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Analysis of Intra-Articular Injection of Triamcinolone Acetonide on Changes in The Quality of Life of Patients With Knee Osteoarthritis

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ABSTRACT

Introduction: Knee osteoarthritis is the most common articular disease in developed countries, which causes chronic disability and reduction of the quality of life in the elderly. Intra-articular (IA) injections are selected if other conservative therapies are ineffective. ***Purpose:*** This study aimed to measure the effect of IA injection of triamcinolone acetonide on the quality of life in patients with knee osteoarthritis. ***Methods:*** This observational research was conducted in three steps: filling out questionnaires by patients, interviewing patients, and retrieving patients' data from medical records. The patients' quality of life scores were measured before and 4 weeks after therapy, using the AIMS2-SF score, VAS EQ-5D-5L, and Indonesian EQ-5D-5L. The result will be declared statistically significant if $p<0.05$. ***Results:*** No statistically significant difference found in AIMS2-SF scores ($p> 0.05$) for Symptoms, Social, Occupational domains, and in VAS EQ-5D-5L ($p> 0.05$). A significant difference was found in AIMS2-SF scores for the Physical and Emotional domains, as well as in the EQ-5D-5L score. Multivariate analysis showed that patients' characteristics and knee osteoarthritis disease did not affect the AIMS2-SF, EQ-5D-5L, and VAS scores. ***Conclusion:*** IA injection of triamcinolone acetonide has a potential effect to increase the number of domains in the patient's quality of life after 4 weeks of therapy.

1. INTRODUCTION

The patterns of disease morbidity and mortality worldwide have changed in both developing and developed countries. Until the 20th century, infectious diseases were a major cause of morbidity and mortality. In this century, the main causes of morbidity and mortality worldwide are non-communicable diseases.[1,2] Osteoarthritis (OA) is the most common arthritis. It is characterized by the presence of joint pain and joint stiffness that lead to functional decline and not only loss in social functional limitations but also quality of life. [3,4]These articular diseases are common in the elderly population largely as a consequence of knee and hip osteoarthritis.[3] In 2025, the prevalence of knee osteoarthritis is expected to increase by 40%, largely due to an aging population and an obesity epidemic.[5,6]

Given the high frequency of osteoarthritis in the population, the economic burden of OA is large.[7] The burden of osteoarthritis disease encompasses physical, psychological, and socioeconomic burdens. OA of the knee is the leading cause of disabilities and overall burden around the world.[8,4] This can be attributed to a significant degree of disability, such as decreased mobility and difficulty with daily living activities. Psychological sequels that can occur in people with osteoarthritis include stress, low self-esteem, and loneliness. Knee OA is known to decrease patients' mobility, mood, sleep, and the risk of death from OA-related cardiovascular disease.[9] The economic costs of osteoarthritis include those related to treatment, adjustments to the patient's and their family's home environment due to the disease, and the loss of work productivity. The

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burden of knee osteoarthritis in individuals, health systems, and social care systems can be considered a public health crisis.[10]

Until now, there has been no treatment that can cure osteoarthritis. The medication for OA is focused on the relief of pain, but no medication has been proven to slow the progression of the disease.[8] According to the ESCEO guideline 2019, non-pharmacological and pharmacological therapies are fundamental principles and core for the disease management.[4] OA Intraarticular injection (IA) is often selected as the last non-operative modality for knee osteoarthritis if other conservative therapeutic modalities are ineffective or limited by any cause. [4] Intraarticular injections of corticosteroids provide short-term pain relief and may be considered advanced pharmacological management in the patient with persistent symptoms.[11,12,4] Although IA is recommended for improving pain and increasing patients' quality of life, intraarticular injection of corticosteroids may reduce cartilage volume if used regularly every 3 months for 2 years so that it can damage the joints. [8,13,14] Immediate and delayed side effects can occur at the local site of injection or systemically, such as postinjection flare, infection, osseous injury, hypersensitivity reactions, and osteoporosis. Operative therapy, such as total joint replacement or unicompartmental knee replacement, can significantly improve the quality of life for patients with osteoarthritis. However, fewer patients are willing to undergo operative therapy for multiple reasons. Clinicians who are concerned, including those with fewer than one-third of the number of patients, have indications.[4]

