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CAN LOCAL MILLIMETRIC WAVES EXPOSURE BE HELPFUL FOR INFLAMMATORY RHEUMATISM CARE? A 4 CASES REPORT ON RHEUMATOID ARTHRITIS AND ANKYLOSING SPONDYLITIS

Debouzy, J.C.*	7th French Army Medical Center, Quartier Reyniès, 38760 Varces, Remedee Labs; 29 chemin du vieux chêne, 38240 Meylan, Armed Forces Biomedical Research Institute (IRBA), Rd point V.André, 91233 Bretigny/Orge, France*Corresponding Author
Minier L.	Remedee Labs; 29 chemin du vieux chêne, 38240 Meylan, France
Pierre V.	Remedee Labs; 29 chemin du vieux chêne, 38240 Meylan, France
Del Vecchio F	Armed Forces Biomedical Research Institute (IRBA), Rd point V.André, 91233 Bretigny/Orge, France
Novellon R	Armed Forces Biomedical Research Institute (IRBA), Rd point V.André, 91233 Bretigny/Orge, France
Crouzier, D.	Remedee Labs; 29 chemin du vieux chêne, 38240 Meylan, France

ABSTRACT Rheumatoid arthritis (RA) and ankylosing spondylitis (SPA) are painful autoimmune, acute or chronic pathologies the joints, muscles and other tissues. Global care implies both medical more or less aggressive therapies, and physical treatments fight against pain and stiffness, vicious positions, and also improve autonomy in daily life. Anti-inflammatory properties of millimetric waves (MMW) have been identified since the end of 20th century, and recently tested using miniaturized MMW transmitter bracelet. We report here 4 cases (2SPA and 2RA) who experienced pain relief, functional and autonomy improvement, while limiting their intake of analgesics. Further extensive investigations are required.

KEYWORDS : pain, inflammatory rheumatisms, millimetric wave

INTRODUCTION

Rheumatological diseases are the most common cause of pain and disability. Among chronic inflammatory rheumatism, rheumatoid arthritis (RA) and ankylosing spondylitis (SPA) represent the most common pathologies (except microcrystalline inflammatory rheumatism such as gout, etc.).]In France, the incidence is 0.3% of the population for RA (200,000 patients) with a high female prevalence, and 0.3% for APS (204,000 cases) with no prevalence with sex[1]. These conditions significantly alter the quality of daily and social life of patients and their caregivers and loved ones and cause a significant cost of medical care[2]. In all cases, early diagnosis is necessary to allow treatment as appropriate as possible, to prevent or limit complications, to fight against pain and to improve the quality of life of patients, including the social consequences of these long-term affections. The health authorities specify the place and the strategy of use of the various therapeutic means, according to their nature and the aggressiveness of these affections [3,4]. The "well-established" therapeutic uses drug treatments, analgesics of different classes, anti-inflammatories (steroidal or not), and/or immunosuppressants (methotrexate, RIC, TNF-inhibitors). Most of these drugs exhibit an own toxicity, and a need for systematic biological monitoring (MTX), and/or a high cost (TNF-) is generally required.

Alongside these basic treatments, physical treatments (ergotherapy, balneotherapy, rehabilitation, physical activities, etc.) play a crucial role at all stages of the disease, to fight against pain, stiffness, and vicious positions, and improve autonomy in daily life. Other stimulation methods are also offered, TENS[5], acupuncture|6], or other passive and/or environmental therapies.

In the cases reported here, the intense pain felt by the patients lead them to acquire a commercial device emitting millimetric waves (Remedee Labs ©) originally intended for well-being [7] and stress control, hoping at least to recover a minimum of quality of sleep and better support their pain.

The biological effects of millimetre waves were proposed in the late 20th: these methods of therapeutic exposure to millimetre waves had been widely used in the countries of the former Soviet Union for various pathologies[8,9]. Among the various applications proposed [10,11], beneficial effects on experimental and chronic pain had been clearly identified [12,13]. In particular, beneficial effects on pain, stiffness and inflammation of various joint pathologies, degenerative[14] or inflammatory[15], had been noted at the time and [confirmed from the beginning of the 21st century[, in particular on rheumatoid arthritis[16] and "juvenile rheumatism" [17], or osteoarthritis[18.]

