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The convenience of family and community health nurses-led care for the treatment of rheumatic diseases with biological or targeted synthetic disease-modifying antirheumatic drugs. The experience of Valcamonica, Italy

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Abstract

Objective. To investigate the role of family and community health nurses (FCHNs) in monitoring the safety and efficacy of biological and targeted synthetic disease-modifying antirheumatic drugs (bDMARDs and tsDMARDs) in chronic rheumatic diseases.

Methods. We followed 141 consecutive patients (median age 59 years; 69% female) with autoimmune diseases, mainly rheumatoid arthritis (RA; 46.1%) and spondyloarthritis (SpA; 46.8%), receiving bDMARDs or tsDMARDs from January 2024 to March 2025 ("IFER" protocol). FCHNs monitored treatment safety and efficacy using patient-reported outcomes every 2 months and composite disease activity indices at 6 and 12 months. Patients with adverse events, disease complications, or high disease activity were referred to the rheumatologist for treatment reassessment. Major adverse events, healthcare costs, and rheumatology visits were compared with data from 2021–2023.

Results. No significant difference in major adverse events was observed compared with previous years (deaths: 2 vs. 3; hospitalizations: 9 vs. 25; emergency room visits: 3 *vs*. 12; p=ns). Agreement between rheumatologists and FCHNs in disease activity assessment was moderate overall (Cohen's $\kappa=0.54\pm0.06$), good in RA ($\kappa=0.65\pm0.08$), and poor in SpA ($\kappa=0.29\pm0.10$). Per-capita annual costs decreased significantly (€5164 *vs*. €4590; $p<0.001$), as did rheumatology visits per patient/year (2.16 *vs*. 1.67; $p<0.001$). First-line treatment significantly increased during the IFER period (Log-rank $p<0.001$).

Conclusions. FCHN-led monitoring of patients receiving bDMARDs or tsDMARDs appears feasible, safe, and cost-effective. Further studies are warranted to confirm these findings.

Introduction

The growing need for resources in the Italian Healthcare System may negatively impact the follow-up of chronic diseases. In chronic rheumatic disorders, such as rheumatoid arthritis (RA) and seronegative spondyloarthritides (SpA), prompt diagnosis and treatment initiation are mandatory to achieve disease remission, prevent damage, and reduce morbidity. Moreover, frequent outpatient visits are necessary to monitor the safety and the efficacy of therapies and to avoid disease relapses, particularly in case of treatment with biological- or targeted-synthetic disease-modifying antirheumatic drugs (bDMARDS or tsDMARDs) (1). However, in real-life settings the long waiting list for rheumatology specialist visits may nowadays cause difficulties in the application of a correct tight control strategy.

Valle Camonica (also called Valcamonica) is an Italian Alpine valley extending for more than 100 km in length, with a mountain territory, in which two Hospitals (Esine and Edolo) serving more than 100,000 inhabitants, including 2200 patients with chronic rheumatic disorders, are based. The geographical characteristics of the valley hinder the access to the Health Centers, for example for drugs distribution. To improve the care of chronic and frail patients, seven Community Houses were instituted in Valcamonica in 2022, with a total of 12 family and community health nurses (FCHN) (2, 3).

Considering this scenario, we designed a collaborative project between rheumatologists and FCHN to follow up patients with rheumatic diseases in treatment with bDMARDs or tsDMARDs, which usefulness is analyzed in this manuscript.

