



Impact of Monazitic Sand Exposition on Profile of Drug Use of Patients with Osteoarthritis

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Resumo – O objetivo deste estudo foi caracterizar o perfil farmacoterapêutico em pacientes com osteoartrose de joelho da atenção primária à saúde, submetidos a tratamento alternativo randomizado com radiação emitida pelas areias monazíticas das praias do Espírito Santo. No método utilizado, os pacientes incluídos no estudo foram randomizados e submetidos a tratamento alternativo na praia com areia com radioatividade (n=20) e praia sem radioatividade (n=19), 2 vezes por semana e por 30 minutos cada sessão, durante três meses, totalizando 24 exposições. O uso e a frequência de analgésicos, anti-inflamatórios e/ou opioides foram coletados para aplicação de questionários estruturados. Como resultado, os pacientes eram principalmente do sexo feminino e idosos e em uso de medicações contínuas. Os medicamentos prevalentes utilizados foram analgésicos como ibuprofeno, paracetamol e tramadol. O tratamento alternativo com as areias proporcionou melhora clínica autopercebida, principalmente nos pacientes expostos a areias monazíticas que apresentaram redução substancial na frequência de consumo de medicamentos utilizados para o tratamento da dor e na percepção de uso após 24 exposições. Concluímos que a frequência de consumo de medicamentos utilizados para tratamento da dor e a percepção de uso após 24 exposições foram diferentes na autopercepção de saúde, o que evidencia enorme potencial terapêutico da terapia alternativa com as areias monazíticas na saúde e qualidade de vida de pacientes com osteoartrose do joelho.

Palavras-chave: Medicamentos; Osteoartrose do joelho; Tratamento alternativo; Areias monazíticas.

Abstract – The objective of this study was to characterize the pharmacotherapeutic profile in patients with knee osteoarthritis from primary health care, submitted to alternative randomized treatment with radiation emitted by the monazitic sands on beaches of Espírito Santo, Brazil. In the method used, patients included in the study were randomized and submitted to alternative treatment on the beach with radioactive sand (n=20) and beach without radioactivity (n=19), 2 times a week and for 30 min each session for three months, totaling 24 exposures. The use and frequency of analgesics, anti-inflammatory drugs, and/or opioids were collected to apply structured questionnaires. As a result, patients were mainly female and elderly and on continuous medications. The prevalent drugs used were painkillers such as ibuprofen, paracetamol, and tramadol. The alternative treatment with the sands provided self-perceived clinical improvements, especially in patients exposed to monazitic sands who showed a substantial reduction in the frequency of consumption of medicines used for the treatment of pain and the perception of use after 24 exposures. We conclude that the frequency of consumption of medications used for pain treatment and the perception of use after 24 exposures was different in self-perceived health, which evidences enormous therapeutic potential of alternative therapy with the monazitic sands in the health and quality of life of patients with knee osteoarthritis.

Keywords: Medications; Knee osteoarthritis; Alternative treatment; Monazitic sands.

1 Introduction

Osteoarthrosis (OA) is a degenerative process that affects the joints causing loss and damage of the articular cartilage with progressive bone alterations (Goldring, 2011). It is a rheumatologic disease that affects the synovial joints and causes cartilage fissures or microfractures, prevalent among individuals over 60 years of age (Verengue et al., 2021).

The disease results from physiological changes in the joint causing unwanted symptoms such as joint pain and stiffness, being considered a pathology with high prevalence, especially in individuals over 60 years of age, being shared in the face of factors such as aging and obesity (Prince; Roop, 2018).

Knee OA is characterized by the inability to perform activities of daily living, with restriction of movements, especially in elderly individuals (Nasiri; Mohammad, 2018).

In recent years, the increased prevalence of chronic diseases, such as knee osteoarthrosis, has been mainly related to population aging with increased disability, which directly interferes with the reduction of quality of life (Pereira et al., 2012); (Costa et al., 2017).

