Original paper

Establishing Rheumatoid Arthritis Care in Zanzibar: A Year of Clinical Outcomes and Challenges

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How to cite this article: Said SS, Johansson KA, Nystad WT, Sadiq HS, Fevang BTS. Establishing rheumatoid arthritis care in Zanzibar: A year of clinical outcomes and challenges. *JOKAP*. 2025; **7**(1): 3 – 11. DOI: https://dx.doi.org/10.4314/jkap.v7i1.2

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Abstract

Background: Chronic Inflammatory Joint Diseases (CIJD) are systematic conditions that primarily affect the joints. If untreated they cause permanent deformity, increased morbidity and mortality. Although treatment options are available in Zanzibar, many patients have delayed presentation.

Objective: This study aims to describe a Rheumatoid Arthritis (RA) patient cohort's presentation and outcomes after implementation of treat-to-target (T2T) strategy.

Methods: A total of 132 patients with RA were recruited across three hospitals in Zanzibar and followed up for one year. Sociodemographic, clinical, radiological, laboratory, medication adherence and expenditure on health data were collected. Descriptive statistics were used for patient characteristics and clinical parameters. Summary statistics were used to describe demographic variables. Paired-sample t-test was used to determine significance of changes from baseline to one year. A p value of <0.05 was considered significant.

Results: The majority were female (86%) with a mean age of 45±13 years and a mean disease duration of six years. At baseline, mean disease activity based on the Clinical Disease Activity Index (CDAI) was moderate but improved at one year to low disease activity (p <0.001). Rheumatoid factor positivity was 60% and 64% had evidence of radiological damage at enrollment. Prior steroid and non-steroidal anti-inflammatory drug use was common.

Conclusion: RA can be adequately managed in resource limited settings in the absence of biologic disease-modifying antirheumatic drugs using the T2T approach with good outcomes. Educational measures are needed to increase awareness among communities and health care providers to reduce delays in diagnosis and treatment.

Key words: Rheumatoid arthritis, Zanzibar, DMARDs, Rheumatology, Inflammatory arthritis, Treat to target

Introduction

Noncommunicable Diseases (NCDs) are a leading cause of morbidity and mortality worldwide and account for over 15 million deaths in sub-Saharan Africa annually (1). They contribute 1.73 billion Disability Adjusted Life Years (DALYs) worldwide of which musculoskeletal (MSK) disorders are a major contributor of Years Lived with Disease (YLD). The global burden of disease 2021 data estimated that 17.6 million people had Rheumatoid Arthritis (RA) globally in 2020 which was an increase of 14.1%

since 1990. Over the same period, the DALYs were over 3 million with YLDs accounting for 76.4% of these (2). Estimates for eastern sub-Saharan Africa suggest there are 197,000 cases of RA in the region with an age-standardized DALY rate of 12 per 100,000 (3). This is equivalent to just under 1% of the global RA DALYs in 2020 (3). These numbers are expected to increase as MSK disorders are on the rise in SSA and are expected to continue doing so given the change in demographics and economic growth (3).

In the past, rheumatologic diseases were often considered rare in Africa and consequently not given adequate attention in health policy (4), especially compared to infectious diseases, maternal and neonatal conditions. In 2010, a systematic analysis by Dowman *et al* (5) estimated a crude prevalence of RA of 0.36% in Africa. However, more recent estimates have shown increased prevalence and burden of rheumatoid arthritis with women more affected than men (3). In Tanzania, prevalence of MSK disorders was found to be 5.9% in a rural community in Northern Tanzania by Krauth *et al* (6) with higher prevalence among women and the elderly. Among black Africans, RA is the commonest inflammatory joint disease while Ankylosing Spondylitis (AS) and Psoriatic Arthritis (PsA) are rarely reported (4).

There is scarcity of rheumatology experts across Africa (7). There is also a shortage of affordable diagnostic tests and effective medication. Methotrexate is the most commonly used Disease Modifying Antirheumatic Drug (DMARD) in RA. Treatment with the newer biologic DMARDs or targeted synthetic DMARDs is not available in the majority of public hospitals and accessible only to those who can afford them (4). Patients often present to hospital at late stages of disease either due to difficulties in obtaining care, symptomatic management at lower-level health facilities, or cultural and religious beliefs which lead them to seek initial care elsewhere (9,10). This is also complicated by the societal view on normalizing pain particularly in the elderly (9).