Materials and Methods

The IFER project

The IFER (from the Italian acronym "Nurse of Family and Rheumatologists") project started on January 1, 2024. The rheumatology center, ASST of Valcamonica, was accredited for the treatment of rheumatic diseases with bDMARDs on March 19, 2019, and bDMARDs or tsDMARDs were dispensed in the Esine Hospital until December 31, 2023. From May 2023 to December 2023, the 12 FCHN of ASST Valcamonica were trained in the use of clinimetrics, composite indexes, and articular count by a rheumatologist expert in the treatment of rheumatic diseases. Since January 1, 2024, bDMARDs or tsDMARDs were delivered to Community Houses, respecting the cold chain, and herein distributed to patients by the FCHN. Since then and till the date of the present evaluation (March 31, 2025), 141 patients were actively followed by the FCHN. At the moment of the first evaluation, FCHN investigated the patients' vaccine profile, their need for social assistance, therapy compliance, disease-related disability, and dependence degree. Furthermore, FCHN were responsible for the education of patients when starting new treatments and for training them in the use and conservation of vials. FCHN were available on the phone during the entire process.

FCHN controls were scheduled one month after treatment start and then every two months; controls included patient's reported outcomes (PROs) evaluation [Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), and Bath Ankylosing Spondylitis Functional Index (BASFI) for SpA and HAQ for RA], adverse events investigation (such as infections and drug reactions), and treatment distribution for the following two months, if no contraindication was present. At months 3, 6 and 12, joint count and composite indexes [Clinical Disease Activity Index (CDAI), Disease Activity Score 28 (DAS28)-CRP, Disease Activity Index for Psoriatic Arthritis (DAPSA), Bath Ankylosing Spondylitis Metrology Index (BASMI)] were also assessed. Therapeutic compliance was estimated by the Morisky Scale (4). Performance in activities of daily living (ADL) was measured by the Barthel Index (5).

Patients were re-evaluated by the rheumatologists 6 months after bDMARD or tsDMARD start, and then, in case of treatment efficacy and safety, every 12 months. However, rapid access to evaluation was available whenever indicated by FCHN (Figure 1). Criteria for rheumatologist alert were predefined: HAQ>1.5, or an increase of >0.5 from the previous evaluation; DAS28-CRP>3.2;

CDAI>10; DAPSA>14; BASDAI, BASFI or BASMI >4.0. Moreover, FCHN alerted rheumatologists when adverse events were observed or reported by the patients.

The IFER project assessment

The usefulness of the IFER process was assessed by comparing major adverse events, such as deaths, need for hospitalization, and emergency room accesses, between the IFER period (January 2024 - March 2025) and three previous years (2021-2023). The concordance between rheumatologist and FCHN assessment of efficacy and safety was evaluated. Costs, dropouts, number of outpatient visits, and new treatment starts were also analyzed.

Statistical analysis

Data were reported as median (10^{th}-90^{th} percentile). The comparison between quantitative variables was assessed by analysis of variance and by the Wilcoxon test for matched data. The univariate analysis (Chi-square of Fisher exact test) was performed between the IFER and non-IFER period, for nominal variables. The concordance rate between two examiners was calculated by Cohen's K (±SE). Kaplan-Meyer analysis was used to compare time to first bDMARDs or tsDMARDs treatment between the IFER period and non-IFER period.

Results

The main demographic and clinical features of the patients enrolled in the IFER process are reported in Table 1. The cohort was mainly composed by RA (46.1%) and SpA (46.8%) patients; other rheumatic diseases included systemic lupus erythematosus (SLE: 1.4%), giant cell arteritis (GCA: 2.1%), systemic sclerosis (SSc: 0.8%), recurrent pericarditis and other auto-inflammatory syndromes (AIS: 2.8%). Most patients were women (68.8%), with a median age of 59 years and a median disease duration of 8 years and 9 months. Comorbidities, such as major cardiovascular events, pulmonary diseases, history of neoplasia or chronic viral infection, were largely prevalent, and many patients had at least one cardiovascular risk factor at baseline (Table 1). The therapeutic compliance, estimated with the Morinsky scale, was good in 92% of patients. Performance in ADL higher than 60% was found in 95.0% of patients. At IFER baseline, median HAQ was 0.25 (0-1.27), 54% of patients were in remission, 19% in low-disease activity, 25% in moderate disease activity, and 2% in high disease activity.