Pharmacological therapy in osteoarthritis has been aimed at alleviating pain and improving the function of affected joints.[15,16] Therefore, much research is aimed at measuring the therapeutic output based on the level of pain and physical function in patients with knee osteoarthritis. Kolansinski et.al.[16] concluded that the short-term intraarticular effectiveness of corticosteroid injections in relieving pain in knee osteoarthritis patients.[17] Intraarticular injections of corticosteroids were also found to be superior to placebo in the total score of Western Ontario McMaster and University Osteoarthritis Index (WOMAC) in four weeks.[17,18] However, the Cochrane Systematic Review 2006 states there is a lack of evidence of quality of life improvement at any point in time after intraarticular corticosteroid injection therapy in patients with knee osteoarthritis.[11,17, 18]

Clinical manifestations of knee osteoarthritis, in addition to causing pain and affecting function, can have a direct impact on other aspects of the patient's life. A study in Indonesia found that occupation, body mass index, illness duration, and the number of affected knees with osteoarthritis are significantly correlated with patients' quality of life.[19] Another aspect influenced by the disease is social interaction, mental function, and sleep quality.[20,21,22] Kovacevic et.al.[22]states that psychological and social factors contribute greatly to the quality of life of osteoarthritis patients. Quality-of-life measurements that include psychological and social factors can help estimate the physical, social, and emotional impact of knee osteoarthritis therapies.[23,24] Measurements of the rate of change in quality of life are also widely used to measure cost-effectiveness in the pharmacoeconomic field.[7] The existence of these reasons leads researchers interested in conducting studies that measure the quality of life in patients undergoing intraarticular injection therapy for knee osteoarthritis.

One way to measure the quality of life in arthritis patients is by using the Arthritis Impact Measurement Scales 2 Short Form (AIMS2-SF) questionnaire. The AIMS2-SF questionnaire, developed by Meenan et al. in 1997, assesses various aspects of quality of life in osteoarthritis patients, including quality of life and outcome, using a specific measurement scale. The AIMS2-SF questionnaire can be used to describe the overall quality of life of patients with osteoarthritis.[25] The AIMS2-SF questionnaire consists of 26 questions grouped into five domains: physical, symptomatic, mood, social, and occupational domains. Each domain utilizes a coding system and assigns five levels of scores, ranging from 1 to 5, where 1 represents the best health condition and 5 represents the worst health condition.[25] The value gained in each domain will then be normalized to produce a total score for AIMS2-SF. The Indonesian version of the AIMS2-SF questionnaire is already available and validated.[26] The IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) consensus recommends determining the changes which is considered important in measuring outcomes for chronic pain therapy.[27] To

determine which one is important, one of the ways is to use a benchmarking method in the form of direct questions to the patient about the quality of life measured in the unit at certain points in time.[25]

To achieve the aim of this study, which was to measure the effect of intra-articular injection of triamcinolone acetonide on the quality of life in patients with knee osteoarthritis, this study was conducted in the Yogyakarta Special Region (DIY). DIY was chosen because it had the best life expectancy in Indonesia, along with Jakarta and Bali, at 73 and 27 years, respectively. Osteoarthritis primarily affects the elderly population. Bethesda Hospital Yogyakarta and Bethesda Lempuyangwangi Hospital Yogyakarta are private hospitals classified as Class B and D in DIY, respectively, that provide specialized medical services and limited subspecialties. Intraarticular injection therapy services are available for patients with joint disease, including osteoarthritis, in these hospitals. We hope this study can help physicians reassure patients with knee osteoarthritis that the intra-articular injection of triamcinolone acetonide has more benefits than risks, thereby improving the patient's quality of life.

