

ABSTRACT

Background: Osteoarthritis (OA) is the most common form of arthritis or joint inflammation. The high prevalence of OA in worldwide becomes one of the reasons of conducting this study. Besides, there are a lot of studies reveal the bad long-term side effects of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). Many alternative therapies include mineral water therapy, balneotherapy, spa water therapy has been conducted. However, researcher would like to use a novel self-therapy using iodized salt. The reason of using the iodized salt as the material for making hypertonic solution is because of its availability in Indonesia so that later the result can be widely implemented.

Objective: To determine the effect of iodized salt water therapy towards the clinical improvement that is measured by the total WOMAC score in patients with knee OA.

Method: This is a single-blind randomized controlled clinical trial study, 22 research subjects were involved. They were allowed to take a standardized medications for OA such as NSAIDs. The respondents were randomly divided into 2 groups: control group and experimental group. The respondents in control group (n = 11) were treated using plain hot water (placebo) at 40° C for 20 minutes for a period of 10 days. Whereas in experimental group (n = 11), the same protocol was used but plain hot water was replaced by 10% of iodized salt water. The data evaluation was taken three times: pre-intervention (day 0), post-intervention (day 10), and 14 days post-intervention (day 24). These data includes patients' characteristics data (age, gender, body mass index (BMI), duration of symptoms, and location of knee OA) and parameter data (Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score including pain, stiffness, and physical function subscales score and total score). For the parameter data, researcher use the minimum clinically important difference (MCID) of 6% from the maximal score.

Result: From the patients' characteristics data analysis, it is found that there was no statistically important difference between each group for all variables showing that the subjects were normally distributed. From the parameter data analysis, it is

found that there was a trend of improvement in experimental group compared to control group. In experimental group, there were significant clinical difference at Delta 1 (by subtracting the post-intervention to the pre-intervention result) for physical and total score (MCID = 5,36 and 6,36, respectively) and at Delta 2 (by subtracting the 14 days post-intervention to the pre-intervention result) for pain, stiffness, physical function, total score (MCID = 1,54, 0,72, 9,81, and 12,09, respectively).

Conclusion: There were significant clinical improvement at certain period in experimental group compared to those in control group. However, there is no statistical significant differences between the groups for all the WOMAC subscales.

Keywords: Osteoarthritis, iodized salt water therapy, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, minimum clinically important difference (MCID).

ABSTRAK

Latar Belakang: Osteoarthritis (OA) adalah tipe peradangan sendi yang paling sering terjadi. Tingginya prevalensi OA di seluruh dunia menjadi salah satu alasan studi ini dilakukan. Disamping itu, terdapat banyak penelitian yang menunjukkan banyaknya efek jangka panjang dari Obat Anti Inflamasi Non-Steroid (AINS). Selama ini, banyak pula dilakukan terapi alternative untuk mengobati OA seperti terapi air mineral, *balneotherapy*, terapi spa, dan lain-lain. Namun, dalam studi ini peneliti menggunakan garam beryodium sebagai bahan dasar. Banyaknya jumlah ketersediaan garam beryodium menjadi alasan peneliti menggunakan ini sebagai bahan dasar penelitian. Disamping itu, peneliti mempunyai harapan supaya penelitian ini dapat diimplementasikan secara luas di Indonesia.

Objektif: Menentukan efek dari terapi air garam beryodium terhadap perbaikan klinis pasien yang diukur menggunakan parameter skor WOMAC pada pasien dengan OA lutut.

Metode: Penelitian ini adalah studi klinis terandomisasi dengan metode *single-blind*. Terdapat 22 subjek pada penelitian ini yang terbagi dalam dua kelompok: grup kontrol dan grup eksperimental. Responden pada grup kontrol ($n = 11$) diberi terapi air hangat (placebo) pada suhu 40°C selama 20 menit. Sedangkan pada eksperimental grup ($n = 11$), protokol yang sama diberikan kecuali adanya penambahan 10% garam beryodium. Evaluasi data dilakukan sebanyak tiga kali: *pre-intervention* (hari ke-0), *post-intervention* (hari ke-10), *14 days post-intervention* (hari ke-24). Data yang dievaluasi termasuk karakteristik pasien (usia, jenis kelamin, indeks massa tubuh, durasi gejala, dan lokasi lutut yang terkena OA) dan data parameter (Skor WOMAC: *pain*, *stiffness*, and *physical function*). Untuk data parameter, peneliti menggunakan perbedaan klinis yang dianggap berarti (MCID) sebanyak 6% dari skor maksimal.

Hasil: Dari analisis data karakteristik pasien, tidak terdapat perbedaan statistik yang bermakna untuk semua variabel baik pada grup kontrol maupun grup eksperimental yang menunjukkan bahwa randomisasi berjalan baik dan pasien terdistribusi normal. Dari analisis data parameter, terdapat trend perbaikan pada

grup eksperimental dibandingkan dengan grup kontrol. Pada grup eksperimental, terdapat perbedaan klinis yang signifikan pada Delta 1 (dengan cara mengurangi hasil *post-intervention* dengan *pre-intervention*) untuk *physical function* dan *total score* (MCID = 5,36 dan 6,36) dan pada Delta 2 (dengan cara mengurangi hasil 14 days *post-intervention* dengan *pre-intervention*) untuk *pain*, *stiffness*, *physical function*, dan *total score* (MCID = 1,54, 0,72, 9,81, and 12,09).

Kesimpulan: Terdapat perbaikan klinis yang signifikan pada periode tertentu pada grup eksperimental dibandingkan dengan grup kontrol yang relatif konstan. Namun, tidak terdapat perbedaan statistik yang bermakna pada semua subskala WOMAC.

Kata kunci: Osteoarthritis, terapi air garam beryodium, Skor Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), perbedaan klinis yang dianggap bermakna (MCID).