The median observation time during the IFER period was 13 months and 14 days. At our last evaluation, 66% of patients were in remission, 18% in low-disease activity, 15% in moderate disease activity, and 1% in high disease activity.

During this period, FCHN performed 950 evaluations and alerted the rheumatologists in ~~31~~55 occasions: in 21 cases, clinimetrics performed by FCHN suggested active disease, which was confirmed by the rheumatologist in 15 cases, leading to bDMARD or tsDMARD switch. In six cases, disease exacerbation was not confirmed by the rheumatologist, who sometimes performed ultrasound to evaluate disease activity, and treatment was not changed. In five cases, FCHN alerted the rheumatologist because of severe adverse events (sepsis, heart failure, respiratory failure, and diarrhea) which led to in-hospital admission. In the other 26 cases, mild adverse reactions were observed by the FCHN (22 mild upper respiratory tract infections, one cutaneous reaction, one deep venous thrombosis, one hearing loss, one onset of arterial hypertension), which required in one case a bDMARD switch and in other cases temporary treatment interruptions. Finally, three patients were reported by FCHN because of incident neoplasms and therefore stopped bDMARD and underwent oncological treatments.

During the study period, 320 scheduled rheumatologist re-evaluations were performed: only in 2 cases the need for a treatment change was found, which had not been detected by the FCHN. Moreover, no additional complications or events were detected by the rheumatologist.

The concordance rate for the interpretation of disease activity performed by FCHN and rheumatologist was calculated in 185 evaluations performed in RA and SpA, and was moderate (Cohen's k=0.54, SE 0.06, 95% CI 0.42-0.65). Considering the clinimetric assay for RA, the concordance rate was good (Cohen's k=0.65, SE 0.08, 95% CI 0.49-0.80) (Table 2), whereas it was poor for SpA (Cohen's k=0.29, SE 0.10, 95% CI 0.08-048). The number of deaths, in-hospital admissions, and accesses to the emergency room in the IFER period did not differ from previous years (Table 3). Two patients were lost to follow-up during this period, compared with a total of 6 patients lost in the previous three years.
During the IFER period, 31 patients started a first-line bDMARD or tsDMARD treatment. The rate of new first-line treatments during the IFER period was significantly higher compared with previous years (Figure 2; p<0.0001), while disease duration tended to be, albeit not significantly, shorter [21m (4-185) *vs.* 39m (3-146); p: 0.12]. Despite the progressive increase in patients treated with bDMARDs or tsDMARDs, the annual pharmacological expenses only marginally increased during the years (Figure 3A), with a reduction in the pro-capita expense [2021 *vs.* 2023: 5164 EURO (789-10390) *vs.* 4657 (829-8455); p:0.001. A not significant trend was confirmed also in 2024: 4590 (708-8274) Figure 3B].
The total amount of follow-up rheumatologist visits remained stable over the years, despite the increased number of patients cared for (199 total annual visits in 2021 *vs.* 224 in 2024, with an increase of 45.6% in 2024, p<0.0001; 208 total visits in 2023 *vs.* 224 in 2024, increase of 10.7% patients in 2024, p: 0.95) (Figure 3C and D).
Additional benefits of the NFHC evaluation were indications to vaccinations: during the IFER period, 12 vaccinations for *Pneumococcus* (8.9%), 11 for Varicella Zoster Virus (8.2%), 7 for Diphtheria-Tetanus-Pertussis (5.2%), and 2 for *Meningococcus* B, A, C, Y, W135 (1.5%) were performed by FCHN. Finally, 9 patients were directly referred by FCHN to the psychological service in the Community House.

