with poor therapeutic compliance decreased to 33.3% at baseline to 13.7% at 3 months and to 9% at 6 months. The MAF decreased significantly from 33.1% at inclusion to 25.6% at 6 months post-intervention ($p=0,001$, $p=0,000$ respectively). HADA and HADD also decreased significantly at 3 months and 6 months.

Conclusions: Our PE program demonstrated in Tunisian RA patients an improvement in the quality of life at 6 months and a significant improvement in adherence in the short and medium term.

Keywords: Rheumatoid arthritis, patient education, adherence, quality of life

RÉSUMÉ

Introduction: La polyarthrite rhumatoïde (PR) peut s'accompagner d'un retentissement fonctionnel important. Dans le cadre des stratégies visant à ralentir son évolution, une démarche médicale «pédagogique» se développe, impliquant le patient dans la prise en charge de sa maladie.

Objectif: Evaluer l'efficacité d'un programme d'éducation thérapeutique patient (ETP) à court et à moyen terme chez les patients suivis pour une PR.

Méthodes: Tous les sujets ont participé à un programme d'ETP de groupe. Les paramètres étudiés comprenaient la qualité de vie évaluée par le HAQ (Health Assessment Questionnaire), les paramètres d'activité, la fatigue évaluée par la MAF (Multidimensionnal Assessment of Fatigue), l'état psychologique évalué selon le HAD (Hospital Anxiety and Depression scale) et ainsi que l'observance. Nous avons comparé ces résultats à l'inclusion, à court (3mois) et à moyen (6 mois) terme.

Résultats: Cinquante et un patients ont participé au programme d'ETP. Le score moyen du HAQ a diminué significativement à 6 mois ($p=0.031$). Le pourcentage de patients ayant une mauvaise observance a diminué à 33.3% à l'inclusion à 13.7% à 3 mois et à 9% à 6 mois ($p=0.013$, $p=0.000$). Une réduction significative du score de la MAF a été notée de 33.1% à l'inclusion à 29.5% à 3 mois et à 25.6% à 6 mois ($p=0.001$, $p=0.000$). Le score HAD a également diminué significativement à 3 mois et à 6 mois.

Conclusions: L'impact de l'ETP a été démontré sur la qualité de vie à 6 mois et sur l'adhérence à 3 et 6 mois chez les patients atteints de PR.

Mots-clés: Polyarthrite rhumatoïde, éducation thérapeutique, adhérence, qualité de vie

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INTRODUCTION

Rheumatoid arthritis (RA) is the most common systemic inflammatory condition. Its prevalence in Tunisia is estimated at 0.3% to 0.4% [1]. In the absence of treatment or in inadequately controlled RA, joint damage may occur leading to functional disability and reduced health-related quality of life. Moreover, RA may cause a huge economic burden in terms of work productivity loss, disability and death. In recent decades, new diagnostic tools and therapeutic strategies like the “treat to target” one have dramatically changed the face of RA. The main objective of the latter was to establish an early diagnosis, achieve remission or a low level of disease activity and prevent structural damage. As a component of these strategies, an innovative “educational” medical procedure was developed, involving the patient in the daily management of his illness [2]. According to the definition proposed in 1998 by the World Health Organization (WHO), Patient education (PE) is an educational and informative process that aims to help patients acquire or maintain the skills they need to better manage their lives with a chronic illness [3]. It is a set of activities designed to increase patient’s knowledge about the disease, improve adherence to treatment and help them become more active in the everyday handling of their health issues. In the 1970s, Sweden adopted the first model for comprehensive educational management of RA, the first «school of polyarthritis» and the very first European experience in the global management of RA. Over time and through reforms, educational structures have multiplied. Since then, the international recommendations of the ACR (American College of Rheumatology) in 2002 as well as of the EULAR (European League Against Rheumatism) in 2015 incorporated PE as part of RA management strategies [4,5].

Our primary endpoint was to assess the effect of a PE program on quality of life and adherence to treatment at 3 and 6 months of follow-up in RA patients. We have additionally evaluated the effect on disease activity, fatigue, and psychological status.

METHODS

Study design

We conducted a prospective longitudinal monocentric study carried out in the Rheumatology department (Mongi Slim Hospital- Tunis) between September 2018 and January 2020. Data were collected at baseline, at 3 (t3) and 6 (t6) months after the intervention. Written informed consent was obtained from each patient. The Human Research Ethics Committee at Mongi Slim department approved this study.