2. METHODS

This observational study employs a prospective data retrieval approach with a self-controlled case series design. This study has received approval from the UKDW Medical Faculty Ethics Commission with numbers 180/C.16/FK/2016 and 634/C.16/FK/2018. This study compared the quality of life scores before and 4 weeks after therapy in patients with knee osteoarthritis who received intraarticular triamcinolone acetonide injections at Bethesda Hospital and Bethesda Lempuyangwangi Hospital, Yogyakarta, using the EQ-5D-5L and AIMS2-SF questionnaires.

The population of this study consisted of patients with knee osteoarthritis who received intra-articular triamcinolone acetonide injection therapy at Bethesda Hospital Yogyakarta and Bethesda Lempuyangwangi Hospital Yogyakarta. The sample was collected using a purposive sampling method. Data collection from patients was conducted from early September 2017 to the end of March 2018.

The inclusion criteria for the research subjects were patients who have been diagnosed by specialist physicians with knee osteoarthritis in the outpatient clinic of Bethesda Hospital and Bethesda Lempuyangwangi Hospital Yogyakarta, will receive intra-articular injections of triamcinolone acetonide according to the specialist doctor's instructions, women or men aged 18 years and over, patients are willing to be included in the study and signed a statement of willingness to follow the research. The exclusion criteria of the study subjects were comorbid which greatly influenced the quality of life (cancer, heart failure, kidney failure, stroke), received intraarticular injection therapy in the previous 3 months, there were abnormalities/weakness of lower extremity limb function that were not caused by knee OA (fracture, congenital disabilities).

Patients who met the inclusion and exclusion criteria had their pain intensity and quality of life measured before receiving intra-articular triamcinolone acetonide injection therapy. Then, at week 4th after therapy, the patients had their pain intensity and quality of life remeasured. This study used a numeric pain scale that classifies the pain from 1 (no pain) to 10 (worst possible pain) from the patient's point of view.[31,32]

To determine the outermost meaning of a therapy from the patient's perspective, this study utilized the EQ-5D-5L questionnaire. The EQ-5D-5L Questionnaire is a general instrument for measuring quality of life at a single point in time, incorporating quality of life measurements in the form of a VAS (Visual Analog Scale) and utility.[28] The utility value (EQ-5D index score) describes and assesses general health status in five dimensions: Mobility, Self-care, Usual Activities, Pain / Discomfort, and Anxiety / Depression.[28] The EQ-5D-5L questionnaire in the Indonesian version is already available and validated.[26,29,30]

Data were taken from the medical record, including sex, date of birth, weight, height, check date, blood pressure, occupational status, current medical history, previous disease history, comorbidities, and prescribed medicines, including the dose of intra-articular triamcinolone acetonide injection therapy.

In this study the data was processed by computer using the following method, which is re-

coding and normalization of value to AIMS2-SF score of respondents, calculating utility score EQ-5D-5L respondent with Indonesian value of set, making descriptive presentation by calculating frequency distribution and average variables, and performing bivariate analysis with paired sample t-tests when the distribution is normal. A paired sample t-test is used to determine whether there is a significant difference between AIMS2-SF and EQ-5D-5L scores before and 4 weeks after therapy. If the distribution is abnormal, the data will be tested with the Wilcoxon signed-rank test. The significance level in this study is expressed when $p<0.05$.

3. RESULT

The subjects who met the inclusion and exclusion criteria for the research were 37 people. All patients received a dose of triamcinolone acetonide at 20 mg per joint. The patients' quality of life was assessed before and 4 weeks after therapy. The basic characteristics of research subjects are presented in Table 1.