In this context, parallel to the aging process, there is a growth in the use of medications necessary to control and prevent health problems (Pereira et al., 2012); (Costa et al., 2017). Drugs have been of central importance in current therapy. Throughout longevity, they have assumed a relevant role in health care, contributing in many cases decisively to the control of diseases and their complications, besides increasing the life expectancy and quality of life of the population (Brasil. Ministério da Saúde. Secretaria de Ciência, 2014); (Monteiro; Lacerda, 2016).

Over the years, the use of radiation emitted by monastic sands existing on beaches on the coast of Espírito Santo has been empirically associated with clinical and well-being improvements related to osteoarticular diseases. It can be classified as an alternative health practice (Rabbit Filho et al., 2004). The alternative use of sands for treatment could be included in a current strand of medical geology, which assesses the impact of materials and processes on human health and the ecosystem, whether positive or negative (Bundschuh et al., 2017); (Hasan, 2021).

Studies on the use of medications and their association with alternative, complementary therapy increase knowledge about the effect of geological medicine on the process of drug use, besides contributing to qualify and quantify the benefit and rationalize the resources applied in health, especially in primary care (Pereira et al., 2012); (Costa et al., 2017).

There is a lack of pharmacoepidemiological studies with chronic diseases in the longevity of individuals and related to the use of standard practices and the increasing consumption of medications, often even by self-medication.

In this context, due to the feasibility and lack of studies on the therapeutic evidence of radiation emitted by the monastic sands as an alternative practice in the treatment of knee OA, it is necessary to study this relationship and its effects on the health, pharmacotherapy, and quality of life of the followed patients.

This study aims to trace the profile of medication uses during exposure to the monastic sands of patients with knee OA and primary health care users in municipalities in the metropolitan region of Greater Vitória.

2 Theoretical Framework

Não há neste artigo uma seção de fundamentação teórica separada, uma vez que toda a base teórica foi integrada à introdução e à discussão dos resultados. Os referencia bibliográficos que embasam o estudo estão listados na seção de referências ao final deste artigo.

3 Materials and Methods

The present study is experimental, analytical, quantitative, and longitudinal in patients with primary knee osteoarthritis.

The self-perceived health reported by patients and related to the behavior of using analgesic, anti-inflammatory, and opioid medications during, for the treatment of pain, in the period of random exposures to the alternative medicine for radiation emitted by the monastic sands will be analyzed.

The study was considered eligible for 262 patients, recruited from the primary health units of the municipality of Vila Velha - ES who met the diagnostic criteria proposed by the National Institute for Clinical Excellence (NICE, 2014), presented joint pain related to the performance of activities of daily living and who gave absence of morning joint stiffness more significant than 30 min. Patients who agreed to participate in the study and signed the Informed Consent Form (Informed Consent) were paired and randomized, randomly in two groups in addition to history, as recommended by (National Institute for Health and Clinical Excellence, 2014).

All eligible patients recruited reported having access and regularly attended primary care health services.

The data stratification had the information provided by all those who completed 24 exposures to alternative treatment on the beaches of both groups.

Only patients diagnosed with primary knee osteoarthritis aged 35 to 80 years, who had access to public health services in basic units, presented stability for locomotion and submitted their reports and radiological tests proving the disease to the selection team of this study were included in the study.

Exclusion criteria were considered for the historical study of previous knee surgery, fracture in the knee region, any treatment for the knee with mettrupe, bleeding disorders, any infiltration in the knee in the last six months, morbid obesity, severe psychiatric disorders, skin cancer, history of diagnosis for advanced knee osteoarthritis, reside in the municipality of Guarapari and not complete 24 exposures to alternative treatment performed the on the beaches.

Criteria were considered for removal of patients from the study when submitted to knee surgery during the research, presented to joint infiltration with corticosteroids or any other type and medication of intra-articular use, no-show to more than four exposures consecutive to alternative treatment, and intolerance to heat or another discomfort during exposure to sand.