These properties were immediately linked to stimulation of peripheral nerve endings (loco dolenti, acupuncture points or others) resulting in a central response in the form of secretion of endorphins, themselves responsible for the hypoalgesia effect.

While the initial exposure systems used in the USSR were necessarily hospitable due to their size, recent technological progress on fast electronic and miniaturization allowed to set cheap integrated hyper frequency emitters, which can be worn by the patient simply like a watch medical device (DM Remedee© [7]. This device emits a 60GHz electromagnetic continuous wave at a power density of 14mW/cm^2 over 2 cm^2 skin surface on palm face of the wrist, 2 sessions of 30 minutes per day). This exposure location was selected not only for practical convenience, while also due to important nervous receptor density and skin thickness at this level. The 4 cases reported here present the consequences of MMW exposure on pain, well-being and functional ability.

CASES DESCRIPTION :

Ankylosis spondylitis (SPA)

Patient 1 : First SPA patient , Ms U..., born in 1960, was initially cared for fibromyalgia (2010) which necessitated the use of morphine LP. Morphin withdrawal for dependence was later obtained using oxycodone 10 (4/d). Beside overweight (100kg

for 1m75), she presented a hypothyroidism treated with levothyrox, a peripheral neuropathy of the lower limbs (confirmed by electromyographic recording), a mixt cryoglobulinemia diagnosed in 2009 in remission, and sleep apnoea's.

The diagnosis of SPA was made in 2014 in the absence of HLA B27 (but positive B25), according to the ESSG [19] criteria as described by the HAS[3,4] on cervical spine damage and lumbar, and of the scapular girdle : pain cotation VAS[20] was 2-3 continuously, up to 6-7 on physical effort, with a maximum in the morning (5-6), morning derusting, and up to 8 in crisis. Peripheral pain (feet) was 2-3 on the right and 3-4 on the left (following a fracture) The background treatment consisted of a TNF- inhibitor (Humira), Oxycodone (50mg), Paracetamol (2- 3g) and Levothyrox 100mg. furthermore, she also suffered from severe chronic insomnia (up to 3 hours of sleep in 2 days). The functional score calculated from the SF36[21,23] survey is presented in table 1. Whereas she overall remained autonomous (driving, washing, meals) several limitations were present (walking limited perimeter, dressing requiring technical assistance due to pain and stiffness, preparation of meals…criteria 1-3 table I). However, she kept a dynamic emotional approach (sections 3,5,6).

Foremost were pain, fatigue, social limitations without overall feeling of "good health". This led her to acquire the MMW bracelet, using 3 sessions a day of 1/2 hour. The first improvement obtained was a sudden disappearance of the insomnia after a month, which required subsequent adaptation (change to 2 sessions per day) finally allowing her to sleep better and manage her pain. Note that she was not able to specify whether it was "because I suffer less that I sleep better or if it is because I sleep better that I suffer less...". Final SF36 score (table I) also evidenced fatigue and overall comfort improvements, (items 5,7,8), more emotional well-being and physical functions enhancement (items 1,2).

TABLE I: Calculated SF36 [22,23] score before and after 1 month MMW trial, for the 2 SAA patients.

SAA	Ms U.		Mr O.	
	before	After	before	After
1.physical functionning	20	30	85	85
2.Role limitation due to physical health	0	0	50	60
3.Role limitation due to emotional problems	100	100	100	100
4.energy/fatigue	5	30	55	40
5.Emotional well-being	76	64	88	88
6.Social functioning	87.5	62.5	45	100
7.Pain	10	32.5	45	58
8.General health	32.5	10	50	45