Participants

Patients with established RA according to the ACR EULAR 2010 criteria were recruited [6]. Before the intervention, patients were evaluated during the educational diagnosis step: the same physician made a one-to-one interview. To be eligible, they had to have 18 years or more of age and suffer in at least one area of the five health domains evaluated with the 5 health star scale by the WHO organization. This scale takes into account the five components of health: physical, mental, social, emotional and sexual. The patient had to respond on a visual analog scale graduated from 0 to 10, where zero refers to the absence of alteration in the corresponding domain and 10 to the maximum of alteration. Inclusion in the PE program concerned patients who had

an alteration in at least one domain: when the VAS was greater or equal to 5. Exclusion criteria were as follows: severe comorbidities, mental disorders and life-threatening conditions.

Intervention

Selected patients were invited to participate in our educational program delivered by a multidisciplinary team trained in PE programs (rheumatologists, rehabilitation specialists, physical therapists, and occupational therapists). Each session lasted half a day and was organized in the form of practical workshops of 45 minutes duration each and included groups of 10 to 12 patients. The sessions were delivered by two health professionals and dealt with specific pre-established RA themes. Uniformity of the RA program across and within groups was maintained using a scripted facilitator manual. Interactive educational tools were used focusing on promoting exchanges and contributions. The main themes included in this program are “Understanding RA”, “Fatigue management and energy conservation strategies”, “Joint protection Program” and “Understanding treatment in RA”.

Data Collection

At inclusion, clinical data were recorded including baseline demographics (age, sex, level of education, occupation, and comorbidities). Disease characteristics included disease duration, patient reported outcomes (PRO), treatment modalities, and extra-articular manifestations. An immunologic assessment was also recorded. Laboratory markers including C-reactive protein (CRP) and Erythrocyte sedimentation rate (ESR) were recorded at inclusion.

Outcomes measures

Outcome measures evaluated pain, fatigue, depression, anxiety, disease activity as well as health related quality of life and compliance.

Quality of life: It was assessed using the Health Assessment Questionnaire (HAQ) [7].

Adherence: Compliance was evaluated using Girerd’s questionnaire. The patients were divided into two groups: the poor observants (total score ≥ 3) and the good observants (total score < 3) [8].

Other measures:

Patient Reported Outcomes: We included the duration of the morning stiffness (MS) in minutes, and the number of night awakenings (NA). Pain was measured via a ten-point incremental visual analog scale (VAS) [9]. An improvement was considered significant if it exceeded 30% of the initial VAS.

Disease activity : Disease activity was assessed using DAS28 score, incorporating 28 swollen and tender joints count, CRP and ESR.

Psychological status: Depression and Anxiety were measured using the 14-item Hospital Anxiety and Depression scale, consisting of 7 anxiety and 7 depression items, scored separately [10]. Each subscale contains seven items, with total scores varying from 0 to 21 for each subscale. Scores between 8 and 10 suggest a “possible case”; and 11 and 21 designate a “probable case of anxiety/depression” [11]. **Fatigue:** The Multidimensional Assessment of Fatigue (MAF) assesses four dimensions of fatigue: severity, distress, degree of interference in activities of daily living, and timing. Respondents were asked to reflect on fatigue patterns for the past week. Scores may range from 1 to 50, In our study, fatigue was

considered severe when the MAF was superior to 30 [12]. Participants completed these baseline (BL) questionnaires prior to the beginning of the program, then at 3 months, and 6 months post-intervention. The same professional evaluated the same patients using the same evaluation methods. The primary endpoints were the changes in outcome measures after 3 and 6 months post-intervention

Data analysis

Data were analyzed using SPSS version 24. We compared the results obtained at 3 months, and 6 months from baseline. The comparisons between means on independent series were carried out by the non-parametric test of Mann and Whitney. Comparisons of percentages on independent series were made by the Pearson chi-square test, and if this test was not valid by the exact bilateral Fisher test. In order to identify risk factors linked independently to the improvement of the quality of life and to treatment adherence, we conducted a multivariate logistic regression step-by-step then a linear regression. Factors chosen for the study were selected according to the literature. The level of significance was fixed at $p < 0.05$.

RESULTS

Patient characteristics

A total of 51 participants (88 % female) with a mean age of 59.1 ± 9.1 were enrolled in the study. Forty-five percent of patients did not have an occupation and 25.5% of them were retired. The main Socio demographic characteristics were reported in Table 1.