As for the exposure, the group exposed to radiation was accompanied on the beach of Areia Preta de Guarapari "latitude: 20° 40' 00" S and longitude: 40° 29' 51" W" recognize sophistic sands(Coelho; al., 2005), and the group not exposed to radiation emitted by monastic sands accompanied on the beach of Itaparica in Vila Velha " latitude: 20° 19' 47" S and longitude: 40° 17' 33" W."

Regarding the experimental protocol, the patients had their knees affected by osteoarthritis completely covered with beach sand, analyzed correctly about radioactivity, temperature, and microbiological safety, for 30 min twice a week from May to November 2019.

For evaluation and follow-up of patients, a characterization work was carried out in parallel on the use of drugs for the treatment of pain, through a study of the use of medications with periotic monitoring through the application of questionnaires for data collection related to the profile of use of drug sites, whether analgesic anti-inflammatory drugs and opioids during the period of exposure to an alternative treatment in both groups, either in the presence of radiation emitted by the monastic sands or in the absence of this factor.

To minimize the occurrence of bias, the use of medications related to the treatment of pain caused by knee OA in the last five days before the interview was questioned. Prescriptions, leaflets, labels, or packages of all medications that patients used were asked to ensure greater accuracy of the names of medicines provided, in addition to avoiding omission of information and reducing potential recall bias.

Data on the use of drugs for pain treatment and the number of medications prescribed and used by self-medication were also tabulated and compiled in both groups. These data were arranged in categories according to their pharmacological classification in analgesics, anti-inflammatory drugs, opioids, and associations involving these classes for statistical evaluation of the frequency of use of these drugs and elaboration of the pharmacotherapeutic profile related to pain treatment during exposures to alternative therapy.

In this sense, the frequency of consumption of medications used in pain treatment was estimated by the proportion of interviewees who reported use when completing 8, 16, and 24 exposures and the perception of the use of these drugs in the context of self-perceived health during the study period.

All ethical considerations for researching human beings were met, as recommended by Resolution No. 466/12 of the National Health Council. The Ethics Committee approved the University of Vila Velha (Authorization CEP N0 3,160,891).

Statistical analyses were performed using the IBM SPSS Statistics version 24 program. The significance level used in all studies was 5% ($p \leq 0.050$).

4 Results and Discussion

The patients in both groups who completed 24 exposures to the sands were primarily women (65% to 68.42%), aged 43 to 80 years, 61.5% of patients over 60 years old, mainly using medications for the treatment of other comorbidities and pain control. Only one patient from the non-radioactive sand group and two patients from the monastic sand group reported not using any medication.

The effect of radiation emitted by the monastic sands on pain was evidenced by the significant reduction in medications used for pain relief compared to the beginning of exposures at the end of the follow-up period, both drugs used by prescription and by self-medication (Table 1). At the beginning of the directions, 18 patients in the sand's monazitic group used medications. After 24 exposures, only three continued to use drugs to treat pain, while in the non-radioactive group, there was also a reduction in the consumption of these medications. Still, of 18 patients who made the use at the beginning, after the 24 exposures, only nine continued to use these (Table 1). The data found to allow us to affirm a significant difference ($p=0.032$) between the groups when comparing the consumption of pain medications at the beginning of the study and after 24 exposures to alternative treatment.

Table 1. Description and association of the frequency of use of pain medications between groups.

Higher analgesics were observed during the exposure period, with dipyrone and paracetamol being the prescribed drugs and self-medication of greater use (Figure 1) and more frequently.

Figure 1. Experimental description of the frequency of analgesics by prescription and self-medication during exposures.

Regarding the use of anti-inflammatory drugs, both by prescription and self-medication (Figure 2), it was observed that ibuprofen was the most common drug during the entire exposure period.

Figure 2. Sample description of the frequency of anti-inflammatory drugs (NAIS) by prescription and self-medication during the exposure period.

