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EFFECT OF SIDAGURI (SIDA RHOMBIFOLIA L) ON WOMAC SCORE ASSESSMENT IN OSTEOARTHRITIS PATIENTS

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ABSTRACT

Introduction : WOMAC scoring is one of the tools to assess the effectivity of therapy in osteoarthritis (OA) patients. The efficacy is proven if there is a decrease in WOMAC score after given therapy. Pain is the major complaint of OA patients, and it is usually connected with inflammatory process. NSAIDs are the most common therapy given in OA to reduce pain. Sidaguri (*Sida rhombifolia* L) is one of the medicinal plants which had anti-inflammatory activities by inhibiting nitric oxide (NO).

Method : a double blind randomized clinical trial was conducted in Adam Malik Hospital in september-november 2017. OA patients were assessed for WOMAC score and screened for liver and renal function before given treatment. They were randomized to receive combination of Sidaguri extract and meloxicam or meloxicam and placebo in a double-blind technique. Each group involved 25 patients who received one month therapy. At the end of therapy, all patients were rechecked their liver and renal function, and also reassessed the WOMAC score. Data were statisctically analyzed.

Result : After one month therapy, we redid the WOMAC assessment to all the patients . The total score of WOMAC after given Sidaguri-meloxicam is 7,2 (3,12-17,7)%, while the meloxicam-placebo is 36,4(22-71,8)% (p=0,0001).

Conclusion : Sidaguri extract can be given as an effective alternative therapy in osteoarthritis patients.

KEYWORDS : Sidaguri, WOMAC score, Osteoarthritis

1.INTRODUCTION

Osteoarthritis (OA) is the most common form of arthritis which cause disability and decrease in quality of life of population over 50 years old. Because OA increases significantly with age, it was long considered to be a degenerative disease that was inevitably consequences of ageing and trauma [1]. However, it is viewed now as a inflammatory process because of the involvement of inflammatory mediators such as cytokines and nitric oxide (NO) [2].

Pain is the major complaint of OA patients which also cause joint stiffness and limitation of daily activities [3]. It should be graded and recorded everytime they come to the physician. The standard tool to assess pain, especially in knee and hip OA is Western Ontario and McMaster Universities (WOMAC) quesstionaire. It is also functioned as a tool to evaluate the improvement of therapy in OA patients. There is 24 questions which involve three subscale, such as pain, stiffness, and disability of daily activities. They were all scored in Likert scale which had same function as VAS scale, ranging from zero (none) until four (extreme) [4,5]. WOMAC quesstionaire had been concluded valid and reliable for Asian OA patients in Singapore [6].

The most common drugs used in OA are non-steroid anti inflammation drugs (NSAIDs). They inhibit cyclooxygenase enzyme and then prostaglandin, so it can relieve pain. Long term usage of NSAIDs can cause side effect in gastrointestinal and cardiovascular system, and also they can't repair cartilage tissue [7].

Indonesia is the centre of biodiversity of vegetation in the world, and ranks second worldwide after Brazil. Altough there are 9600 plants which can be used for medication, but only 300 that were manufactured as traditional drugs. Sidaguri (*Sida rhombifolia* L) is one of the plants which is usually used as anti inflamation and anti hiperurisemia agents [8]. Latest research by Mah said that Sidaguri extract had relatively high activity as anti inflammation and anti oxidant. It said that Sidaguri can inhibit inflammatory marker such as NO [9]. The active compenent of β-sitosterol within Sidaguri also has anti inflammation activity [10].

2.METHODS

2.1 Patients Selection

A double blind randomized clinical trial was conducted on fifty consecutive knee or hip joint OA patients whom admitted to Rheumatology division at Adam Malik General Hospital Medan, Indonesia, from September until November 2017. Patients age should be at least 40 or more with visual analogue scale (VAS) minimum 4. Meanwhile, for the exclusion criteria included consuming anticoagulant user, history of meloxicam allergic reaction and gastrointestinal bleeding less than 6 months, hiperurisemia, liver and kidney failure. All patients were taken record for BMI, blood pressure, WOMAC score, and laboratory examination. Then, they were randomized into two group, experimental group whom treated with meloxicam and Sidaguri extract (MS), and control group with meloxicam and placebo (MP). Both group followed for one month, and after that we assess side effect by clinical and laboratory (liver and renal function) and WOMAC score after therapy.