Table 1. Socio demographic characteristics of the intervention group

Age (mean,years) \pm SD	59.1 \pm 9.1 [36-81]
Sex ratio	0.13 (88% women)
Disease duration (mean,years) \pm SD	10.8 \pm 5.3 [1-21]
Immunologic Assessment	
RF positivity (%)	64.7
ACPA positivity (%)	58.8
Coxitis (%)	11,8
Treatment Modalities	
Corticosteroids (%)	80.4
Methotrexate (%)	64.7
Sulfasalazine (%)	58.8
Biologics (%)	23.5

RF: rheumatoid factor, ACPA: anti-citrullinated peptide antibodies, SD: standard deviation

Impact of the educational program

Quality of life

HAQ did not decrease significantly at 3 months but a showed significant improvement at 6 months ($p=0.084$, $p=0.031$ respectively). The percentage of patients with severe disability decreased from 15.7% at 3 months to 7.8% at 6 months. These variations were significant at 3 months ($p = 0.023$).

Observance

At inclusion, 33.3% of patients had poor compliance. After the intervention, non-adherence decreased significantly to 13.7% at 3 months ($p = 0.013$) and to 9% at 6 months ($p = 0.000$).

Other measures

Patient Reported Outcomes: At inclusion, the mean VAS pain was estimated at 5.3. Through the course of the study, pain numerical rating score showed a non-significant decrease of 9,4% at 3 months and 13,2% at 6 months of follow-up ($p=0,196$; $p=0,104$ respectively). The mean

number of NA decreased significantly at the first control compared to inclusion ($p = 0.015$) but this improvement was not maintained at 6 months ($p = 0.9$).

Disease activity: ESR decreased at 3 and 6 months post intervention. The reduction at 6 months was statistically significant ($p = 0.0095$). DAS28 showed an improvement at 3 months which was not maintained at 6 months. ESR, CRP and DAS28 values during the study were shown in table 2.

Table 2. Patient reported outcomes and disease activity at different controls

Mean	t0	t3	t6	p-value (T3-T0)	p-value (T6-T0)
NA (number)	1.7	1.2	1.7	0.015	0.9
MS (minutes)	21.1	14.4	12.0	0.061	0.058
VAS (cm)	5.3	4.8	4.6	0.196	0.104
ESR(mm/hour)	44.3	42.1	40.2	0.519	0.009
CRP (mg/l)	14.6	12.7	14	0.497	0.842
DAS28ESR	4.4	4.2	4	0.383	0.073

NA=Night awakenings, MS=Morning stiffness, VAS=Visual analogue scale, GPA=Patient global assessment, TCJ=Tender count joint, SCJ=swollen count joint, ESR= Erythrocyte sedimentation rate, CRP= C-Reactive protein, DAS28= Disease activity score.

The percentage of patients with low disease activity increased at t3 (27.5%) and t6 (13.5%) compared to inclusion (5.9%) ($p = 0.02$, $p = 0.06$ respectively). The percentage of patients with high activity decreased from 27.5% to 20.5% at t6 ($p = 0.01$) (Table 3).

Table 3. Distribution of disease activity scores during the different controls

	t0	t3	t6	p(T3-t0)	p(T6-t0)
High	27.5%	25.5%	20.5%	0.05	0.01
Moderate	58.8%	45.1%	50%	0.3	0.06
Low	5.9%	27.5%	13.6%	0.02	0.06
Remission	7.8%	2%	15.9%	0.06	0.04

t0: inclusion, t3: 3 month post intervention, t6: 6 month post intervention

Psychological status and fatigue: Results showed a statistically significant improvement in anxiety and depression at different controls. Similarly, The MAF decreased significantly at 3 and 6 month post-intervention (Table 4).

