ESJ Natural/Life/Medical Sciences Peer-reviewed

Study of the Efficacy of *Moringa Oleifera* Roots Applied as a Poultice in the Symptomatic Treatment of Gonarthrosis

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Doi:10.19044/esj.2026.v22n9p35

Submitted: 20 October 2025
Accepted: 21 March 2026
Published: 31 March 2026

Cite As:
Dossou-Yovo, V.R., Dossou-Yovo, H., Osseni, A.R., Zomalheto, Z.C. & Laleye, A. (2026). *Study of the Efficacy of Moringa Oleifera Roots Applied as a Poultice in the Symptomatic Treatment of Gonarthrosis.* European Scientific Journal, ESJ, 22 (9), 35. https://doi.org/10.19044/esj.2026.v22n9p35

Abstract

Introduction: The roots of *Moringa oleifera* are widely used for arthralgia. The aim of this study is to evaluate the effectiveness of a poultice made from *Moringa oleifera* root powder in the symptomatic treatment of gonarthrosis. **Material and methods**: It was a randomized, double-blind study, controlled against a placebo and against standard drug treatment in an open setting, conducted in the rheumatology department of CNHU-HKM in Cotonou. The patients included in the study had an arthritic flare at the beginning of the study. Two parallel groups were established, one group received a knee poultice containing Moringa oleifera, while the other group

ISSN: 1857-7881 (Print)
e-ISSN 1857-7431 (Online)

received a placebo poultice. The primary outcome measure was based on the calculation of the effect size for pain intensity and the secondary endpoint was the mean duration of pain recurrence. Data was processed using Epi Info software version 7.2.1.0. The Hedges statistic was used to assess the effect size between the two groups. **Results**: Sixty-five patients were randomized (Moringa=35, Placebo=30). The studied population was characterized by a female predominance of 90,47%, with an average age of 57.94 years. The results of the effect size calculation for pain intensity showed a standardized difference greater than 0.8 in the Moringa and Placebo groups over a duration of 2 weeks ($p < 0.0001$). The mean duration of pain recurrence in the Placebo group was 4.62 days after treatment discontinuation, with a range of 1 to 15 days. It was 59.11 days after treatment discontinuation in the Moringa group, with a range of 1 to 222 days. Only 5.88% of patients in the Moringa group reported adverse effects such as mild itching after removing the poultice. **Conclusion:** This study showed that *Moringa oleifera* roots could constitute a potential therapeutic alternative in flare-ups of gonarthrosis.

Keywords: Gonarthrosis, Poultice, *Moringa oleifera*, efficacy

Introduction

Knee osteoarthritis is a chronic pathology that mainly affects women, with a sharp increase in the post-menopausal period (Guillemin F et al, 2011). It is a source of disability due to the pain and functional impotence it causes. In Black Africa, the hospital frequency is 13.19% in Côte d'Ivoire and 8.55% in Benin (Zomalheto Z et al, 2014). Drug treatment for gonarthrosis is essentially symptomatic and long-lasting, and consists of analgesics, anti-inflammatory and possibly corticosteroid infiltrations (Zhang W et al, 2005). In addition to these conventional therapies, traditional medicine also offers a number of plant-based treatments. In Benin, among the many medicinal plants used, *Moringa oleifera* stands out for its therapeutic effects in the symptomatic treatment of gonalgia (Agoyi E et al, 2014). However, its effectiveness in gonarthrosis has not yet been formally proven. Thus, this work brings the results of a clinical study that evaluated the efficacy of *Moringa oleifera* root powder applied as a poultice to the knee in the symptomatic treatment of gonarthrosis.

Patients and Methods

Study framework

The preparation of *Moringa oleifera* root powder, Placebo, their packaging and labeling, and storage were carried out at the Institute of Applied Biomedical Sciences of the Faculty of Health Sciences of Cotonou in 2019. The clinical trial took place in the University Clinic of Rheumatology of the

ISSN: 1857-7881 (Print)
e-ISSN 1857-7431 (Online)

Hubert Koutoukou Maga University Hospital Center (CNHU-HKM) of Cotonou in 2019.