Discussion

The EULAR recommendations emphasize the role of nurses to support the follow-up of patients with chronic rheumatic diseases (6). Several studies performed in Northern Europe and in the US justified these recommendations (7-11). Nevertheless, this approach is seldom applied in Italy, and such studies are lacking in our country. FCHN, according to the 2022 revision of the National Health Care System for the follow-up of chronic disease, are new health care professionals who might be suitable to assume the role suggested by the EULAR recommendations. Therefore, considering the lack of rheumatologists to cover the entire territory of Valcamonica, we decided to train FCHN in the care of patients with rheumatic diseases, with particular attention to monitoring safety and efficacy of bDMARD or tsDMARD treatments. To the best of our knowledge, the IFER project represents the first Italian proposal for a revision of follow-up of patients with rheumatic diseases treated with bDMARDs or tsDMARDs, in which FCHN act as case managers, simplifying the rheumatologist's work through filter visits which allowed a tight surveillance of treatment safety and efficacy. We examined the results of such an approach from different points of view, including the economic one.
The primary objective of the IFER protocol was patients' safety. Considering the entire time of evaluation, IFER did not differ from previous years in terms of major negative events. In particular, the warnings for patient hospitalizations were always promptly signaled, and in one case, the FCHN intervention contributed to switch-off a potentially life-threatening complication (incoercible diarrhea with severe malabsorption syndrome). Contrarily, in 2023, a patient died due to a septic complication, which might have been prevented by rapid notification to the specialist. Furthermore, the evaluation of disease activity performed with composite index by FCHN resulted reliable and showed a good degree of concordance with what assessed by- rheumatologists.
In the era of artificial intelligence and telemonitoring devices, telemedicine may be another way to surveil the safety and efficacy of treatment, as demonstrated by some non-inferiority trials (12-14).

However, some critical points recently emerged regarding drug toxicity surveillance (14). Contrarily, the FCHN evaluation in our protocol provided both efficacy and safety monitoring. Nevertheless, we consider it might be worthwhile to exploit telemedicine also in our FCHN-led care model, especially in PROs recording.

The reduction in the number of rheumatologist visits for patient/year during the IFER period may imply important consequences, such as the reduction of the waiting list for rheumatological evaluation. Interestingly, during the IFER period, an increase in first-line biological treatment initiation was observed in our cohort. This result suggests that the rheumatologist had more possibilities to introduce early treatments, when necessary, according to the treat-to-target strategy and the international guidelines.

The secondary endpoint was the analysis of economic aspects of the process, including not only the direct pharmacological costs but also indirect expenses, such as those for annual visits. The pharmaceutical expense may be influenced by different factors, such as periodic variation of drug prices and dose tapering due to achievement of stable remissions. Notably, at the start of the protocol, most patients were in good disease control, and therefore with a low economic impact. Nevertheless, a trend of decreased drug expenses was observed during the IFER period, and possibly related to the FCHN intervention. In fact, the role of FCHN in IFER was also to establish the real need for drugs for every single patient, avoiding unnecessary stocking in hospital pharmacies.

Independently from drug treatment, FCHN-led care improved other aspects of our management of patients with chronic rheumatic diseases. In particular, vaccinations are important aids to prevent complications induced by immunosuppressive treatments (15, 16). However, despite recommendations, the rate of properly vaccinated patients may remain lower than needed (17). In our experience, the FCHN-led care, thanks to their rapid interaction with other professionals in the Community House context, enhanced direct access to vaccine ambulatory and increased the rate of protected patients. Another crucial aspect of management of chronic diseases is the care of their psychological impact. In fact, it is known that physical wellness is associated with correct compliance and, *vice versa*, a bad psychological status may negatively influence the patients' self-evaluation of disease (18-20). The FCHN also improved these aspects, directly addressing nine patients for psychological intervention because of referred additional problems. Notably, patients used to discuss with FCHN about their family, economic, and job problems much easier than with the rheumatologists. Furthermore, the organization of the Community House itself facilitates direct access to psychologists thanks to FCHN intervention.