Table 4. Evolution of MAF and HAD at different controls

Moyenne	t0	t3	t6	p	p
MAF	33.1	29.3	25.6	0.001	0.000
HADA	11.5	10.7	9.8	0.012	0.006
HADD	10.5	9.1	7.8	0.001	0.000

MAF= Multidimensional Assessment of Fatigue; HAD=Hospital Anxiety and Depression Scale

Determinants of variation of quality of life and adherence

At 3 months, the improvement in HAQ was not correlated with age ($p=0.8$), level of instruction ($p=0.56$), fatigue ($p=0.56$), HADA ($p=0.55$), HADD ($p=0.75$), disease activity ($p=0.3$) as well as the presence of coxitis ($p=0,84$). At 6 months, we did not find an association between age ($p=0.59$), the level of instruction ($p=0.16$), fatigue ($p=0.4$), HADA ($p=0.55$), HADD ($p=0.73$), disease activity ($p=0.07$), the presence of coxitis ($p=0.19$), and the improvement of HAQ at 6 months. Linear regression was not able to retain independent factors associated with HAQ improvement. We conducted then a multivariate analysis that showed that the improvement of HAQ at 3 months was a determinant of HAQ improvement at 6 months ($p < 0.01$). Regarding adherence, a younger age was associated with an improvement in adherence ($p=0,000$). However, no association was found between sex ($p=1$), level of instruction ($p=0.9$), anxiety ($p=1$), depression ($p=0.9$), disease activity ($p=0.4$) and improvement of adherence.

DISCUSSION

Our study assessed the impact of a PE intervention on different outcome measures in RA at three and six months. Many patient education interventions were reported in the literature. Goals and interventions varied greatly and programs were organized differently, which made it difficult to decide and compare between interventions. Quality of life in RA is altered by several factors including disease activity, deformities as well as psychological status. In our study, function showed a significant improvement at 6 months. Results from the literature were discordant. A randomized controlled trial in the study of Riemsma et al showed statistically significant improvement in HAQ between 3 and 9 weeks ($p=0.01$) [13]. Another literature review included 17 studies involving various educational interventions (basic knowledge, pain management, diet, physical activity, behavioral therapies, and joint protection). Among the 17 studies, improvement in quality of life was found in 6 [14]. Another Moroccan study had set up an educational intervention combining information on PE and multidisciplinary management with various workshops. At 6 months, a significant improvement in function was found [15]. Finally, workshops focusing on physical activity as part of a PE program showed a decrease in HAQ in the study of Mayoux-Benhamou et al [16]. This improvement may be linked to learning new behaviors in the activities of daily life, to the implementation of technical aids and to a better overall perception of health. Other studies found negative results on HAQ. According to Pot Vaucel's study, HAQ remained stable after 6 months of follow-up [17]. Moreover, Carandang's recent meta-analysis highlighted the beneficial effect of PE on function but this impact was minimal with a low level of evidence (Level 3) [18]. In addition, no factors associated with the improvement of quality of life were found in our results. However, we found that the improvement of HAQ at 3 months was an independent factor of the improvement of HAQ at 6 months. In the literature, there are no studies that have evaluated the determinants of improvement during a PE program regarding quality of life, our result is a basis for further trials.

The lack of positive effect of PE on HAQ could be explained by methodological problems related to the sensitivity of the questionnaires, unclear intervention procedures with inadequate workshops and non-selective eligibility criteria [19]. It would be interesting in this context to devote more studies to physical activity given its beneficial effect on quality of life [16]. In addition, patients with recent RA are more likely to experience beneficial effects on function than advanced RA [19].

The effectiveness of different treatments depends, on the degree of therapeutic adherence, which is not always important. Indeed, the rate of drug adherence in patients with RA varies between 30% and 80% [20]. In our patients, the percentage of poor adherence had decreased significantly at 3 and 6 months. A recent study by Taibanguay whose educational program included a workshop on treatment management showed more compliance to RA medication at 3 months [21]. In a controlled British randomized study of 100 RA patients who received drug adherence education sessions and one control group receiving standard treatment, adherence to therapy was significantly better in the educated group compared to the control group after 6 months [22].

In contrast, Pot Vaucel and Lovisto Neto did not find any effect on treatment adherence in the short and medium term, as their programs did not include workshops on treatment management [21,23].

The reasons for therapeutic non-compliance are multiple,

in the case of a chronic disease, adverse effects can occur, disease denial can be a source of non-adherence. Moreover, patient adherence to a treatment program is difficult to achieve without directing attention to the patient's experience, characteristics, and wishes [24]. Similarly, the unavailability of drugs or the lack of insurance coverage may explain the lack of adherence. In our study, the only factor associated with an improvement in adherence at 3 months was younger age. No significant reduction in pain was recorded in our study. Gendey's trial evaluated a PE program that included various interventions alternating collective theoretical training and workshops by a multidisciplinary team over a 3 days [25]. VAS of pain decreased at 6 months with a rate of 12% with no statistical significance. Pain was even increased in 17.7% of patients. According to Giraudet, there was also no improvement ($p=0.6$) [26].