Regarding the frequency of opioid use, it was more frequent in the non-radioactive sand group and at the end of the exposure period, with a higher use for the drug paracetamol + codeine in this group. In contrast, a more punctual frequency of use was observed during exposures on monazite sand, especially for tramadol (Figure 3). It is emphasized that at the end of 24 exposures, no opioid use was reported in the sand group.

Figure 3. Description of the frequency of use of opioids by prescription during the exposure period.

It is observed that with the evolution of the study, a patient who made 16 and 24 exposures in the monastic sands begins to present a higher perception about the reduction in the frequency of use of drugs used in the treatment of pain, respectively 11.1 and 13.8 times higher, when compared to the beginning of exposures a patient who reported continuous perception of the use of drug sites (Table 2, $p < 0,050$).

Table 2. Association of the patient's perception about the frequency of use of medications for the treatment of pain during exposures in the monastic sand group.

OR - Odds Ratio; *. Simple logistic regression; (1) Reference category; significant if $p < 0,050$.

The results indicate that as exposures to radiation emitted by the monastic sands occur, the possibility of making it necessary to use medications to treat pain is reduced in the group of patients exposed to radiation.

Limitations

Regarding the limitations observed in the present study is the fact that it is based on data reported by the patient regarding the use of medications, which involves the possibility of memory bias of the interviewee. However, to minimize this risk, the strategy used by the researchers was to the adoption of standardized procedures during data collection, such as the request for medical prescriptions, packaging or package leaflet of the continuous prescription drugs reported.

Important limitations also consisted of the difficulty of recruiting a larger number of eligible individuals with availability to participate in the exhibitions, which impacted the sample n of both groups and also on the exposure period. More comprehensive periods and a larger sample n during exposures to alternative treatment should be conducted in other studies for a better evaluation of the therapeutic effect, not only on the profile of drug use as found in this study but also on other factors such as disease and other therapeutic properties.

Other limitations observed are the impossibility of masking the groups formed and the influences of the behavior of individuals on the use of medications. Such facts become practically impossible to minimize in studies involving this theme, given the ease of access to information, including about the "empirical benefits" of the monastic sands in the health disclosed, which may have influenced the use of drugs and especially in the self-perception of health reported by the volunteers.

Discussion

The clinical improvements self-reported by patients exposed to the monastic sands promoted a more significant reduction in the frequency of use of medications in the treatment of pain. Medical geology addresses the impacts on human health (Bundschuh et al., 2017); (Hasan, 2021) being an approach to the harmful effects in most cases. The use of alternative practices for pain reduction has been studied for chronic diseases (Lamba et al., 2019); (Eaton et al., 2017).

Exposure time was a determining factor for observing the therapeutic potential of alternative treatment with radiation emitted by the monastic sands in the health and quality of life of patients with primary knee osteoarthritis. In this context, it is essential to highlight that exposure to both sands was beneficial for patients, higher in patients exposed to radioactive sands.

The greater use of paracetamol as an analgesic between groups and in all follow-up, periods can be justified by its effect on pain treatment, availability in basic health units, and easy access (Queiroz et al., 2020). The use of analgesics during exposures, by prescription and self-medication between groups, consists of the frequency of consumption, being more frequent at the beginning of the study in both groups about the end of exposures. A high frequency of analgesic drug use found in the adult

population was reported by (Filler et al., 2020). This study is in line with data on the frequency of use and clinical importance of this class of medications in the patients' profile.

The pharmacological use of anti-inflammatory drugs was observed in both groups, with ibuprofen being the most used during the entire exposure period. THE ATEs are among the most prescribed medications worldwide, is mainly used to treat inflammation, pain, and edema, and in osteoarthritis and musculoskeletal disorders (Batlouni, 2010).

Tabela 1 – Description and association of the frequency of use of pain medications between groups.

