Research Group on
Rheumatism and Thermalism

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Evaluation of the therapeutic effects of thermal cures on gonarthritis at Djerba Les Bains Spa

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Introduction

Arthritis is the most frequent rheumatic disease. It is a major public health problem because of its considerable impact on the quality of life and its high socio-economic cost.

Arthritis results from the mechanical and biological phenomena that destabilize the balance between the synthesis and the degradation of cartilage and the subchondral bone. It causes the loss of articular cartilage, a sclerosis of the subchondral bone, with the production of ostheophytes and subchondral cysts..

Although ageing is not the cause of arthritis, its frequency significantly increases with age. It affects more than 80% of the population between 75 years and more.

Knee articulation is the most frequent osteoarthritis (three times more frequent than coxarthrosis). Its frequency increases with age. A recent Tunisian epidemiological study identified a gonarthritis prevalence of 27.3% among subjects above 40 years and 49.2% among subjects above 60 years.

Its physiopathology reveals many factors: those inducing the disease, such as local and general factors, which have been so far unknown, and those sustaining it and whose mechanisms are better understood. The disease generates a functional discomfort, resulting in a disability or an added handicap, even if surgery has considerably improved functional prognosis.

Its management is first and foremost medical and must use the therapeutic arsenal, without neglecting nonmedical treatments. Resorting to surgery is envisaged in some cases.

To evaluate the effect of thermal cures on gonarthritis symptoms, we have undertaken a therapeutic test at Sidi Zikri spa in the Tunisian island of Djerba.

MATERIALS AND METHODS

This is a prospective double-blind therapeutic test. The impact of thermal cures was compared to the impact of a rehabilitating treatment carried out at the same spa.

Patient selection criteria

The study deals with patients suffering from femerotibial gonarthritis, diagnosed according to ACR criteria and sufficiently symptomatic to justify a thermal cure. The symptomatic nature of the gonarthritis was defined by a Visual Analog Scale (VAS) with a pain higher than 30 and a Lequesne's Algo-functional Index (AFI) higher than 5.

Frail patients, especially those in need for assistance, and those with reduced intellectual capacities, were excluded from the study. Patients presenting contra-indications to thermal cures (Infectious pathology, unbalanced HTA reports, decompensated heart failure, progressive cancer, progressive inflammatory pathology, decompensated psychiatric disorder) were also excluded. We also used the following exclusion criteria: congestive gonarthritis, recent intra-articular infiltration (< 30 days), gonarthritis at the surgical stage (IAF>15, walking range <1000m, flexing abilities limited to less than 90°), presence of a rheumatic disease likely to interfere with the measured indices (symptomatic ankle or foot arthropathy, radicular pain) and the use of WHO Class III analgesics.

Study protocol

To reach the sensitivity thresholds of statistical tests, the sample size was set to 240 patients, recruited by the physicians of the participating spas in the study. Two groups, of 120 each, were formed.

Front and profile knee load radiographies were made for all the patients.

During the enrolment visit, the investigating physicians checked the enrolment criteria and asked each patient to sign the informed consent. The informed consent was available in French and Arabic. During this first visit, we collected all the demographic data and clinical history.

Patients were divided into seven contingents who stayed at the spa between February and July 2006. The choice of the treatment to be delivered, the thermal cure or rehabilitation was determined by a draw made by the officer-in-charge of the Djerba spa. Neither the participating physicians nor the patients were informed beforehand about the type of treatment to be delivered.

To preserve the double-blind nature of the study, and for the sake of convenience at the spa, the draw was made according to patient groups and not individual patients.

Each group stayed for twenty days at the spa. Treatments were delivered every morning, except on Sundays.

The thermal treatment used sodium chloride waters, slightly sulphated, calcic and magnesic, hot at 36°. The patients benefited from four out of the five following treatments: underwater shower, massage-shower, hydro-massage, pool rehabilitation and application of heated peloid.

The physical rehabilitation treatment was delivered without using thermal waters. This is a classical rehabilitation of gonarthritis: analgesic physiotherapy, electrotherapy, muscular reinforcement and in-group rehabilitation.