2.2 Diagnosis of knee or hip joint OA

The diagnosis of knee or hip joint OA were based on American College of Rheumatology (ACR) criteria. Knee OA was diagnosed based on clinical (such as knee pain for most days of prior month and at least one of these which are joint stiffness less than 30 minute, age more than 40 years old, and crepitus on active joint movement) and radiologic with osteophytes at joint margins. Meanwhile, for hip joint OA was diagnosed also based on clinical (hip pain for most days of the prior month) and at least two of these which are ESR ≤ 20 mm/hr, the femoral and/or acetabluar osteophytes, and hip joint space narrowing in radiologic founding.

2.3 Laboratory Examination

In order to fulfill inclusion and exclusion criteria, we did laboratory examination such as routine hematological analysis, uric acid, liver and renal function. After one month therapy, liver and renal function rechecked again to see side effect.

2.4 WOMAC Score

All patients were assessed WOMAC score by filling WOMAC quesstionaire before and after therapy. It consisted of five question for pain, two questions for stiffness, and seventeen questions for disability. Every respondent filled their own form and must be ready within five until ten minutes. Total score divided with 96 and then turned into percentage. The effectivity of therapy were proven if there was descent in total WOMAC score after one month therapy.

2.5 Statistical analysis

Data were analized using SPSS 22nd version (SPSS Inc, Chicago) with

a 95% confidence interval. It was significant if p < 0,05.

3.RESULT

The majority of gender in both group were female, which there was 16 (43,2%) in MP group and 21 (56,8%) in MS group. All the variables were homogenoues in both group.

Table 1. Baseline Characteristics in OA Patients

Variable	MS Group (n = 25)	MP Group (n = 25)	*p-value*
Sex,n(%)			
Male	4 (30,8%)	9 (69,2%)	0,107
Female	21 (56,8%)	16 (43,2%)	
Age, Mean	59,64 (11,39)	58,92 (10,43)	0,817
Occupation, n(%)			
Teacher	0 (0%)	2 (100,0%)	0,176
Housewife	21 (58,3%)	15 (41,7%)	
Farmer	1 (20,0%)	4 (80,0%)	
Entrepreneur	3 (42,9%)	4 (57,1%)	
Race, n(%)			
Batak	13 (59,1%)	9 (40,9%)	0,042
Jawa	11 (61,1%)	7 (38,9%)	
Karo	1 (14,3%)	6 (85,7%)	
Melayu	0 (0%)	3 (100,0%)	
BMI,	24,9 (18,30-33,30)	24,2 (20-28)	0,67 0,510
VAS	5 (4-6)	4 (4-5)	
Target Joint, n(%)			
Genu	22 (50.0%)	22 (50,0%)	1,000
Hip	3 (50.0%)	3 (50,0%)	

Although there were slight escalation in laboratory result of all variables after one month therapy, but the number were insignificant to cause abnormality. Statistically there were no significance of all variables in both group.

Table 2. Liver and Renal Function Before (Pre) and After (Post) Therapy

Variable	MS Group (n = 25)	MP Group (n = 25)	*p-value*
AST-Pre	16 (12-44)	19 (10-30)	0,983
AST-Post	20 (13-48)	21 (10-36)	0,602
SGPT-Pre	16 (11-63)	19 (11-46)	0,889
ALT-Post	25 (13-69)	23 (15-48)	0,305
Ureum-Pre	17 (11-51)	24 (19-92)	0,063
Ureum-Post	23 (11-55)	28 (19-94)	0,124
Creatinine -Pre	0,73 (0,55-1,09)	0,78 (0,6-1,3)	0,128
Creatinine-Post	0,81 (0,57-1,20)	0,88 (0,6-1,4)	0,208

Based on the assessment of WOMAC score before therapy, it shown that there were no significant differences between every WOMAC subscales (such as pain, stiffness, and activity) and total WOMAC score itself in both group.