The comparison of our results with those of the literature shows similar results in terms of efficacy, safety and cost-effectiveness of the nurse intervention (7-11). However, previous trials included only patients affected by chronic inflammatory arthritis with low disease activity or in remission. In our project, all patients with a rheumatic disease in treatment with bDMARDs or tsDMARDs were enrolled, independently of the status of disease itself. In particular, 7.1% of subjects were affected by an autoimmune systemic disease, such as SLE, SSc, GCA and AIS, and 27% were in moderate or high activity disease at baseline. At difference with the other studies, in the IFER process the FCHN entirely followed patients in collaboration with a rheumatologist, who validated the final step. Therefore, we are confident that our model might provide a precious contribution for the follow-up of all rheumatic diseases and might be helpful also for other chronic diseases.

Conclusions

The FCHN-led model in rheumatology may give important advantages for patients, especially in terms of tight control of treatment safety and efficacy. Further studies are needed to clarify whether this intervention may reduce costs and waiting list for specialist evaluation.

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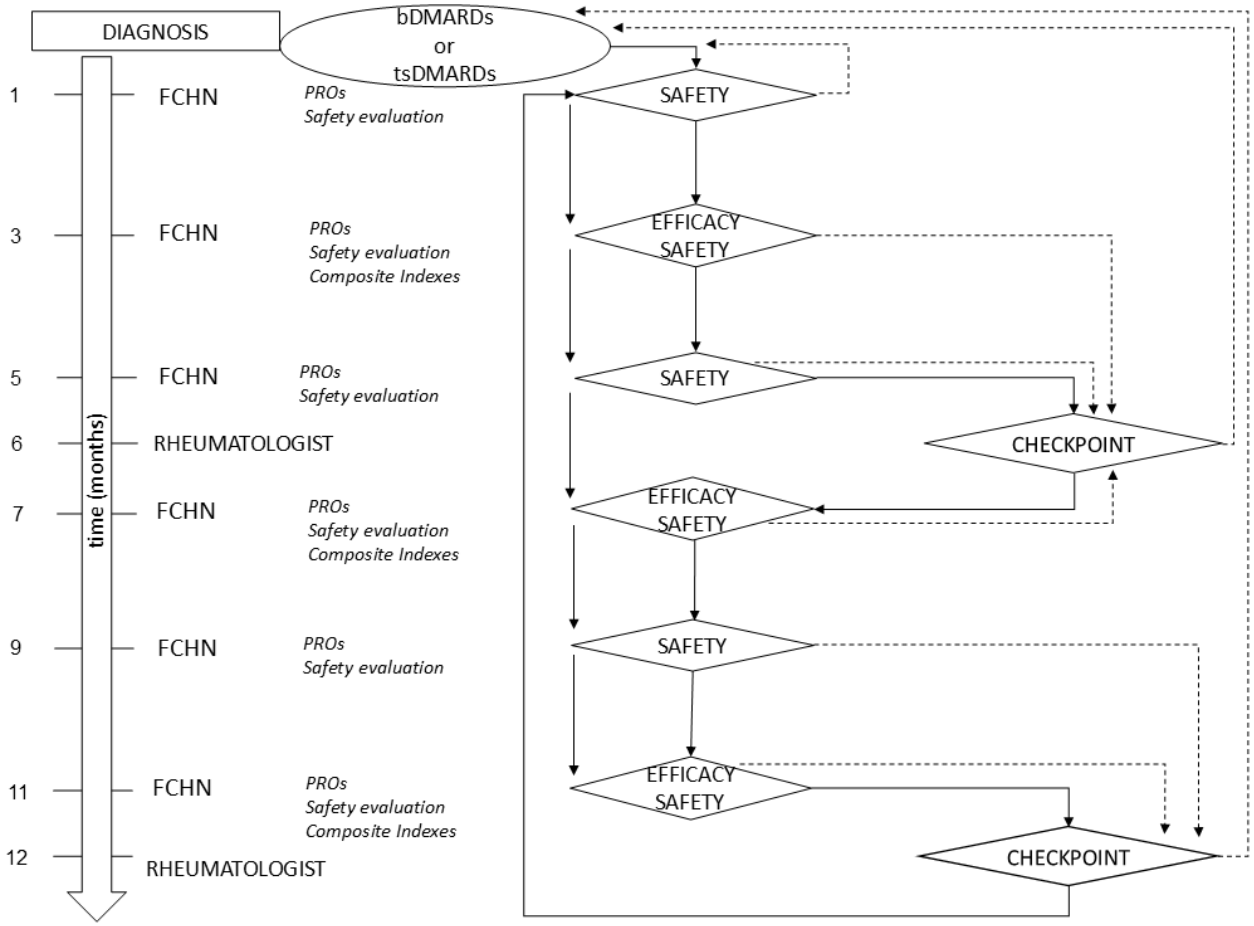