Study type

This was a randomized, double-blind, Placebo-controlled study to assess the efficacy of *Moringa oleifera* root powder used as a poultice in the symptomatic treatment of gonarthrosis. At the baseline visit, eligible patients who agreed to randomization were randomized to receive either Placebo or *Moringa oleifera* root powder:

- **Group 1**: received a knee poultice of 30g of *Moringa oleifera* root powder once a day combined with Paracetamol 1g in the morning and evening for three consecutive days. The poultices were kept on at least 12 hours.
- **Group 2**: received a knee poultice of 30g of Placebo powder once a day combined with paracetamol 1g in the morning and evening for three consecutive days. The poultices were kept on at least 12 hours.

The choice of dosage and duration of treatment

According to studies by Agoyi E et al. (2014), *Moringa oleifera* roots are used in traditional medicine in southern Benin to manage joint pain. Fresh *Moringa oleifera* roots were applied as a poultice to the knee once or twice a day (depending on the intensity of the pain) until the pain decreased significantly or disappeared completely. On average, after three days of treatment, the pain decreased considerably over a period of at least three months. Like any treatment, the poultice made from fresh *Moringa oleifera* roots has side effects such as burns and skin ulcerations due to the aggressive gas they contain. To mitigate these adverse effects, we dried the fresh roots, thus eliminating the gas responsible for these side effects. After drying, the quantity of fresh roots applied to the knee according to traditional use, the mass of dried roots obtained was approximately 30g. To increase the contact surface area and improve the diffusion of the active ingredient, we pounded the dried roots into a powder. As a precaution, we decided to apply the powder as a poultice once a day for at least 12 hours, for three (3) consecutive days, representing the minimum duration for which pain significantly decreased during observation. Therefore, the dosage defined for this study was: 30g of *Moringa oleifera* powder applied as a poultice to the knee daily for an adult subject of any weight for three consecutive days.

Randomization and maintenance of blinding

Randomization was performed by the research associate in the rheumatology department. It consisted of preparing doses of *Moringa oleifera* or Placebo, packaged in identical plastic boxes chosen specifically for this

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purpose. The *Moringa oleifera* root powder and the Placebo were the same color, packaged, and labeled. The boxes were numbered in triplets. Each set of three boxes with the same number represented a three-day treatment for one patient, with one dose per day. Only the research associate was able to identify the contents of the boxes. For each patient included in the study, a number was assigned by the research associate after successive draws without replacement from an urn containing numbered boxes (Moringa or Placebo). The patient's name and assigned patient number were recorded on the unblinding form, to which access was restricted to the research associate. The patient was then taken to the rheumatology ward. This room contained the necessary equipment for applying the poultice. The research associate gave the treatment corresponding to the patient's number to the nurse after removing it. Therefore, neither the patient nor the nurse can identify the treatment received. The poultice was applied by the same nurse once a day for three (3) consecutive days.

Patient selection and follow-up were conducted by the principal investigator without identifying the patient's group. At the end of the patient follow-up period, the research associate unblinded the patients, allowing the researcher to assign them to their assigned group.

Addition of paracetamol

The addition of an analgesic to both groups was made for ethical reasons, specifically the Declaration of Helsinki, in its three successive versions from 1975 to 1989, which states that «A physician should not be able to leave a patient without treatment when one exists. Researchers should not use pure Placebo groups (without treatment) if a treatment exists, even an imperfect one (the best available) » (Beauchamp TL et al, 2019). Thus, paracetamol was added to the poultice at a dosage of 1g morning and evening.

Study population

The study population consisted of subjects followed in the rheumatology department of the CNHU-HKM and meeting the following criteria:

Inclusion criteria

- ✓ Have a diagnosis of retained gonarthrosis based on ACR criteria;
- ✓ Be in osteoarthritis flare at the start of the study;
- ✓ To be naïve to any analgesic or anti-inflammatory drug treatment at least one week before the start of the study;
- ✓ Have given written consent to the study.

