Anti-arthritic potential of microencapsulated *"SmartHit Curcumin^{IV}"*: preclinical and clinical studies

Dominyka DAPKUTE[1,2], Zydrunas SAUKEVICIUS[2,3]

[1]Life Sciences Center, Vilnius University
[2]Scientific research and development department, JSC „Valentis"
[3]Faculty of Natural Sciences, Vytautas Magnus University

INTRODUCTION

Arthritis – a systemic **inflammatory** disease affecting joint cartilage. Arthritis causes pain, stiffness, swelling of the joints, restricts range of motion, decreases strength, places a person at increased risk of work disability, affects quality of life.

There is **no known cure for arthritis.** Although nonsteroidal anti-inflammatory drugs **(NSAIDs)** decrease arthritis inflammation and pain, they increase the risk of gastrointestinal and cardiovascular complications.

Curcumin, an active extract of turmeric, is a strong anti-inflammatory and antioxidant agent with **therapeutic effect** against progression of arthritis and low incidence of side effects. Yet, pure curcumin has **low bioavailability.**

Microencapsulated food supplements have been developed to increase nutrients' absorption and their tolerability. **Microencapsulated curcumin** contains microsized vesicles made from phospholipid bilayer **(liposomes)** dispersed in water. Due to similarity of these microcapsules to cell membranes, microencapsulated **nutrients are absorbed a few times better** than standard oral supplements.

In this study, we evaluated, which form of curcumin vehicle has the biggest impact on its **bioavailability and anti-inflammatory effect** in adjuvant-induced arthritis (AIA) in rats. Later, the efficiency of microencapsulated curcumin was tested in 502 human subjects with osteoarthritis in questionnaire-based study.

MATERIALS AND METHODS

PRE-CLINICAL STUDY

- The study was done in Vilnius University Life Sciences Center (ethics approval No. G2-47, 30/06/2016).
- Wistar rats (*n*=32) were used in the study. Experimental arthritis was induced with Complete Freund's Adjuvant (CFA) injected subcutaneously at the base of the tail.
- Treatment with four different curcumin substances (Fig. 1) (170 mg/kg curcumin) *per os* was started at day 6 and continued daily until day 24.
- Blood samples were analysed with veterinary hematology analyzer Exigo EOS (Jainam Biomedical).
- Inflammatory cytokines in serum were determined by enzyme-linked immunosorbent assay (ELISA) using commercial kits for rat IL-1, IL-6, and TNF-α (Invitrogen, Thermo Fisher Scientific, MI, USA).

CLINICAL STUDY

- The study enrolled 502 patients (male 221/female 281, average age 64 years) complaining of chronic joint pain. Patients were recruited in clinics in Warsaw after they were informed about ongoing study.
- Patients participated in open, product evaluation study for the complementary management of joint pain due to arthritis. Patients signed a consent form. Patients had mild-to-moderate pain controlled with anti-inflammatory drugs prescribed by their rheumatologist.
- Subjects consumed 5 ml of "SmartHit Curcumin" daily for a month. One study dose contained 170 mg turmeric extract (160 mg curcuminoids).
- Patients filled a questionnaire after the study.