Similarly, in the Zanzibar Islands where this study was undertaken, the local population of 1.9 million inhabitants have no rheumatologist. Awareness regarding rheumatological conditions among health care providers and the community is low. Only one tertiary government facility offers rheumatology care and DMARDs at no cost but with frequent stockouts. The rheumatology clinic is led by an internal medicine specialist. Diagnostic tests are also free but limited. The recently revised 2022 Zanzibar Essential Health Care Package (ZEHCP) gave high priority to RA care. The interventions which include low dose steroids, folic acid and conventional synthetic DMARDs, were considered to be of high priority, medium cost-effectiveness with a low budget impact (10).

The study aims to describe a cohort of patients with rheumatoid arthritis, undergoing treatment in Zanzibar. We will discuss the implementation of newer treatment strategies, such as treat-to-target, in our setting.

Materials and methods

Study design, setting and population: An observational prospective cohort survey was conducted from September 2019 to December 2023. All patients ≥18 years with a diagnosis of RA, PsA and AS attending the rheumatology outpatient clinic were invited to participate. Consecutive sampling was undertaken, and we included patients at three study sites: Mnazi Mmoja Hospital, the main government referral hospital, and Taskhtaa and Tawakal Hospital which are private hospitals.

An interview and physical examination were carried out on all participants. Patient records were assessed to identify other diagnoses as well as past and present medication. Data was collected on paper forms and later filled into a database Vervig®. Patients were scheduled to attend clinic at baseline, one month, three months and every six months if they had reached remission. At every visit clinical and medication adherence data were collected and medication was prescribed according to a pre-determined treatment protocol in accordance with international guidelines (Supplement 1), using the treat-to target approach for management of RA (11).

Study variables: Socio-demographic data, medical history, expenditure on health, medication adherence using the 19-item Compliance Questionnaire Rheumatology (CQR19) and a set of locally relevant questions were collected via patient interviews. Laboratory and radiological results were obtained from patient records.

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For socio-demographic variables we collected data on age, sex, time to diagnosis (time lapse from first symptom to diagnosis), disease duration (time lapse from first symptom until enrolment), marital status, education level, smoking history. Participants were also asked about other pre-existing medical conditions. These were: cardiovascular disease, endocrine disorders, neurological disorder, renal disorder, chronic infections, chronic respiratory disease, inflammatory back pain, malignancy, liver disease, skin disease, uveitis and inflammatory bowel disease. We chose to report both time to diagnosis and disease duration because some patients were diagnosed many years before the baseline, and might, despite this, have received no or some treatment before inclusion. Medical records were assessed to determine prior steroid and/or current steroid use, prior methotrexate dose, Erythrocyte Sedimentation Rate (ESR) results, rheumatoid factor, Anti- Citrullinated C-Peptide Antibodies (ACPA) and radiology reports for chest and hands. Patients were considered to have evidence of radiological damage if features of RA damage (juxta-articular osteopenia, joint space narrowing, uniform cartilage destruction and erosive changes) were reported.

For the initial three visits, patients were interviewed about expenditure on health. They were also interviewed about medication adherence using the CQR-19 and some additional questions (When was the last time you took your medication? Was it on time? Was the dose as prescribed? Did you forget to take your medication? Did you run out of medication?).

Physical examination was conducted to determine system-specific findings and CIJD related deformities. From the physical examination of 28 joints Clinical Disease Activity Index (CDAI) was calculated to determine the level of disease activity. A score of >22 was considered high disease activity, >10 to ≤22 moderate disease activity, >2.8 to ≤10 low disease activity and ≤2.8 remission.

Statistical analysis: For patient characteristics and clinical parameters descriptive statistics were used. Demographic variables were summarized using mean and Standard Deviation (SD), median and Interquartile Range (IQR). Categorical data were summarized as number and percentage. To determine whether the changes from baseline to the 1-year visit was statistically significant we used the paired-sample t-test. A p-value of < 0.05 was considered significant.

Ethical approval: Ethical approval was obtained from the Zanzibar Health Research Institute (ZAHREC/02/JULY/2019/43) and Norwegian Regional Committee for Medical Research Ethics (2019/472/REK vest) for the Zanzibar CIJD study. Informed and written consent was obtained, for participants who were illiterate consent was obtained via thumbprint. Written informed consent for publication of the clinical images was obtained from the patient.

Results

A total of 135 patients were enrolled during the study period, of whom 132 were diagnosed with RA. Majority of patients were female with a mean disease duration of 5.9 years and time to diagnosis of 3.5 years (Table1).