Figure 1. Flow-chart of the IFER process. Continuous line: uneventful follow-up; dotted line: adverse event and/or flare of disease, by-pass to rheumatological evaluation. FCHN, family and community health nurse; PROs, patient's reported outcomes; bDMARDs, biological disease-modifying antirheumatic drugs; tsDMARDs, targeted synthetic disease-modifying antirheumatic drugs.

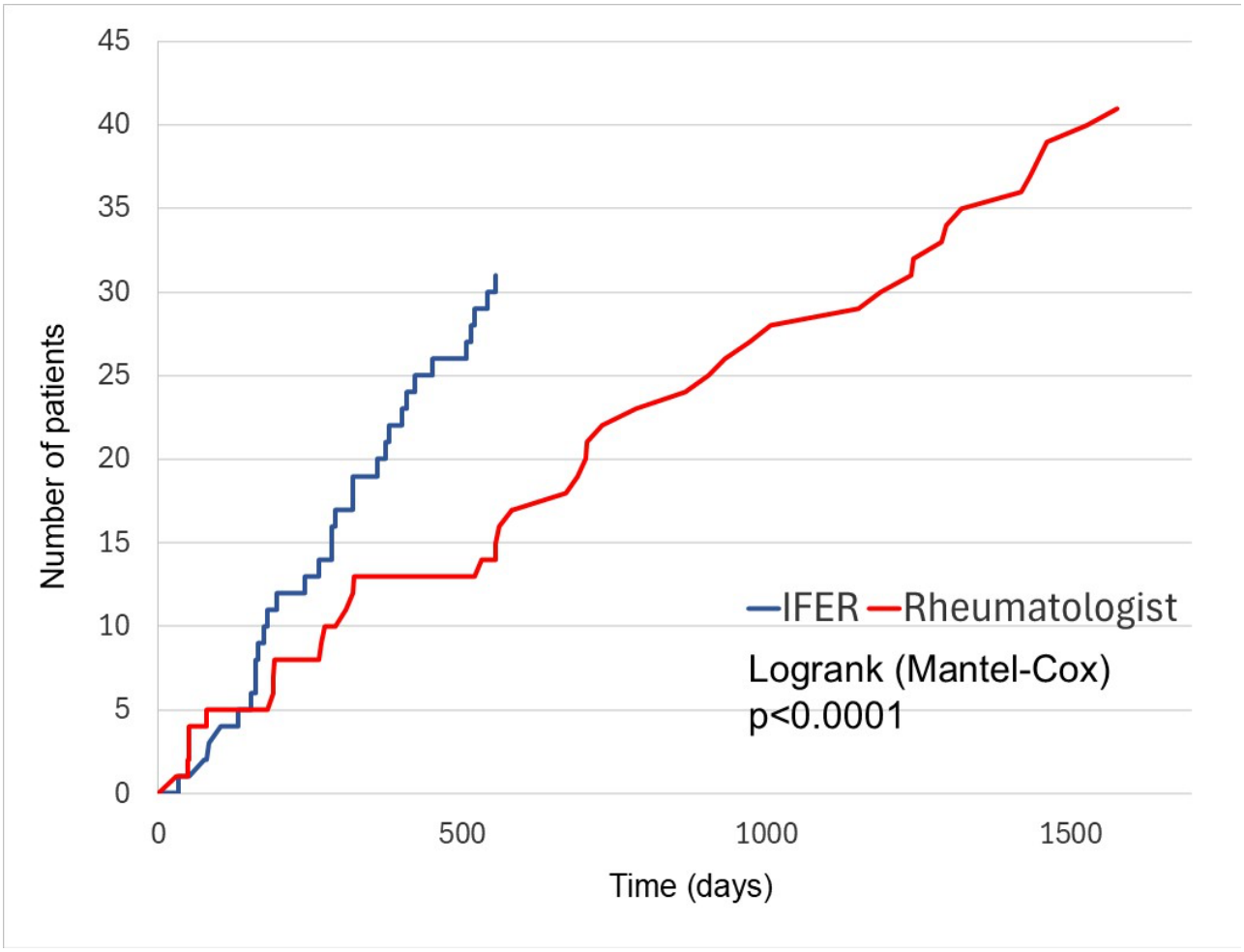

Figure 2. First-line new biological disease-modifying antirheumatic drug/targeted synthetic disease-modifying antirheumatic drug treatment before and during the IFER period.