RESULTS PRE-CLINICAL

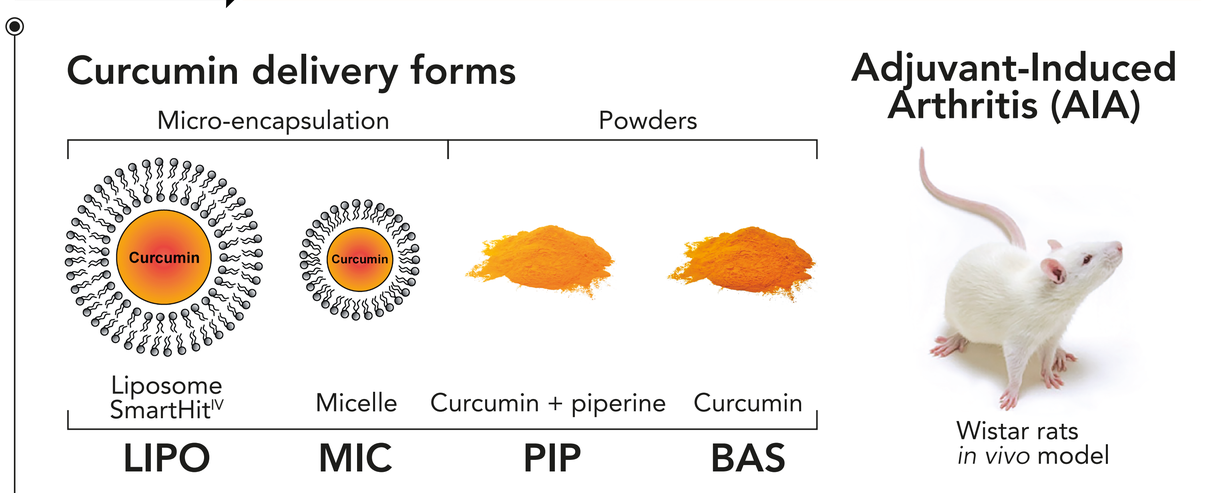

Fig. 1. Different curcumin delivery forms used in the study.

Fig. 2. Swelled hind paws 15 days after CFA injection.

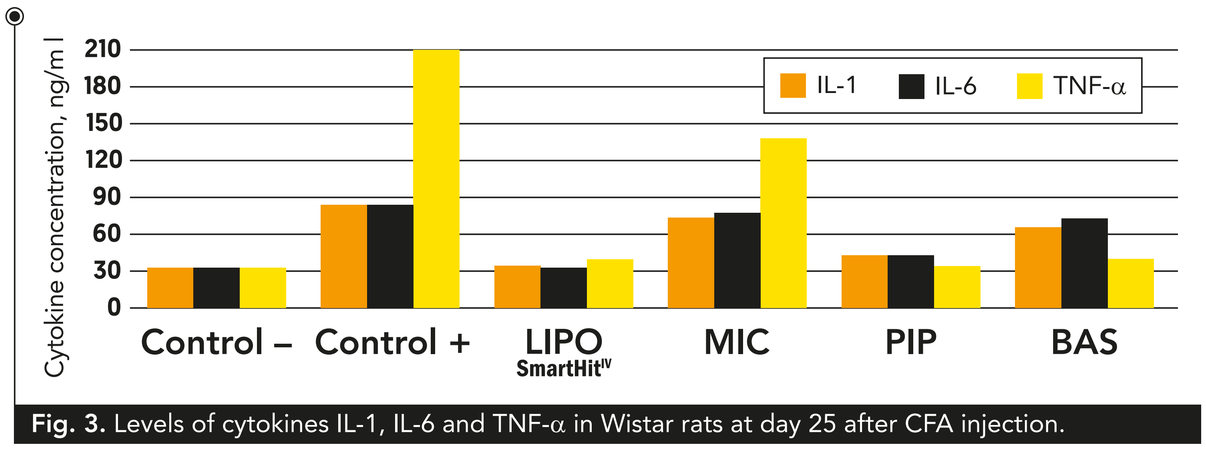

Fig. 3. Levels of cytokines IL-1, IL-6 and TNF-α in Wistar rats at day 25 after CFA injection.

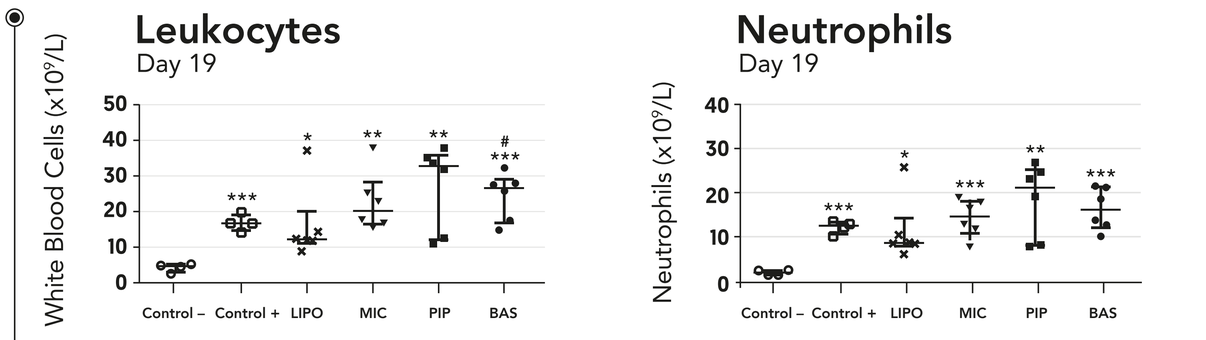

Fig. 4. Leukocyte and neutrophil parameters in Wistar rats at day 19 after CFA injection.