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Non-inclusion criteria

- ✓ Patients with a chronic pathology and long-term treatment containing anti-inflammatory and/or analgesic drugs;
- ✓ Patients with motor deficits and/or impaired upper functions; patients with a history of gastric pathology;
- ✓ Patients having received infiltration or visco-supplementation less than six months prior to the study entry date;
- ✓ Patients with concomitant pain or a history of knee surgery that could disrupt or interfere with efficacy assessment;
- ✓ Pregnant and breastfeeding women were not included in the study.

Exclusion criteria

Patients who did not receive all three doses of Placebo or Moringa on three consecutive days, patients who were noncompliant with drug treatment over the 15 days of treatment, and patients who were lost to follow-up were also excluded from the study.

Size and type of sampling

The sample size was estimated using the Schwartz formula based on the hospital frequency of knee osteoarthritis, which was 8.55% in 2014 (Zomalheto Z et al, 2014).

$$N=(Z^2\times P\times(1-P))/M^2= 120$$

Z: statistic corresponding to level of confidence (1.96 for 95% confidence)
P: 08,55%
M : precision corresponding to effect size (5%)

All patients meeting the inclusion criteria were systematically included in the study until the sample was exhaustive.

Data collection, frequency, and duration of monitoring

Patients were recruited during rheumatology consultations by the principal investigator over the course of one year. Patients meeting the inclusion and exclusion criteria were thoroughly informed about the study and its objectives to obtain their informed consent. Patients who provided written consent were included in the study. Each patient included in the study completed a questionnaire that recorded their identity, clinical examination, diagnosis, the date of initiation of topical treatment, the date of discontinuation of topical treatment, and the initial values of knee pain intensity and the Lequesne index.

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After the 3 days of treatment, the patients underwent a clinical examination (knee examination) at the hospital or at home for those who were unable to move, at about Days (D)3, D7, D15, D30, D45, D60, D90. This examination enabled pain to be assessed using the visual analog scale (VAS) and Lequesne index at D0, D3, D7, D15, D30, D45, D60 and D90. When pain reappeared in a patient with intensity greater than or equal to the initial at VAS, the patient was withdrawn from the study and referred to his rheumatologist for medical care in accordance with ethical rules.

Criteria for assessing the efficacy of *Moringa oleifera*

Primary efficacy endpoint for Moringa oleifera root powder

The primary endpoint was therefore the evaluation of effect size (g*) for VAS at D3, D15, D30, D60, D90. Application of the *Moringa oleifera* poultice was considered very effective if g* ≥0.8; moderately effective if g* ϵ [0.5; 0.8[and not very effective if g* ϵ [0.2; 0.5[.

Secondary efficacy criteria for Moringa oleifera

Lequesne index

The first secondary endpoint was the evaluation of effect size for Lequesne index (LI) at D3, D15, D30, D60, D90. Application of the *Moringa oleifera* poultice was considered very effective if g* ≥0.8; moderately effective if g* ϵ [0.5; 0.8[and not very effective if g* ϵ [0.2; 0.5[.

Duration of recurrence of gonalgia after discontinuation of treatment

The last second secondary endpoint was the mean duration of pain recurrence. The efficacy of the Moringa arm was demonstrated if the mean duration of pain recurrence after treatment discontinuation was greater than that of the Placebo arm.

Data processing and statistical analysis.

Data were processed using Epi info software version 7.2.1.0. We calculated an effect size at D3, D15, D30, D60, D90 using the Hedges statistic corrected for small samples as follows:

$$\text{Hedges'g} = \frac{\frac{m1-m2}{sd*pooled}}{\frac{m1-m2}{sd*pooled}}$$

$$Sd^{*}_{pooled} = \sqrt{\frac{(n_1-1)SD_1^2+(n_2-1)SD_2^2}{(n_1+n_2)-2}}\sqrt{\frac{(n_1-1)SD_1^2+(n_2-1)SD_2^2}{(n_1+n_2)-2}}$$

$$\text{Hedges'g}^{*}\text{ corrected} = g\left(1-\frac{3}{4(n_1+n_2)-9}\right)\left(1-\frac{3}{4(n_1+n_2)-9}\right)$$

m1 and m2: Average at a given time, SD: standard deviation of a group, SD*pooled: weighted and pooled standard deviation, n1 and n2 group sizes.