	Non-radioactive Sand Group		Monastic Sand Group		
Consumption of pain medications	N	%	N	%	P*
Consumption of pain medications per patient					
Time 0 (Start of exposures)	18	50.00	18	50.00	0.032
Time 1 (With 8 exposures)	15	51.72	14	48.28	0.032
Time 2 (With 16 exposures)	12	63.16	7	36.84	0.032
Time 3 (With 24 exposures)	9	75.00	3	25.00	0.032
Use of medicines during prescription exposures					
Time 0 (Start of exposures)	15	44.12	19	55.88	0.277
Time 1 (With 8 exposures)	10	40.00	15	60.00	0.277
Time 2 (With 16 exposures)	9	60.00	6	40.00	0.277
Time 3 (With 24 exposures)	6	66.67	3	33.33	0.277
Use of medicines during self-medication exposures					
Time 0 (Start of exposures)	15	36.59	26	63.41	0.201
Time 1 (With 8 exposures)	7	46.67	8	53.33	0.201
Time 2 (With 16 exposures)	4	50.00	4	50.00	0.201
Time 3 (With 24 exposures)	4	66.67	2	33.33	0.201

* Pearson chi-square test; significant if $p < 0.050$.

Tabela 3 – Association of the patient's perception about the frequency of use of medications for the treatment of pain during exposures in the monastic sand group.

Dependent variable - Exposure site (Black Sand)	Perception of frequency of use of medicines for pain treatment	OR	95% CI Lower	95% CI Upper	P*
T0 (Start of exposures)	Decreased	0.571	0.057	5.775	0.635
T0 (Start of exposures)	Continuous use	1.400	0.168	11.679	0.756
T0 (Start of exposures)	Increased	1	—	—	—
T1 (With 8 exposures)	Decreased	3.250	0.870	12.137	0.080
T1 (With 8 exposures)	Continuous use	1	—	—	—
T2 (With 16 exposures)	Decreased	11.083	1.208	101.684	0.033
T2 (With 16 exposures)	Continuous use	1	—	—	—
T3 (With 24 exposures)	Decreased	13.818	1.520	125.648	0.020
T3 (With 24 exposures)	Continuous use	1	—	—	—

* Simple logistic regression; (1) Reference category; significant if $p < 0.050$.

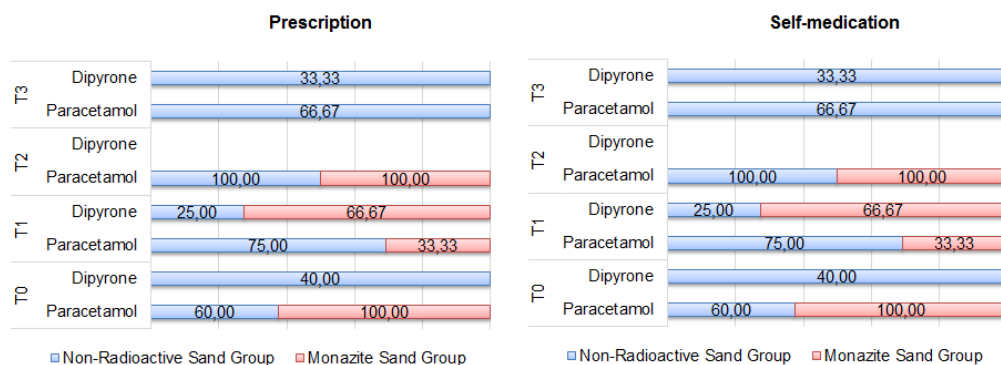


Figura 1: Experimental description of the frequency of analgesics by prescription and self-medication during exposures.