Table 1: Patient characteristics at baseline

Characteristics	Cohort (n=132)
Sex (female n, %)	114 (86)
Age, years (mean, SD)	45±13
Disease duration[1], years (mean, SD)	5.9±6.4
Time to diagnosis[2], years (mean, SD)	3.5±0.7
Clinical Disease Activity Index (CDAI) at baseline (mean, SD)	18.3 ± 12.6
Pre-existing medical conditions[3] (yes, %)	51 (39)
Marital status: (number, %):	
Single	16 (12)
Married	84 (64)
Divorced	24 (18)
Widowed	8 (6)

Education level: (number, %)	
None	16 (12)
Primary	33 (25)
Secondary	65 (49)
Tertiary	28 (14)
Smoking history: (number, %)	
Never	120 (91)
Previous	9 (7)
Current	3 (2)
Rheumatoid factor (positive, %) (n=126)	76 (60)
ESR at baseline (mean, SD) (n=124)	46±34
Radiological damage[4] at baseline (yes, %) (n=105)	65 (64)
Monthly expenditure on health[5], USD (median, IQR) (n=104)	16 (8-30)
Monthly expenditure on alternative therapies[6], USD (median, IQR) n=23	26 (13-174)
Previous methotrexate use[7] (yes, %)	47 (35)
Previous steroid use[8] (yes, %)	89 (66)
Previous NSAIDs use[9] (yes, %)	107 (79)

SD=Standard deviation, IQR=Inter-quartile range, RF=Rheumatoid factor, ESR=Erythrocyte sedimentation rate, USD=United States dollars, NSAIDs = Non-steroidal anti-inflammatory drugs

[1] Disease duration - time lapse from first symptom to enrolment

[2] Time to diagnosis - time lapse from first symptom to diagnosis

[3] Pre-existing medical conditions include: cardiovascular disease (hypertension, congestive heart failure, myocardial infarction, peripheral vascular disease), endocrine disorders (diabetes, thyroid disorder), neurological disorder (stroke, dementia), renal disorder, chronic infections, chronic respiratory disease, inflammatory back pain, malignancy, liver disease, skin disease, uveitis and inflammatory bowel disease

[4] Radiological damage includes any joint damage caused by rheumatoid arthritis visualized on radiological imaging such as juxta-articular osteopenia, joint space narrowing, uniform cartilage destruction or erosive changes

[5] Expenditure on health includes monthly expenses for transport, drugs, investigation, consultation at a health facility and caregiver costs

[6] Expenditure on alternative therapies includes expenses for seeking care at any caregiver not considered to practice conventional medical therapy

[7] Previous methotrexate use from disease onset to enrollment.

[8] Previous steroid use from disease onset to enrollment.

[9] Previous NSAID use from disease onset to enrollment.

Patients with a negative rheumatoid factor 50 (40%) were asked to perform Anti-Citrullinated Peptide Antibody (ACPA) test at their own costs. Only 16 patients were able to perform the test, and it was found positive in 14/16 patients with titers as high as >7200 IU/ml (normal range 0-7).

From our cohort, 45 participants had received methotrexate prior to enrolment into the study. However, many of them received sub-optimal doses, as low as 5mg per week. Steroid use was also very common with patients receiving up to 40mg of prednisolone without concurrent DMARD therapy.

From the chest radiographs, four participants were found to have RA lung disease that was confirmed by high Resolution Computed Tomography (HRCT) scan described elsewhere (12). Three other patients were diagnosed with pulmonary tuberculosis and completed anti-tuberculous therapy. Of these, one was diagnosed with multi-drug-resistant tuberculosis.

At the end of one year, patients were on various therapies. Rituximab was the only biologic DMARD available and was used in patients who had not reached remission or low disease activity on triple therapy. Over the study period a Janus kinase

inhibitor also became available and was offered to four patients. At the end of one year 73 (94%) patients were on conventional synthetic DMARD therapy while 5 (6%) patients were on rituximab.

Over the four-year period, many of our patients were lost to follow up. At the end of one year, data was available for 78 participants. Disease activity scores were as follows: 29% remission, 41% low, 21% moderate and 9% high. The mean CDAI score was 8.6 ± 8.4 which was significantly lower than at baseline ($p < 0.001$) despite only 49 (64%) participants adherent to medication. The mean ESR at the end of one year was 38 ± 30, a change from baseline which was not significant ($p = 0.35$).