Unlike these studies, a significant reduction in VAS pain was noted at 6 months in the Carson study ($p=0.002$) [28]. This improvement may be explained by the fact that the PE program used was specialized, based primarily on coping and pain adjustment strategies, designed to enhance patients' abilities to control their pain [27]. Regarding disease activity, no significant improvement was found in different controls. A systematic review of the literature published by the Cochrane Library in 2003 aimed to evaluate various educational interventions during RA [13]. A total of 31 randomized controlled studies were analyzed, including 17 high-level studies (according to Cochrane Library criteria). All the programs had an educational component that could be associated with exercise, psychological and social support. The beneficial effect of PE on disease activity (VS, CRP, DAS28) was not confirmed at 3 months [23].

Improvement in anxiety and depression were noted in our study at 3 and 6 months of follow-up. GENDEY et al, found a significant decrease of 20% in HADA and 30% in HADD at 6 months [25]. Similarly, Vermaak et al, whose study focused on several themes, found a statistically significant decrease in the 6-month average score from 7.8 to 6.7 for HADA and 6.1 to 5.2 for HADD [27]. As for depression, a positive effect was observed with the HADD score ($p=0.04$) [13]. According to Carandang's meta-analysis, there was a positive effect of PE on the affect and maintenance of a positive attitude towards the disease (strong level of evidence 1) [18]. Improvement of psychological status in our study could be linked to a better comprehension of the disease and a sharing of experience promoting exchange and compassion. It is possible that a greater knowledge and understanding of disease gained, would reduce fear, worry and/or frustration felt concerning RA. Fatigue in RA is multifactorial and may be due to sleep disturbances, pain, disability, cognitive distress, illness perception, etc. In the VERMAK trial, 113 patients who received a 2.5-hour-per-week PE for 6 weeks with workshops on fatigue management and energy conservation, the average VAS fatigue score decreased significantly at 3 months [27]. Another randomized controlled trial showed a significant decrease in VAS fatigue in patients participating in a PE program compared to simple information [13].

Other studies did not find a positive effect on fatigue. In this context, Pot-Vaucel, whose intervention did not include workshops on fatigue management, did not show a significant variation in VAS fatigue at t3 [21]. Also, according to Carandang, a beneficial effect was observed on fatigue but with a low level of evidence (level 3) [18]. Note that in this metaanalysis, few studies have focused on the evaluation of fatigue [18]. Thus, a PE program efficacy requires workshops on fatigue.

To our knowledge, this is the first study conducted in Tunisia in rheumatology assessing the effectiveness of a

structured PE program in RA. The population supported in this school of RA is recruited according to an educational diagnosis. The multidisciplinary team that carried out the PE program was made up of trained staff. Several dimensions of RA were assessed: quality of life, adherence to therapy, then disease activity, psychological status and fatigue using quantitative objective criteria and included multiple health status measurements.

We opted for a compliant structured PE program with various workshops involving patients in the educational process, with interactive workshops. The importance of the teaching tools used is worth-mentioning. Multimedia tools incorporating playful games, videos, etc. have more impact and help patients better verbalize their experiences and manage their illness.

Limitation of our study

First, the interpretation of our results is limited by material and human constraints as well as the absence of a control group. Second, more extended period of time seems necessary for a more complete assessment of this program. Moreover, disease duration varied in our population which may affect the response to the intervention. Finally, health literacy and knowledge about RA were not assessed in our study [18]. Further studies should be focusing on increasing health literacy rather than providing disease information. Indeed, this asset refers to the cognitive and social skills needed to critically assess the applicability of health information to personal situations and to exert greater control over the disease, including a better medication adherence.

CONCLUSION

Our PE program demonstrated in Tunisian RA patients a slight improvement in the quality of life at 6 months and a significant improvement in adherence in the short and medium term. However, no immediate post-intervention results were recorded for disease activity.

Abbreviation list:

RA: Rheumatoid arthritis
WHO: World Health Organization
PE: Patient education
ACR: American College of Rheumatology
EULAR: European League Against Rheumatism
PRO: Patient reported outcomes
CRP: C-reactive protein
ESR: Erythrocyte sedimentation rate
HAQ: Health Assessment Questionnaire
MS: Morning stiffness
NA: Night awakenings
VAS: Visual analog scale
MAF: Multidimensional Assessment of Fatigue
BL: Baseline

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