The enrolment phase, starting in February 2005 and ending in June of the same year, was carried out in accordance with the pre-established protocol.

Treatment response was evaluated by rheumatologists at Mongi Slim Hospital at regular intervals: before the cure (D0), last day of the cure (D21), 3 months, 6 months and 12 months after the end of the cure. The evaluation used the Simple Verbal Scale (SVS) to assess pain, the Lequesne Algofunctional Index and the WOMAC index.

Statistical data analysis

Data were entered in Epi-Info1 software (Version 2000) and exported to the Dbase III+® prior to analysis using SPSS® version 9.0. The significance level was set at 0.05 for all statistical tests. The X2 test was used to compare percentages. In case of test invalidity, we used Fischer exact bilateral test for four-cell tables.

Results

Out of 240 randomized patients at Djerba spa, we recorded six early dropouts for personal reasons. Thus, 234 patients had a complete cure and were evaluated at 21 days at the end of the cure.

During the following evaluations at 3 months, 6 months and 12 months, the absentee rates were 7, 16 and 22%. Details on the respective numbers of persons taking health cures evaluated at different stages of the study are summarized in Table 1.

Table I : Number of evaluated patients at each visit

	Inclusion	**Evaluation D21**		**Evaluation 3 months**		**Evaluation 6 months**		**Evaluation 12 months**	
	n	n	(%)	n	(%)	n	(%)	n	(%)
Evaluated patients	240	234	(97)	218	(93)	198	(84)	187	(78)

Characteristics of the studied population: The average age of patients was 59.9 ± 8 years. 89.6% of them were women. Most patients were obese, with a body mass index of 33.77± 5.72. Gonarthritis was internal and unilateral femerotibial gonarthritis in 55.9% of the cases. 67.6% were advanced gonarthritis cases at the radiological stages II and III, according to Kellgren and Lawrence classification (1).

At enrolment, one third of the patients were under inflammatory treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and 63% took analgesics only. The average SVS was 61.6 and gonarthritis was responsible for an important functional discomfort, as witnessed by Lequesne average index values of 11.57 ± 2.7 and Total WOMAC at 1296.3 ± 426.2.

When anonymity was uncovered, it was found out that that 121 patients had a thermal cure and 119 had a rehabilitation without the use of thermal waters. The demographic and clinical characteristics of the two sub-groups were comparable. No statistically significant result was found in relation to the starting different demographic and clinical parameters, thus allowing for a comparison without a recruitment bias (Tables II and III).

Table N°II : Demographic characteristics of patients by treatment type

	G1 N=119	G2 N=121	p
Sex F	89	90.2	NS
Age	59.5 ± 8	60.3 ± 9	NS
Weight	81.1 ± 14	85.1 ± 14	NS
Size	155 ± 7	157.2 ± 9	NS
BMI	32.5 ± 5.3	34.5 ± 5.4	NS

G1 : Thermal group G2 : Rehabilitation group

Table N°III : Gonarthritis pre-therapeutic evaluation parameters by treatment type

	G1 N=119	G2 N=121	p
SVS pain	61.9 ± 14	64.3 ± 13	NS
Lequesne's Index	11.3 ± 2	11.8 ± 3	NS
Total WOMAC	1312 ± 400	1279 ± 460	NS
WOMAC Pain	277 ± 86	267 ± 84	NS
WOMAC Stiffness	103 ± 40	103 ± 39	NS
WOMAC Function	911 ± 274	909 ± 313	NS

G1 : Thermal treatment G2 : Rehabilitation treatment

Table N°VI: *Variations in evaluation parameters in the thermalism group*

	D0	D21	3 months	6 months	12 months
SVS Pain	61,2 ± 14.3	31,5 ± 18.4**	46,4 ± 20.6**	46,4 ± 23.5**	46.5 ± 22.4**
Lequesne's Index	11.5 ± 2.2	2.6 ± 3**	9.4 ± 3.4*	11.2 ± 3.8	10.3 ± 3.8
Total WOMAC	1297± 354,8	315 ± 297**	745 ± 452**	936± 482*	1067,4 ± 1370
WOMAC Pain	275.5.5 ± 88.8	110,9± 96,8**	179± 91.2**	197±105**	189± 103**
WOMAC Stiffness	104.1±39	44.8 ± 43.2**	69.5± 44**	78.8 ± 51**	70.17 ± 47**
WOMAC Function	910,9 ±276	339 ± 310**	610 ± 311**	664,7±344**	674±371**