During the entire follow up period 17 (13%) patients received intra articular injections which included knees, elbows, wrists and ankles. This treatment was initiated as an option from the second year of the study and was increasingly used during the last year of the study. These were targeted at patients who had a few affected joints.

Figure 1: Hands of a 24-year-old woman with rheumatoid arthritis. Rheumatoid arthritis- related deformities of the hands. Boutonniere deformity of the thumbs and fingers with ulnar deviation of the metacarpo-phalangeal joints

Figure 2: Radiograph of a 62-year-old woman with long-standing untreated rheumatoid arthritis

The image shows bilateral symmetrical diffuse osteopenia with erosive attritions of the ulna heads. Radio-carpal, intercarpal and carpo-metacarpal erosive changes with variable ankylosis. Metacarpo-phalangeal erosive attrition and remodeling with ulnar angular deformities. 'Pencil in cup' deformities involving the metacarpo-phalangeal joints. Inter-phalangeal joint variable erosive changes with ankylosis.

Discussion

According to the 2022 population census, almost 43% of the Tanzanian population is below 15 years of age, which is higher than the African average of 40%. About half of the population is of reproductive age (13) with a mean fertility rate of 4.6 births per woman (14). There has also been a 5% increase in urban compared to rural dwellers over the last decade (13). In addition, life expectancy has increased gradually from 52.4 years in the year 2000 to 67.6 years in 2023 (14). Due to a combination of these factors, Zanzibar can expect to see a rise in the number of people diagnosed with RA over the coming years.

To our knowledge, this is the first study describing a consecutive CIJD cohort in Zanzibar. Other similar studies have been undertaken at various rheumatology centers across Africa. The majority of which were cross-sectional and focused on patient clinical, serological and radiological presentations (15–18). In many of the studies, the patients had access only to conventional synthetic DMARDs (csDMARDs) (15,17,19). Our study looked at patients' baseline characteristics and progress during follow-up in accordance with a pre-set treatment guideline based on the recommended treat-to-target approach (11). Based on the findings in our patient cohort, we noted a number of factors of interest to the further development of treatment strategies and care for patients with RA in African countries and other similar settings.

Patient and disease characteristics

The presentation of RA in relatively young patients, delayed diagnosis and high disease activity at presentation is common across most of Africa. In our cohort, the mean age at presentation was 45 years which is similar to other studies reporting a mean age of 36.1 to 51.2 across several studies (16–18). The study found RF positive in 59% of our patients. Interestingly, RF positivity was variable with countries such as Kenya and Uganda having high positivity rates of over 70% (20,21) and others

having positivity rates of less than 50% (16,17). RF positivity has been linked to more severe forms of RA (16) and subsequently, radiological damage at presentation was common in our cohort.

During the study period, only 135 patients were included in the overall study despite Zanzibar having a population of 1.9 million people. Studies from various African countries have given a prevalence of RA ranging from 0.1-2.5% (22). Several measures were undertaken to educate the public and health care workers on the disease and availability of services. We undertook television and radio talks as well as the distribution of patient education leaflets. The relatively low number of included patients may be attributed to low awareness on RA among health care providers and the general population, financial constraints, as well as lack of access to diagnostic tools at peripheral facilities. In our cohort, the majority had moderate or high disease activity at presentation, and we believe there is a larger number of patients with early disease and lower disease activity who do not seek care for their complaints. A continued focus on awareness is likely to change patients' threshold for seeking care and subsequently increase the number of patients and decrease the time to diagnosis.

Disease activity and treatment outcomes

Baseline disease activity was moderate to high in our cohort. Fortunately, we found significant improvement at one year. We believe this improvement was due to a combination of implementing the treat-to-target strategy, structured follow-up, together with medication adherence counselling. RA improvement at one year in our cohort is comparable to studies from other parts of the globe (23), but because of the low numbers at follow-up, these findings must be interpreted with caution. Our findings may also be used to highlight the fact that aggressive treatment with csDMARDs alone still has a role, particularly in settings where biologic- or targeted synthetic DMARDs may be unavailable.

The study noted a high loss to follow up among our patients. We believe this may be due to many factors such as poor understanding of the chronicity of rheumatoid arthritis and the need for long term management. Also, economic constraints and geographical distances involved in reaching the hospital may have had an influence. The low adherence to therapy in our patient group was similar to other patient groups across Africa such as hypertension and diabetes (24) and cancer (25). Low adherence has been attributed to economic factors as well as use of traditional medication (24). These will need to continuously be addressed to further improve patient care.