Patient 2. Second SPA patient, Mr Aubin O, born 1982, presented since the age of 25 very painful synovial effusions of both knees (VAS 8 in crises lasting several days requiring bed rest) initially attributed to existence of pronounced hallux valgus. After 5 years of trying various unsuccessful treatments (until surgery) he was recurrently on NSAIDs (bi-Profenid), before the diagnosis of SAA was made from AMOR[23] criteria (i.e. diffuse spinal pain, MRI confirmed bilateral sacro ileitis, Oligo arthritis of the fingers, elbows and shoulders, response to NSAIDs, morning stiffness), despite the absence of absence of anti-nuclear and anti-CCP antibodies): and also ESSG classification[24] (inflammatory spinal pain, synovitis of the lower limbs). Treatment with Salazopyrine (4/d) for 2 years (2012-2013) then made it possible to reduce the intensity of pain (VAS) [20] from 8 to 2, then on stopping treatment without much increase in pain until in 2015 or the pain reappears continuously (VAS 7) aggravated by efforts, fatigue and environmental conditions. He took no medication then, but decided to experiment the bracelet (borrowed from his wife), first with 3 sessions a day. He rapidly noticed that, when used in the evening (up to VAS 5) he could wake up with less joint pain (return to VAS 0-1 in the morning, no need for morning stretching). The schedule of this session was later adapted for reasons of comfort).

The morning session (up to VAS 7): carried out systematically during painful awakenings (up to VAS 7), allows a marked improvement until the pain completely vanished at midday (return to VAS 0). In the followings, he only used this session "on demand". A shown on table I, SF36 score evolution underline the improvement in physical conditions, pain, social limitations and general sense of well-being.

RA: Rheumatoid Polyarthritis

Patient 3. First RA patient, Ms D., 80 years old (born 1941). The diagnosis of RA was made in 2007 based on the present clinical criteria [25] as described by HAS: "morning stiffness for more than 30 minutes; duration of symptoms for more than 6 weeks"; "arthritis affecting at least 3 joints, symmetrical"; here all peripheral joints symmetrically from the scapula-humeral to the fingers and toes, with permanent pain reaching a VAS level 8-10. This diagnosis was confirmed by biological data, including both the presence of rheumatoid factor (RF), anti-protein antibodies/citrullinated peptides, elevated sedimentation speed (ESR) and C-reactive protein. The background treatment consisted of methotrexate, speciafoldin and corticosteroids, class 1 and 2 analgesics (Ixprim, Lyrica, then Zaldiar 37.5mg 5/day, up to 6/day when crisis…).

An assessment of overall RA activity in June 2021 (14 years of evolution) showed a VAS almost 8 -10 everywhere, and a Ritchie index [26] estimated around 50.

The evaluation of the activity of RA did not use the questionnaire (Disease Activity Score [27,28], nor the functional handicap (Health Assessment Questionnaire (HAQ), that could not be reconstituted, but a functional score SF36 [22,23], presented in table II. There clearly appears a limitation of functional and physical performance (item 1), as well as severe limitations of the general rules of life linked more to physical limitations and fatigue (items 2 and 4) and to chronic insomnia, than to emotional repercussions (item 3) In accordance with the VAS (see figure 1), pain is in the foreground (the SF36 number 0 corresponds to maximum pain intensity, as opposed to the EVA where the maximum is calculated at 10/10). She then decided to test the MMW device (July 9, 20121), at least in the hope of improving her well-being and acting on the pain. Indeed, the changes noted on the first report (regular reports every 15 days) relate to general criteria of well-being (easier to fall asleep, feeling of calm and waking up less tired). At the same time, the number of analgesics/day (ZALDIAR 37.5) is reduced to 3 (figure 1) while the VAS goes from 9 to 7. . Such features were still present in subsequent assessments (on August 20, the VAS is at 5, medication intake remains at 3, and sleep quality was improved, even increased in duration and quality.

Despite a painful crisis of the hands in September (local VAS at 6, while global VAS was between 4 and 5), this evolution was still present in september, and also a decrease in morning stiffness/pain (although she was less assiduous in the use of the bracelet). Finally, her physical condition allowed her to travel and participate in family events, related with -according to herself- an improved dynamism. The ultimate evaluation (see table II) objectifies these observations.

TABLE II: Calculated SF36 score before and after MMW trial, for the 2 RA patients.