** : p<0.05* *** : p<0.001*

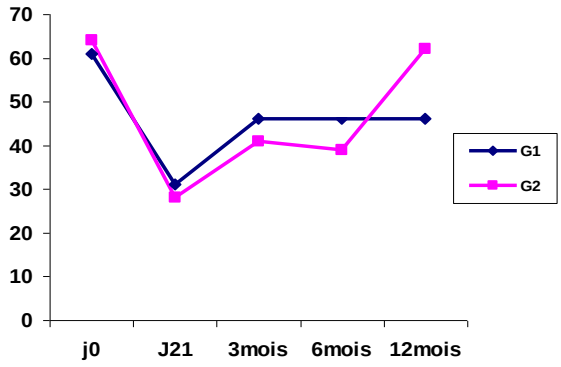
Effects of treatment by thermal cure: In the group of patients treated by thermal cure, the average increase in SVS Pain, Lequesne's and WOMAC indices, at different evaluation times, are summed up in Table VI.

There is a statistically significant improvement in the evaluation parameters at D21, 3 months, 6 months and 12 months, except for Lequesne Index at 6 months and 12 months, and WOMAC Total Index at 12 months.

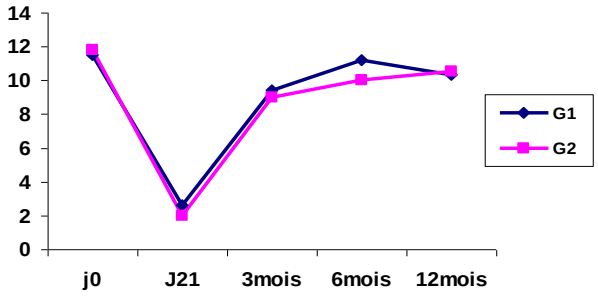
Comparing the results of both groups:

Comparing the evaluation parameters according to the tested treatments showed some statistically significant differences, as summarized in Graphs 1 to 6.

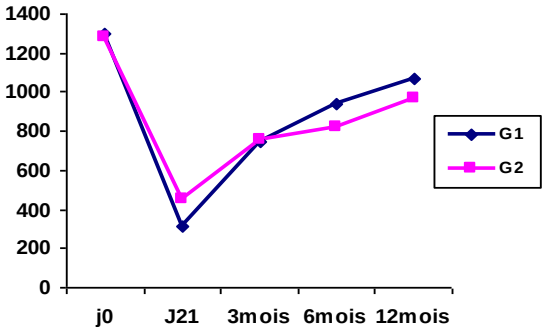
Thus, SVS Pain WOMAC Pain at one year were significantly lower than the treated group by thermal cure. Conversely, Lequesne IAF at six months and the domain function of the WOMAC index at one year were significantly lower in the group treated with physical rehabilitation.



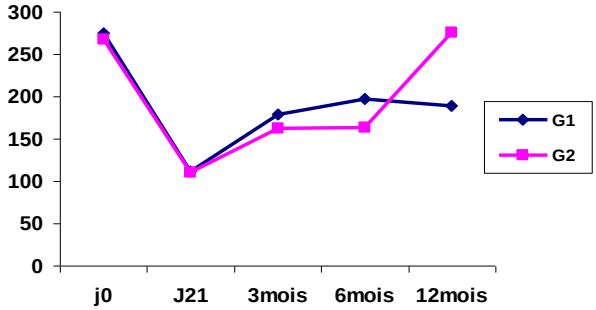
Graph 1: Evolution of SVS pain by treatment type