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Throughout the study, “positive g” favors Moringa and “negative g” favors Placebo or drug treatment. The Hedges’ g values were 0.2 as small, 0.5 as medium, and 0.8 as large. Student's superiority of means test was also used to assess the difference between the different groups. This difference is statistically significant if $p < 0.05$.

Ethical considerations

Ethical Committee

The present study was submitted for approval to the Ethics Committee of the Cotonou Faculty of Health Sciences, which gave its favorable opinion No. 002-20/UAC/FSS/CER-SS.

Information and consent

All patients were informed that participation in the study was completely voluntary and that they could withdraw at any time. They signed the consent form after being read and
explained to them.

Results

Seventy (70) patients were examined, of whom sixty-five (65) were included in the study. The 65 randomized patients were divided into two groups: the Moringa group, containing 35 patients; and the Placebo group, containing 30 patients. 01 patient in each group was excluded. Thus, 34 patients completed the study in the Moringa group and 29 in the Placebo group, as shown in Figure 1.

The study population was characterized by a female predominance of 90,47%, with a mean age of 57.94 years, ranging from 34 to 85 years. Grade I obesity was found in most patients. Clinically, the average intensity of knee pain at the beginning of the study was 6.91, with extremes ranging from 3 to 10. The average functional impact of gonarthrosis on daily life at the start of the study was 14.33, with extremes from 8 to 23. The majority of patients were presented with tricompartmental, bilateral gonarthrosis of Grade III (Table 1).

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Figure 1: Distribution of patients according to their group

Table 1: Sociodemographic, clinical and paraclinical characteristics of patients

Characteristics		**Moringa**	**Placebo**
Sex	Male	02 (5,88%)	4 (13,86%)
	Female	32 (94,12%)	25 (86,21%)
Age (years)		**58,02±1,02**	**58,10±1,01**
Body mass index		34,21±2,3	32,08±1,8
Pain intensity in VAS	< 5	01 (2,94%)	03 (10,44%)
	≥ 5	33 (97,05%)	26 (89,65%)
	Average	**6,91 ± 0,34**	**6,91 ± 0,60**
Lequesne index	< 10	01 (2,94%)	01 (3,44%)
	≥ 10	33 (97,05%)	28 (96,56%)
	Average	**14,57± 1,28**	**14,10± 1,23**
Seat of gonarthrosis	Tricompartmental gonarthrosis	24 (70,58%)	26 (89,65%)
	Femorotibial gonarthrosis	10 (29,41%)	03 (10,34%)
Grade of gonarthrosis	II	07 (20,59%)	04 (13,79%)
	III	23 (67,65%)	18 (62,07%)
	IV	04 (11,76%)	07 (24,14%)

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The standardized effect size calculation for pain intensity for the Moringa and Placebo groups was 1.07 (95% CI [1.02; 2.10]) and 3.10 (95% CI [2.92; 3.11]) at D15 with p< 0,0001. As a follow-up, Placebo patients were stopped at D15, the effect size for pain intensity could not be calculated beyond D15. These different values suggest that Moringa-based treatment proved more effective than Placebo over a period of more than 03 months, as shown in Figure 2.