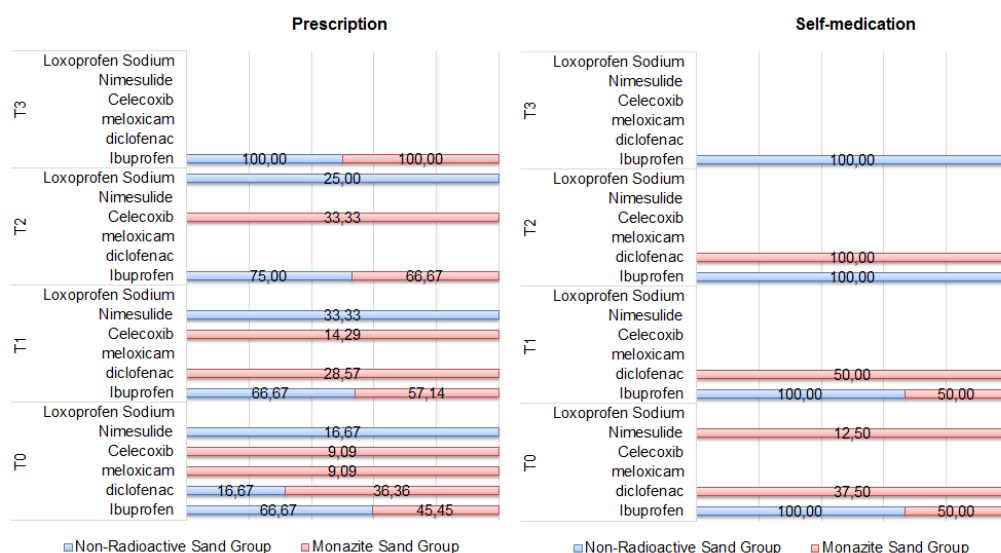


Figura 2: Sample description of the frequency of anti-inflammatory drugs (NAIS) by prescription and self-medication during the exposure period.

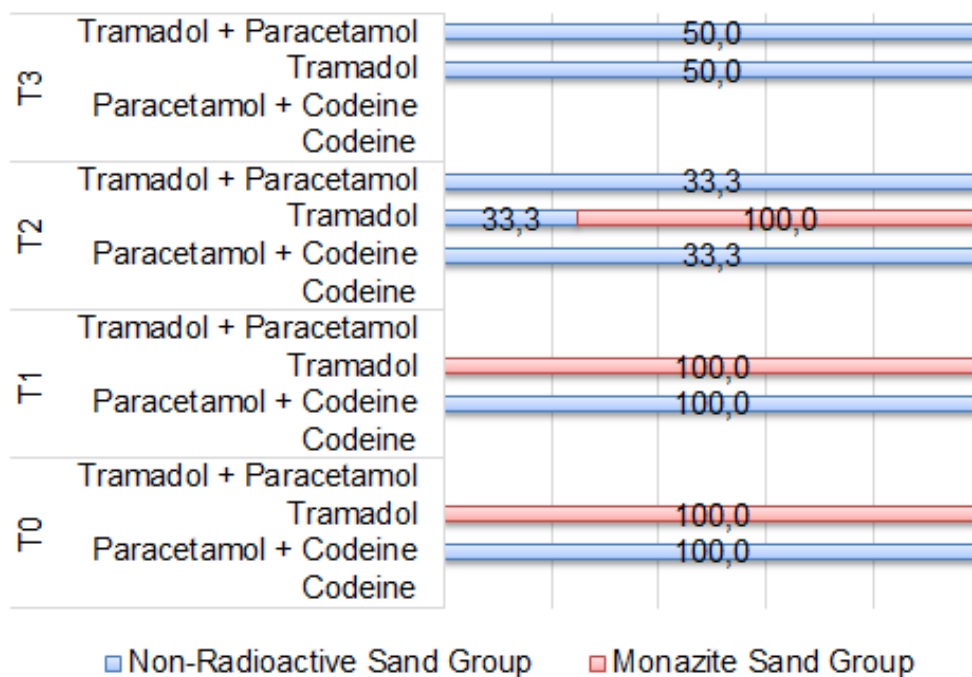


Figura 3: Description of the frequency of use of opioids by prescription during the exposure period.

5 Conclusion

Although this study is pioneering and has found statistically significant differences in the profile of pain treatment medications after 24 exposures to monazite sands, new projects should be carried out, especially with a more substantial number of patients affected by knee osteoarthritis and a more extended exposure period, to find better evidence of this alternative treatment disease and mainly the frequency of drug use.

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