RA	Ms D.		Mr G.	
	before	After	before	After

1. physical functionning	20	40	30	40
2. Role limitation due to physical health	25	80(*)	12.5	0(+)
3. Role limitation due to emotional problems	66	100	100	66(+)
4. energy/fatigue	25	80	45	50
5. Emotional well-being	60	88	66	68
6. Social functioning	63	0	37.5	37.5
7. Pain	0	62.5	32	50
8. General health	75	60	42	38

(*)Physical limitation improvement limited by an intercurrent traumatism (bone fracture). (+) limitations related with a fracture of L2 vertebra after a fall down.

Patient 4. Second RA patient, Mr G., 47 years old (born 1974). His rheumatoid arthritis was diagnosed at 9 years (1983) and treated with Methotrexate since 1994, then with Anti TNF Alpha (Remicade) since 2002 with regular haematological follow-up.

At the beginning of the observation period reported here, the assessment (table II) therefore showed three components: RA, so-called mechanical low back pain, and sleep disorders, fatigue, loss of energy related to restless legs as well. although with painful manifestations.

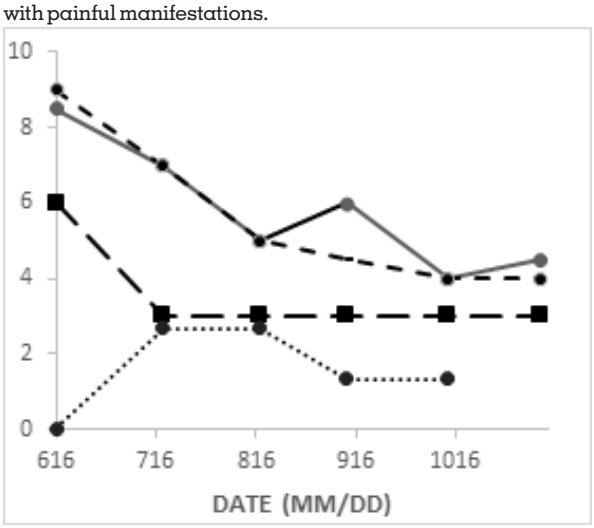

Figure 1 : time course (MM/DD) of overall EVA(–), Hands EVA(--); mean daily antalgic use (- -); mean daily use of MMW (....)

He also presented since 2008 a succession of herniated L4-L5 and L5-S1 discs that were finally treated surgerically. However a left sciatic pain remained, attributed to a posterior joint syndrome. His treatment was thus completed by Gabapentin (700mg/day) essential because of the pain, associated or not with Izalgi (500mg/day). The moral consequences of this long-term evolution required the use of -Duloxetine (90mg/day), and he had to limit work to a therapeutic part-time job. Local treatments (corticosteroid infiltrations) as physical (osteopathy, physiotherapy, cryoneurolysis, hypnotherapy) were totally ineffective) and an acupuncture trial even aggravated the painful symptomatology. Since 2010 he also presented a restless legs associated with sleep apnea. Faced with the relative failure of all treatments, in this painful and depressive context, he tested the MMW device.The evolution of these three components is shown schematically in Figure 2.
As far as RA is concerned, the evolution is marked from the start by a drop in VAS (during April, point 402 before use - VAS6- and 428 recorded during the first month of use -VAS5). This evolution continued during the observation period, eventually reaching a d VAS of 2. It should be noted that from the beginning, the patient stopped analgesics (Izalgi, gabapentin, doliprane), and only resumed anti-inflammatories after a lumbar traumatism that occurred in July (point 704) (fracture of L2 after a falldown), which also caused a rebound in low back pain.