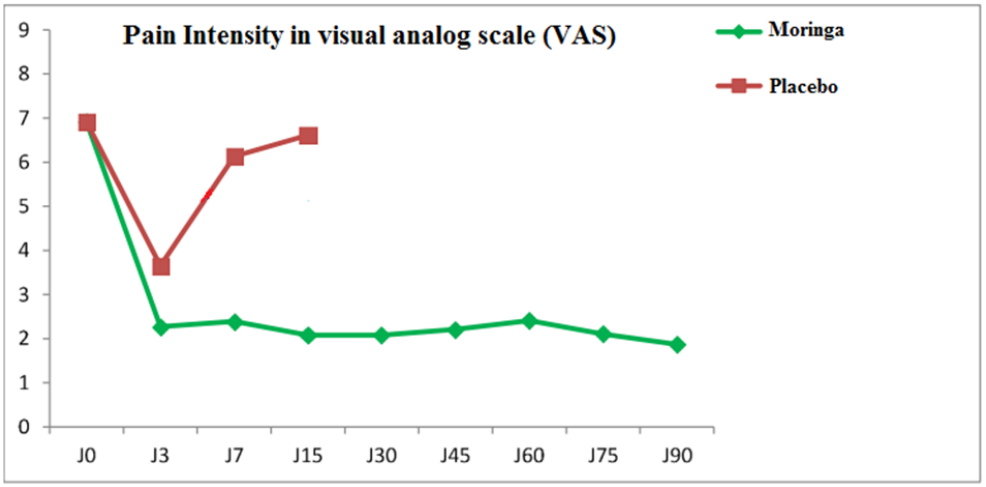

Figure 2: Evolution of patients' pain intensity in the Moringa and Placebo groups

The standardized effect size calculations for LI at D3 and D15 were 1.75 (95% CI [1.26; 1.96]) and 2.98 (95% CI [2.28; 4.30]), respectively, in the Moringa and Placebo groups, with p<0.0001. As follow-up of Placebo patients were stopped at d15, the effect size for LI could not be calculated beyond D15. In terms of improvement in the functional index assessed by the LI, Moringa-based treatment proved more effective than Placebo over a period of more than 03 months, as illustrated in Figure 3.

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e-ISSN 1857-7431 (Online)

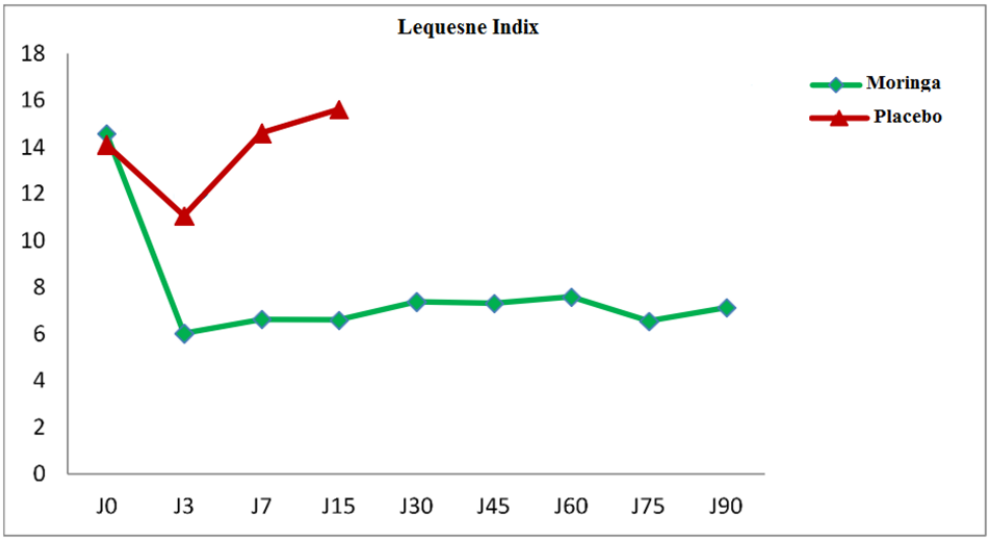

Figure 3: Evolution of functional impotence and patient autonomy in daily living activities over time in the Moringa and Placebo groups

All patients in the Placebo group experienced a recurrence of knee pain with an intensity equal to or greater than the baseline value 15 days after treatment discontinuation. In contrast, at D90 of follow-up, knee pain had not recurred in 9 patients (26.47%) in the Moringa group (Figure 4). The mean duration of pain recurrence in the Placebo group was 4.62 days after treatment discontinuation, with a range of 1 to 15 days. It was 59.11 days after treatment discontinuation in the Moringa group, with a range of 1 to 222 days.