Table 1.
Basic Characteristics of Research's Samples (N = 37)

Patient's characteristics	n	%
Age		
≥ 60 years	25	67,6
<60 years old	12	32,4
Gender		
Man	14	37,8
Woman	23	62,2
BMI		
Overweight and Obese (BMI ≥ 25)	23	62,2
Normoweight (BMI < 25	14	37,8
Complicated disease		
> 1 comorbid illness	14	37,8
≤ 1 comorbidities	23	62,2
Job status		
Work	13	62,16
Unemployed	24	37,84
Flare conditions		
Flare	31	83,8
No flare	6	16,2
The number of knee joints affected		
Unilateral	24	64,9
Bilateral	13	35,1
Initial pain level		
< 6	24	64,9
≥ 6	13	35,1
Long since being diagnosed with OA		
< 5 years	29	78,4
≥ 5 years	8	21,62
Use of other drugs besides TA intraarticular injections		
< 2 drugs	35	94,6
≥ 2 drugs	2	5,40

EQ-5D-5L score assessment

The descriptive value of the EQ-5D-5L score before therapy revealed that the most frequently reported health problems were in the pain/discomfort dimension (91.89%), followed by mobility (59.46%), anxiety/depression (56.76%), daily activities (51.35%), and self-care (21.62%).

The descriptive value of the fourth weekly EQ-5D-5L score after therapy showed that the most common reported health problems were in the pain/discomfort (81.08%), followed by mobility (48.65%), daily activities (40.54 %), anxiety/depression (27.03%), and self-care (13.51%).

Table 2.
Statistical Test With Effect Size For EQ-5D

Domain	Median*	CI 95%*	z-statistik	Nilai p	Effect size	Cohen's D
VAS	-5,0	-10,0 – 2,5	176,5	0,162	0,230	0,053
UTILITY	-0,108	-0,187 – (-0,023)	185	0,020	0,381	0,145

* is the difference before and after therapy and analysis using non-parametric tests, the Wilcoxon signed rank test.

Table 2 presents the results of quality of life values using the EQ-5D-5L measuring instrument in osteoarthritis patients before and after intraarticular injection therapy with triamcinolone acetonide. The results showed that VAS and utility values after 4 weeks of intraarticular triamcinolone acetonide therapy were higher than before therapy. Both mean and median utility values showed significant improvements after therapy compared to before treatment. The non-parametric Wilcoxon signed-rank test was used because the data quality scores of life quality, as measured using AIMS2-SF and EQ-5D questionnaires, did not follow a normal distribution.

AIMS2-AF scores assessment

Table 3 shows the results of quality of life values using AIMS2-SF questionnaires in osteoarthritis patients before and 4 weeks after receiving intraarticular injection of triamcinolone acetonide. AIMS2-AF scores in the Physical and Emotional domains indicate that both the mean and median values were significantly lower after receiving therapy compared to before treatment. While the Symptom, Social, Occupational, and Total Score domains also showed a decrease in score after therapy, the results were not statistically significant.

Table 3.
Statistical tests, along with the effect size for AIMS2-SF

Domain	Median*	CI 95%*	z-statistic	p Value	Effect size	Cohen's D
PHYSICAL	0,418	0,000 – 0,940	387,5	0,050	0,313	0,098
SYMPTOMS	0,417	-0,833 – 1,249	259	0,374	0,146	0,021
EMOTIONS	0,750	0,250 – 1,500	347,5	0,018	0,389	0,151
SOCIAL	0,000	-0,625 – 0,625	280,5	0,763	0,050	0,002
WORK	1,250	-1,250 – 4,375	47	0,225	0,337	0,113

* is the difference before and after therapy and analysis using non-parametric tests, the Wilcoxon signed rank test.

Multivariate Regression Test Assessment

In the multivariate regression test, the basic characteristics of the patients did not affect the VAS and EQ-5D-5L quality of life score using the utility score after intraarticular injection of triamcinolone acetonide. Only the EQ-5D-5L utility score before therapy (especially in terms of mobility, self-care, anxiety/depression, and overall utility) has a significant positive correlation with the EQ-5D-5L utility score after therapy.

In multivariate regression testing, baseline characteristics of patients generally did not affect the AIMS2-SF quality of life score after intraarticular injection of triamcinolone acetonide. Only the AIMS2-SF quality of life score before therapy had a significant positive correlation to the AIMS2-SF quality of life score after therapy.