Table 3. WOMAC Score Assessment Before (pre) Therapy

Variable	MS Group	MP Group	*p-value*
Pain-Pre	8 (4-20)	10 (5-19)	0,166
Stiffness-Pre	3 (1-6)	3 (0-7)	1,000
Activity-Pre	21 (14-52)	23 (15-53)	0,833
Total WOMAC-Pre*	36.45 (22,9-73,95)	37.5 (22-79,16)	0,583

After one month therapy, it could be seen that there were improvement between before and after therapy in both group. From the table 4, MS group had better result of improvement compared to MP group. There were significant differences in all WOMAC subscales and the total WOMAC score between MS group and MP group (p<0,05)

Table 4. WOMAC Score Assessment After (Post) Therapy

Variable	MS Group	MP Group	*p-value*
Pain-Post	2 (1-8)	8 (3-18)	0,0001
Stiffness-Post	1 (0-3)	3 (0-7)	0,0001
Activity-Post	4 (1-13)	22 (15-50)	0,0001
Total WOMAC-Post*	7,29 (3,12-17,70)	34,37 (19,79-69,79)	0,0001

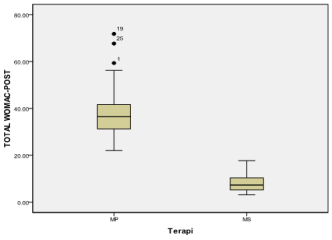

Figure 1. Box Plot of Total WOMAC Score Between Meloxicam-Placebo (MP) and Meloxicam-Sidaguri (MS)

4.DISCUSSION

Sidaguri is one of the traditional medicinal plants in Indonesia. It has been proven that Sidaguri has anti inflammatory effect. Khalil conclude that hydroalcohol extract of Sidaguri leaves with dose 400 mg/kg BW can inhibit oedem in mice that had been induced with 1% carrageenan [11]. Another research by Gupta said that there is active compound of β-sitosterol that mimic hydrocortisone and oxyphenylbutazone in Sidaguri plant that had anti-inflamation effect [10]. Tanumihardja also said that Sidaguri has anti-inflamatory potency on rat periapical lesion, by reducing the level of C-reactive protein (CRP) which is usually known as anti inflammatory marker [12]. Mah in 2017 conclude that Sidaguri extracted with n-hexane had high anti inflammatory activity, which it could inhibit nitric oxide (NO) [9].

Sidaguri as therapy for OA has been conducted by Marpaung. The combination meloxicam and Sidaguri can reduce CRP and erycthrocyte sedimentation rate (ESR) after given for one month [13]. It also can be used in gout arthritis patients to reduce uric acid and CRP [14].

On this research combination of Sidaguri dan meloxicam has shown superior improvement compared with meloxicam and placebo. The mean total score of WOMAC after one month therapy in group MS is 7,29%(3,12%-17,7%) compared with group MP which is 36,45%(22%-71,8%). It is statistically significant not only in all subscales, such as pain, stiffness, and disability, but also total score WOMAC itself (p<0,05).

WOMAC quesstionaire as the assessment of therapy improvement in OA patients has been made previously by Yocum. His research conclude that group of OA patients treated with meloxicam 15 mg/day has significant improvement in term of pain and stiffness scale, compared with plasebo group [15].

The effectivity therapy assessment of Sidaguri in OA patients has never been done before, whether using VAS score or even WOMAC score. So this research is the first that did it.

Limitation in this study are the small amount of the sample studies and the time given therapy which were only one month. Further research are needed by using larger sample size and longer timer therapy.

4.CONCLUSION

There is significant improvement in WOMAC score in patients with osteoarthritis after consuming Sidaguri (Sida rhombifolia L) extract.

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