ISSN: 1857-7881 (Print)
e-ISSN 1857-7431 (Online)

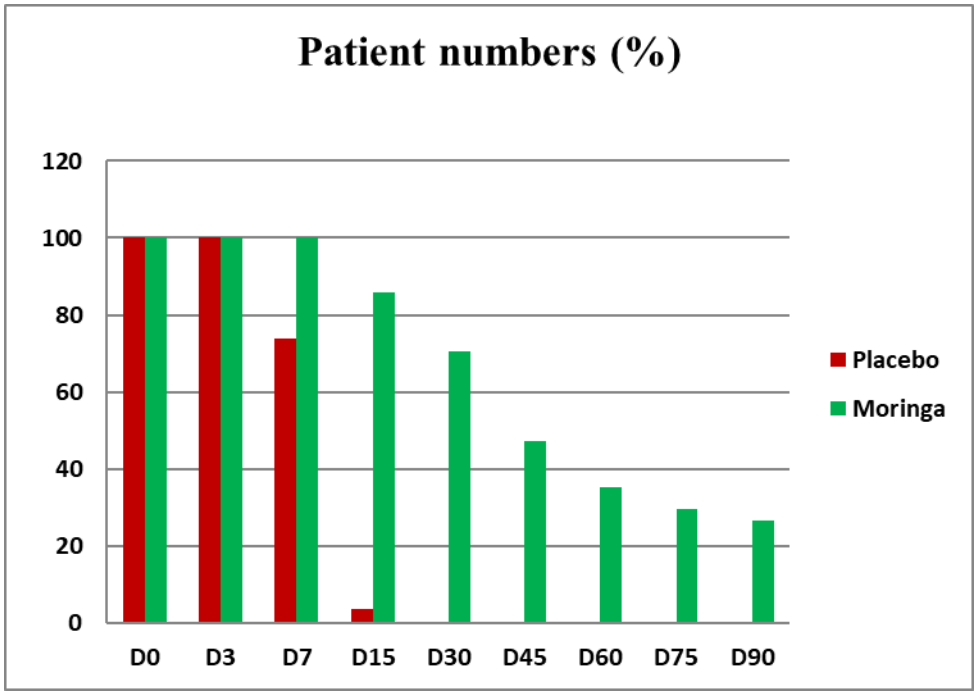

Figure 4: Evolution of the number of patients in the different groups after stopping treatment

No patients in the Placebo group experienced adverse effects, while two patients in the Moringa group (5.88%) reported mild itching after removing the poultice.

Discussion

The clinical characteristics of the studied patients were typically those of a population with knee osteoarthritis (Zhang W et al, 2005). The severity of arthritic pain and functional disability was significant at the beginning of the study.

The results of the effect size calculation for pain intensity and LI showed a standardized difference greater than 0.8 in the Moringa and Placebo groups over a duration of 2 weeks ($p < 0.0001$). Thus, patients treated with the *Moringa oleifera* poultice experienced significantly greater clinical improvements compared to patients treated with the Placebo. This clinical improvement became significant as early as the third day and continued throughout the follow-up period. The efficacy of the Moringa-based poultice compared to the Placebo can be easily explained by its chemical composition, which has revealed the presence of several molecular families, most of which have anti-inflammatory and analgesic properties (Kasolo JN et al, 2011). First, according to Tabart J. (20011), flavonoids possess anti-inflammatory activity

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by inhibiting the expression of pro-inflammatory genes, pro-inflammatory molecules (cytokines), PLA2, COX, LOX, INOS, and myeloperoxidases (Tabart J, 2011; Martini MC, 2003). Therefore, flavonoids exert an inhibitory action on the entire catabolic reaction of osteoarthritis by decreasing not only the synthesis but also the biological effect of chondrolytic chemical substances. Then, Mota R et al (2001) showed that tannins exert acute and chronic anti-inflammatory activity by reducing the vascular permeability of the postcapillary venules in the synovial membrane, thus preventing the migration of neutrophils and macrophages. The poultice made from *Moringa oleifera* roots would therefore have an inhibitory effect on all phases of the inflammatory reaction, unlike NSAIDs, which are only COX inhibitors (Betina-Bencharif S, 2014). Finally, the superiority of the efficacity of the Moringa-based poultice over Placebo could also be explained by a synergy of the simultaneous effects of several molecules with anti-inflammatory properties, such as flavonoids (Tabart J, 2011; Martini MC, 2003), coumarins **(**Fleurentin J et al, 1990) tannins **(**Mota R et al, 1985) saponins (Betina-Bencharif S, 2014) and analgesics like alkaloids (Badiaga M, 2011). This anti-inflammatory property of *Moringa oleifera* root extracts was demonstrated orally in the works of Caceres A et al. (1992) and Tall A. (2000).