4. DISCUSSION

Triamcinolone acetonide intraarticular injections remain recommended as a last-resort non-surgical therapy for knee osteoarthritis due to their effectiveness in reducing pain and improving patients' quality of life compared with other interventions, such as other corticosteroid injections, hyaluronic acid therapy, and autologous therapy.[32] According to a meta-analysis by Pereira et.al.[32] triamcinolone acetonide intraarticular injection has the highest probability of being the best intervention to reduce pain in knee osteoarthritis patients compared with other interventions.[32] Although triamcinolone acetonide is expected to be the best treatment for osteoarthritis, triamcinolone acetonide still has adverse effects that need to be considered, such as postinjection pain or swelling, infection, and allergic reactions.[11,12] Long-term side effects of corticosteroid

intraarticular injections can arise from prolonged use, with osteoporosis being the most common concern.[11,12,8]

In this study, 37 patients with knee osteoarthritis received an intra-articular injection of triamcinolone acetonide. All patients had their pain intensity and quality of life measured right before intraarticular injection therapy was given and 4 weeks after intraarticular injection therapy using AIMS2-SF and EQ-5D-5L simultaneously. The difference in quality of life score before and after intraarticular injection therapy was then statistically tested to determine whether a significant difference existed. Endarti et al.[28] compared EA-5D-5L and EQ-5D-3L to measure patients' quality of life in acute diseases, chronic diseases including osteoarthritis, and the general population. They found that the EQ-5D-5L has better psychometric properties than the EQ-5D-3L for measuring value.[28] Ibrahim et.al.[33] and Ayala et.al. [34] have quite different research results. Ibrahim et.al.[33] compared EQ-5D-5L and SF-6D to assess patients' quality of life and found that SF-6D has a higher utility value than EQ-5D-5L in osteoarthritis patients, making it a better instrument for assessing utility value. Ayala et.al[34] stated that although the ED-5D-5L is a valid and reliable instrument for assessing quality of life, clinical trials usually use the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) to measure patients' quality of life. WOMAC has high sensitivity to detect changes and differences in patients' quality of life, but can not provide preference-based economic evaluations.[34]

Regarding the difference in life quality score using VAS EQ-5D-5L before and 4 weeks after injection therapy with triamcinolone acetonide, the result is $p > 0.05$ ($p = 0.162$), indicating no statistically significant difference. This is by the Cochrane Systematic Review 2006 and Ayhan et al., which states that there is a lack of evidence of quality of life improvement at any point in time for intraarticular corticosteroid injection therapy[11,16] These results differ from the study conducted by Utamawatin et.al.[4] They showed that there were significant improvements in quality of life using the same measurement tools.[4] These differences may be caused by the different dose of triamcinolone acetonide used in the study and the time of observation. Utamawatin et al.[4] used 10 mg and 40 mg of triamcinolone acetonide to be injected intraarticularly and took two measurements, i.e., 4 weeks and 12 weeks.

The EQ-5D-5L utility score before and 4 weeks after treatment showed a significant difference, with a meaningful result of $p < 0.05$ ($p = 0.02$). This result was obtained after the quality of life score, as measured by the EQ-5D questionnaire, was converted to a specific value set for the Indonesian population.[17,29] This was consistent with the Utamawatin et.al.[4] study, which showed significant results at week 4.[4]

The statistically significant results on the measurement of quality of life using the VAS EQ-5D-5L and EQ-5D-5L utility can indicate a difference in the quality of life values in people's perceptions and the true value of quality of life. The value of EQ-5D-5L utility in this study is adjusted to the value set of Indonesia because, if patients are asked directly about the improvement of their health, they tend to answer according to the perception of the surrounding community, for example, 'tolerable', rather than providing the real result. After adjusting the value set for Indonesia to reflect the real quality of life, the statistical test results are meaningful. Purba et.al.[29] stated that EQ-5D-5L should represent the culture, living standards of Indonesians, and particular wording that accurately reflects the real value of quality of life. [29] Wang et.al.[35] found that in Asian countries EQ-5D-5L instruments might lack sensitivity due to not only culturally specific health dimensions but also strong family and community support, which influenced more positive self-assessments even under chronic illness conditions.[35] Although it has its limitations, Endarti et.al.[28] found that EQ-5D-5L is a better instrument than EQ-5D-3L to measure patients' quality of life in chronic diseases like osteoarthritis.[28]