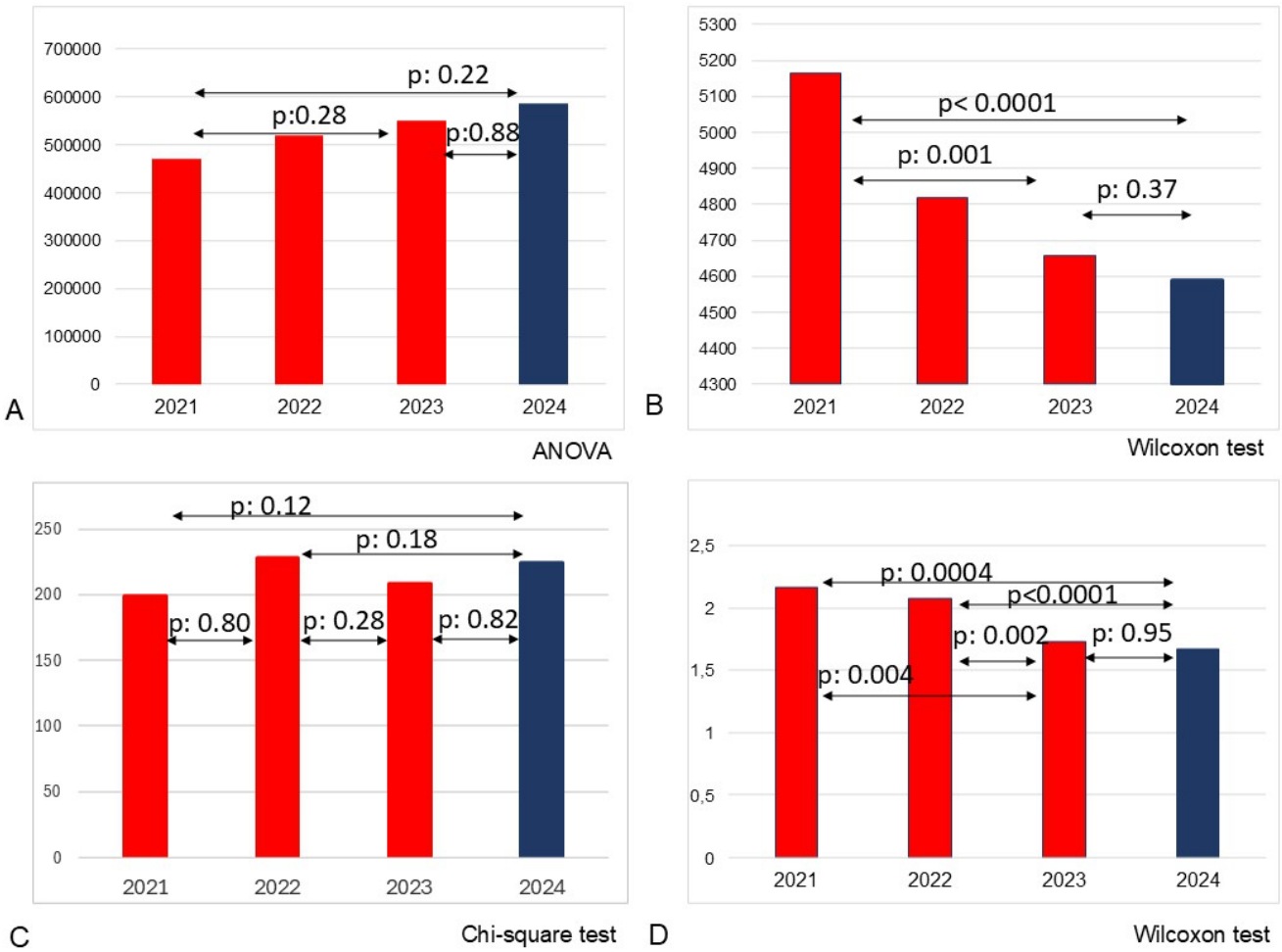

Figure 3. Economic aspects and number of rheumatologist evaluation before and during IFER process. A) pharmacological expense during years (euro); B) per capita pharmacological expense (euro); C) total number of visits per year; D) number of visits/patients. Red columns: years before IFER start; blue columns: IFER period

Table 1. Baseline clinical and demographic features of the cohort followed by family and community health nurses.

Age (years)	59 (37-76)
Female (%) Male (%)	97 (68.8%) 44 (31.2%)
Rheumatoid arthritis Psoriatic arthritis Ankylosing spondylitis Systemic lupus erythematosus Giant cell arteritis Systemic sclerosis Recurrent pericarditis and other autoinflammatory syndromes	65 43 23 2 3 1 4
Disease duration (months)	105 (28-223)
Observation time (days)	410 (252-473)
Main comorbidities (median number) Smoking Overweight/obesity Dyslipidaemia Arterial hypertension Diabetes mellitus Major cardiovascular events Pulmonary diseases History of neoplasia HBV (occult carrier / chronic infection) HIV infection	1 (1-4) 23 31/12 21 33 7 29 10 4 6/1 1
Barthel Index <80% <60%	100 (94-100) 4 3
Morinsky Index good compliance middle compliance bad compliance	11 (9-11) 92% 7% 1%