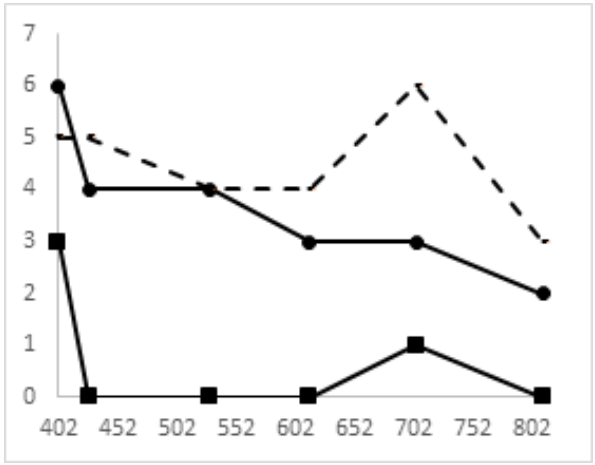

Figure 2 : time course (MM/DD) of RA-related EVA(–), Lowback pain (- -); number of daily antalgic/AIS use (- -)

*Point 704 corresponds to intercurrent accident -fall with vertebral fracture L2-

This accident also explains the apparent anomaly in the evolution of points 2 and 3 (Role limitation due to physical health or emotional problems) de la table II.

The restless legs syndrome was not modified in a real or lasting way, despite the use of Sifrol and the improvement in sleep reported by the patient, (found in points 4, 5 of table II, (fatigue, energy, emotional well-being).

Finally, besides basic necessary RA treatment (TNF-inhibitor, Methotrexate), a real efficacy on pain associated with RA, sleep, use of analgesics and general well-being were well obtained after MMW use (item 7 table II).

DISCUSSION

The observations presented here relate to the effects of local exposure to low-power millimetric radiation (60GHz, 14mW/cm^2, continuous waves) mainly on overall well-being and pain on patients suffering of very frequent inflammatory diseases , Rheumatoid arthritis (PCR) and ankylosing spondylitis (SAA). The global care of these painful autoimmune, chronic pathologies the joints, muscles and other tissues implies both medical more or less aggressive therapies. Besides these anavoidable treatments, antalgic, anti-inflammatory drugs are generally necessary to overcome painful periods. Physical physiotherapy methods are also frequently used useful with miscellaneous success. In the cases described here, the patients acquired and tested the MMW device (Remedee ©) in the hope to obtain a bit of well-being and sleep which was greatly affected by pain. Hence, specifically for the 2 RA cases the use of antalgic drugs was stopped or reduced. Also, morning articular derusting was not further required in the cases of SPA. It is worth to note that, in common between the 4 patients with 2 different inflammatory diseases, sleep quality, pain, global well-being and energy was improved (see items 4 to 8 of SF36 scores) , even if intercurrent events (fall-down, accident) puzzled role limitations results (items 2 and 3) for two of them. From a basic point of view, such results have been early observed by Radjiesky[9] and reported later by Pakhomov[10] in his

review, 1998, and also recently actualized in Ziskin's review, 2019[]. MMW antalgic and anti-inflammatory properties are generally related with a local stimulation of peripherical cutaneous receptors leading, via nervous centripetic information to central nervous secretion of endorphins[9,] and also others neuromodulators or regulation systems involved in inflammation mechanisms[].This hypothesis is supported by several experimental results and publications. Rojavin, using the cold water tail-flick test (cTFT) in mice evidenced an hypoalgesia effect of a single exposure to low power electromagnetic millimetre waves (MW) with MW exposure characteristics very close to those used in the present report (61.22 GHz; incident power density 5 to 15mW/cm^2 for 15min exposure duration on the glabrous skin of the footpad. Beside direct nervous fiber stimulation, other elementary mechanisms such as MMW dynamics interactions or collective vibrational « resonance-like » phenomena with cell membranes, have also been more recently proposed.

CONCLUSIONS

The cases presented here show clinical improvements obtained using a device intended for another use (well-being or sleep). The clinically most important finding of this case study is that low power, 60GHz CW MMW wrist exposure can significantly improve functional performances and quality of n all day life at the cost of constraints as minimal as wearing a watch designed device. This MMW device, devoid of any deleterious side effects, whereas excluding any major classical treatments suppression, allows to reduce medical treatments with major painkillers. Extensive clinical trial have to be performed to confirm such properties, antalgic, anti-inflammatory, all day life improvement, in PCR and SAA, and probably in other inflammatory diseases, e.g. psoriasis rheumatism, or Ehlers-Danlos syndromes.

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Patients agreements : all patients gave their agreement for publishing their clinical case, under anonymized name.

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