Other plants can be used to relieve joint pain. Some have been the subject of clinical studies, and their effectiveness is recognized by various organizations such as the WHO, EMA, and ESCOP (Bourgeois L, 2016). Indeed, the work of Schmid et al. demonstrated the effectiveness of the bark of Salix alba (white willow) in the symptomatic treatment of gonarthrosis compared to a placebo. A significant clinical improvement was observed from 240 mg of willow bark extract (salicin) taken once daily orally after 15 days of treatment (Schmid B et al, 2001). The efficacy of willow branch bark is due to the anti-inflammatory properties related to the salicylic derivatives it contains. Willow bark extract is a COX inhibitor (Bourgeois L, 2016). However, willow branch bark is less effective than NSAIDs, which justifies its use only as a traditional remedy validated by the EMA for this indication. Similarly, several researchers have studied the therapeutic effects of the root of Harpagophytum procumbens on arthritic pain. It has been found to reduce mild to moderate pain and functional disability after 12 weeks of treatment with a dosage of 2400 mg of Harpagophytum root extract per day taken orally, according to the work of Wegener et al. in 2003 (Bourgeois L, 2016**;** Wegener T et al, 2003). Its effectiveness in treating osteoarthritis depends on its chemical composition, rich in harpagoside, which gives the roots anti-inflammatory properties. The extract of Harpagophytum roots would inhibit the synthesis of eicosanoids (Bourgeois L, 2016). According to Frerick et al., extracts of Harpagophytum could be used as a complementary treatment to NSAIDs (Frerick H et al, 2021). These plants are all effective in the

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symptomatic treatment of gonarthrosis, but the roots of *Moringa oleifera* seem to stand out due to their very short onset time (3 days) and their very long duration of action despite being applied topically for three days.

The average and maximum durations of knee pain recurrence after stopping treatment seem to support the superiority of the efficacy of Moringa-based treatment compared to Placebo. The origin of the long-lasting action of *Moringa oleifera* roots could not be determined in our study, so we put forward the following hypotheses in an attempt to explain it:

- **Reservoir effect:** The long-lasting action of extracts from *Moringa oleifera* roots would be due to the accumulation of the active ingredient in the stratum corneum during the three days of treatment, followed by a gradual release over several months.
- **A long half-life:** The long duration of action of *Moringa oleifera* roots may be due to the long half-life of the active ingredient in the joint cavity.

This study also identified adverse effects of the poultice made from *Moringa oleifera*, primarily skin-related, such as itching, which are less significant compared to the adverse effects of NSAIDs and intra-auricular corticosteroids.

This study has limitations. The constraints, including eligibility criteria and patient availability for 3-month follow-up, made patient recruitment very difficult, not allowing the initially defined sample size from being reached after one year. Our small sample size does not allow us to establish the therapeutic efficacy of *Moringa oleifera* powder, nor its adverse effect profile. However, it did highlight a presumption of efficacy that can support the realization of more rigorous and extensive clinical studies.

Conclusion

This study showed the therapeutic interest of *Moringa oleifera* roots in managing flare-ups of gonarthrosis. A poultice made from *Moringa oleifera* roots could represent a potential therapeutic alternative to medication due to its effectiveness, route of administration, dosage, and fewer side effects. It is also useful to determine in future studies whether the co-administration of Moringa and medication would be an alternative to surgical treatment indicated in the terminal stage of gonarthrosis.

Conflict of Interest: The authors reported no conflict of interest.

Data Availability: All data are included in the content of the paper.

Funding Statement: The authors did not obtain any funding for this research.

ISSN: 1857-7881 (Print)
e-ISSN 1857-7431 (Online)

Declaration for Human Participants: This study has been approved by the Ethics Committee of the Faculty of Health Sciences of Cotonou (N°002-20/UAC/FSS/CER-SS), and the principles of the Helsinki Declaration were followed.

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