Although health care is declared to be free in Zanzibar, DMARDs stock-outs lead to out-of-pocket spending to meet health care needs. With over-the-counter steroids and painkillers available, patients who cannot afford DMARDs often opt to use these instead. Patients tend to self-prescribe these drugs with little knowledge of their side effects. Similar to what we found, prolonged steroid use is a common practice in other settings such as Ethiopia (19) and Uganda (20). In SSA seeking alternative care for ailments is also common practice, and occasionally exorbitant amounts may be paid to achieve a quick fix. Around 17% of our patients reported to have sought alternative therapy. We do believe the numbers may be much higher as patients are usually hesitant to disclose alternative medicine use for various reasons. These factors cause delays in seeking care and sub-optimal disease control.

Various questionnaires have been developed for the assessment of medication adherence in RA. The three commonest are the Medication Adherence Report Scale (MARS), the Morisky questionnaire and the 19-item Compliance Questionnaire on Rheumatology (CQR-19). We opted to use the CQR-19 as it has been validated for use in patients with inflammatory rheumatic disease. We however found that the patients' responses to the CQR-19 were arbitrary and did not capture those who were non-compliant. We therefore had to use context specific questions targeting patient compliance. Although the CQR-19 is validated in the West, there is a need to create tools and questionnaires that put into consideration the local setting and patient values to ensure that information collected is accurate.

Future rheumatology care in Zanzibar

Rheumatology is an extremely under-explored specialty in our setting and awareness is very low. Despite the main referral hospital existing since 1896, there has never been a rheumatologist, nor a rheumatology clinic established prior. Patients may live in pain without a proper diagnosis or treatment for many years and learn to accept the pain as part of the ageing process as is common in African settings (10). However, from our study, we have found that rheumatology services can be run successfully by a physician using locally applicable treatment guidelines and expert support. Remission can be achieved even in the absence

of biologic DMARDs (15). There was a tendency of patients having very low doses of methotrexate with steroids prior to the commencement of the project but this has now shifted and is similar to international recommendations leading to a higher standard of care.

To align with the ZEHCP recommendations, the government will need to scale up rheumatology services across both Unguja and Pemba islands. Unguja island has a population of 1.3 million while Pemba's population is just over 600,000 (13). A pragmatic and parallel approach will be necessary. This entails educational activities targeting community awareness of common rheumatological disorders and availability of care as well as health care providers' education on early recognition, diagnosis and timely referral of patients. Primary health care units will be required to refer these patients to district hospitals which should be equipped with basic laboratory and radiology services to be able to correctly diagnose patients. Those found positive should be referred to the referral hospital on either island. The presence of rheumatology care in Pemba will reduce the need for patients to travel to Unguja and increase accessibility to care. At referral hospitals, rheumatology services may be run by internal medicine specialists with an interest in rheumatology while at least two rheumatologists are trained with a target of four rheumatologists in ten years. These specialists would be expected to not only cater to the RA patients but also other rheumatological disorders which have not been covered by our study. Although there is a global scarcity of rheumatologists, the number of specialists per population should be determined by local needs and context. For specialization, two-year online courses run by the European Alliance of Associations for Rheumatology (EULAR) may be considered. This would ensure that personnel remain on site to offer services while learning about the patients they attend to. Support can also be provided by linking the clinics with rheumatology specialists where monthly meetings using online platforms can be used to discuss difficult-to-manage cases. Referral hospitals should be equipped with a total of at least four technicians able to perform musculoskeletal ultrasound, more specialized laboratory tests, as well as DMARD and other immunosuppressive therapies. As patients present quite late, there may be a need to consider rehabilitative care and surgery for some patients in the future. The government will also need to encourage and ensure research on MSK disorders is undertaken to accurately map and determine the population's needs for care. These recommendations can also be tailored to various settings in the African context as well as other resource limited settings who aim to improve rheumatology services.

Conclusions

A similar study has never been undertaken in this setting and presents new findings from our population. Although not novel, our study highlights relatively easy measures that can be replicated in almost any resource limited setting, with little or no rheumatology experts, to improve rheumatology care. Study weaknesses include the low number of patients at one year follow up for comparison.

Acknowledgements

We would like to acknowledge the contributions of various individuals during the data collection and study period particularly Drs Noorein, Faiza, Asya, Naila and the nurses at the rheumatology clinic Asma and Zuhura. We are also grateful to Amina for the extra assistance to the patients and Dr Clive for his hands-on training and guidance on patient care.

Conflict of interest statements: The authors have no competing interests to declare.

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