Health Assessment Questionaire	0.25 (0-1.27)
Disease-modifying antirheumatic drug treatment (first line biological treatment at IFER start, new treatment initiation during the IFER period) Abatacept Adalimumab Anakinra Baricitinib Belimumab Certolizumab Etanercept Filgotinib Golimumab Guselkumab Ixekizumab Sekukinumab Tocilizumab Upadacitinib	 25 (18.3) 26 (20.8) 6 (5.2) 6 (3.1) 2 (2.2) 11 (5.1) 26 (19.4) 1 (1.1) 7 (2.1) 1 (0) 6 (4.1) 7 (5.1) 16 (14.7) 1 (0)

Table 2. Evaluation of disease activity in patients with rheumatoid arthritis performed by rheumatologist and family and community health nurse.

		Family and community health nurse	
		Remission or low disease activity	Moderate or high disease activity
Rheumatologist	Remission or low disease activity	61	15
	Moderate or high disease activity	0	22

Table 3. Comparison of major adverse events between the rheumatologist only (2021-2023) and nurse follow-up (from 2024).

	2021	2022	2023	2024	p (Fisher exact test)		
	n: 92	n: 110	n: 121	n: 134	2024 *vs.* 2021	2024 *vs.* 2022	2024 *vs.* 2023
Deaths	0	0	3	2	0.27	0.25	0.67
Dropouts	3	3	0	2	0.31	0.33	1.0
Hospitalizations	4	9	12	9	0.57	0.81	0.37
Emergency room accesses	5	5	2	3	0.27	0.47	1.0