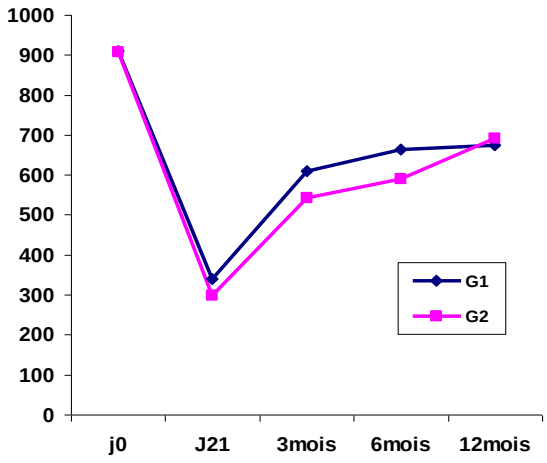
Graph 2 : Evolution of Lequesne's Index by treatment type



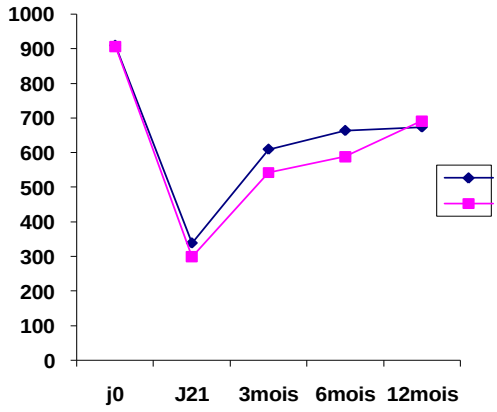
Graph 3: Evolution of WOMAC Total Index by treatment type



Graph 4 : Evolution WOMAC Pain Index by treatment type



Graph 5: Evolution of WOMAC Stiffness Index by treatment type



Graph 6: Evolution of WOMAC Index by treatment type

Commentary

If the effect of the different medical treatments has been widely confirmed by scientific research, the effect of thermal treatment has not been sufficiently investigated (2). This is partly due to the fact that double blind comparative studies are difficult to carry out, especially as the benefits observed during treatment by thermal care are largely attributed to the cure effect.

To overcome this difficulty, we compared thermal care to rehabilitation treatment without the use of thermal waters, knowing that the two types of care are provided in the same centre and under the same accommodation conditions.

In our study, a positive action on pain and quality of life was observed in the two groups.

Thermal treatment was efficient in relation to the painful symptomatic component of gonarthritis, with a benefit that lasted for a year. Its positive effect was also observed in relation to functional components and quality of life. However, the difference was no longer significant from 6 months for Lequesne's Algofunctional Index and from 12 months for the Total WOMAC Index.

In addition, the obtained results with thermal treatment, at the end of the cure and at 3 months, are fully comparable to those with physical rehabilitation. Beyond this period, some significant differences were identified. Some are in favour of thermal cure treatment and others in favour of physical rehabilitation.

On account of thermal treatment, we note a more sustainable efficiency for the painful symptomatic component of gonarthritis, as witnessed by a SVS Pain and a WOMAC Pain lower at 12 months than those obtained in the comparison group.

Conversely, physical rehabilitation treatment seems more efficient to the functional component, given that the indices of functional capacity at 6 months (Lequesne's Algofunctional Index) and at one year (function and stiffness domain of WOMAC Index) are the lowest.

The beneficial effects of thermal waters have ben largely used in the treatment of degenerative diseases, especially low back pain and gonarthritis. These are essentially open studies. The few published randomized studies usually have small samples and lack distance (3, 4, 5).

To our knowledge, our study is the only study to have compared thermal treatment to physical rehabilitation, with a fair number of patients, in addition to its prospective double-blind character. Our study is characterized by a fair sample size and a sufficient period of medical follow-up.

CONCLUSION

The study confirms the beneficial effect of thermal cures on gonarthritis. The loss of long-term benefits (12 months) in functional capacity underscores the benefit of repeated cures at an average interval of one year.

The observed superiority of physical treatment over thermal cure treatment in the functional component of gonarthritis suggest adding a rehabilitation programme of muscular reinforcement in a humid environment to the thermal cure protocol. The aim is to improve the results of thermal treatment.

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