The WHO currently recommends measuring the outcome of medical therapy in patients worldwide using an EQ-5D-5L questionnaire, especially for pharmacoeconomic purposes. The use of different value sets at the same initial descriptive EQ-5D-5L score is also likely to yield different results due to variations in public perception of health status.[35] In September 2017 there was an Indonesian value set for EQ-5D-5L Indonesia, which was used to adjust the quality of life measurement results based on public perceptions, so that the measurement results were more

accurate for Indonesians.[29] Therefore we used the Indonesian value set in the study this to represent the real perception of the surrounding community on a Indonesian health status.

In measuring the quality of life of patients using AIMS2-SF questionnaires, there was no significant difference in scores before and after intraarticular triamcinolone acetonide injection in terms of Symmetric, Social, and Occupational Symptoms (Table 3). At the same time, significant results were obtained in the Physical and Emotional domains. This result, as shown by Alabajos-Cea et.al.[36] showed no significant correlation between social participation and osteoarthritis.[36] Social participation is associated with depression caused by osteoarthritis, not by the disease itself.[36] However, many researchers such as Kovacevic et.al.[22], Sananta et.al.[36] , and Sudaryanto et.al.[37,38] agreed that psychological factors are associated with the quality of life. We separate the measurements of the quality-of-life results in each AIMS2-SF dimension. The measurement of quality of life values using AIMS2-SF scores relies on respondents' cumulative recall of their personal health status over the past 4 weeks. It does not assess actual results on the spot, thereby increasing the potential for bias in this study.

In a multivariate statistical test using linear regression, it was found that the patient's characteristics and knee osteoarthritis disease did not affect the AIMS2-SF quality score or the VAS and EQ-5D-5L utility values. Only AIMS2-SF scores and EQ-5D-5L utility values before therapy showed a significant positive correlation with the quality of life domain after therapy. This result is contrary to many research works worldwide, such as Shalhoub et.al.[39], which found a significant association between age, educational level, occupation, number of joints affected, number of comorbidities, duration of disease, and severity of pain and EQ-5D-5L score. Shalhoub et al.[39] also found that gender, age, educational level, occupation status, pain medications, number of affected joints, disease duration, number of comorbidities, and pain interference are associated with the EQ-VAS score.[39] Different results may be caused by the indirect effect of knee osteoarthritis, such as anxiety and depression, that affect the patient's quality of life.[36] Depression is known to be associated with lower social participation rather than pain and osteoarthritis itself.[36]

Limitations of this study include the possibility of bias from other factors that may affect the overall health of patients. The EQ-5D questionnaire has a general characteristic that measures the quality of life of patients from a broad perspective, encompassing multiple specific items. Two patients reported other health disorders that they thought were quite severe when they became research respondents during the interview session. Different ways of filling out questionnaires can also cause bias, such as the presence of patients requiring assistance from their families or research assistants due to visual disturbances or literacy difficulties, largely because patients are mostly elderly (67.6%). The questionnaire should be self-administered. This study is also self-controlled, meaning there is no control group with which to compare the results of other individuals.

5. CONCLUSION

Intraarticular injection of triamcinolone acetonide has no improving effect on the total quality of life of patients with knee osteoarthritis measured by both AIMS2-SF and VAS in EQ-5D-5L questionnaire. The utility aspects measured by EQ-5D-5L showed significant improvement after intraarticular injection of triamcinolone acetonide. Intraarticular injection of triamcinolone acetonide showed significant improvements only in physical and emotional aspects of the AIMS2-SF score after 4 weeks of injection. The results indicated that the intraarticular injection of triamcinolone acetonide still has a potential effect on increasing the number of domains in the patient's quality of life after 4 weeks of therapy.

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