RESULTS CLINICAL

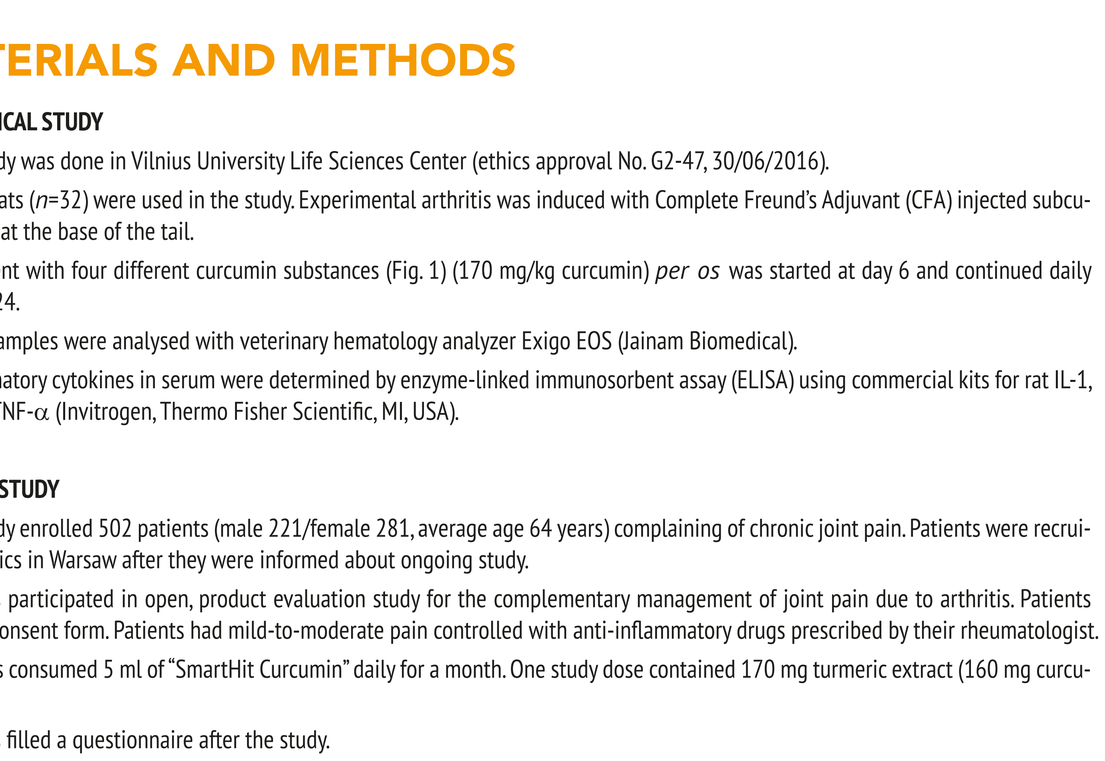

Fig. 5. Changes in physical comfort after one month of "SmartHit^{IV} Curcumin".

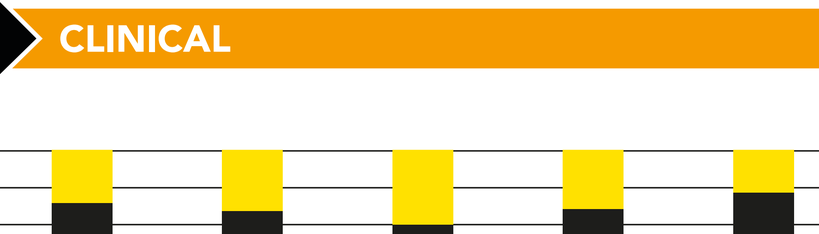

Fig. 6. Changes in NSAIDs use after one month of "SmartHit^{IV} Curcumin".

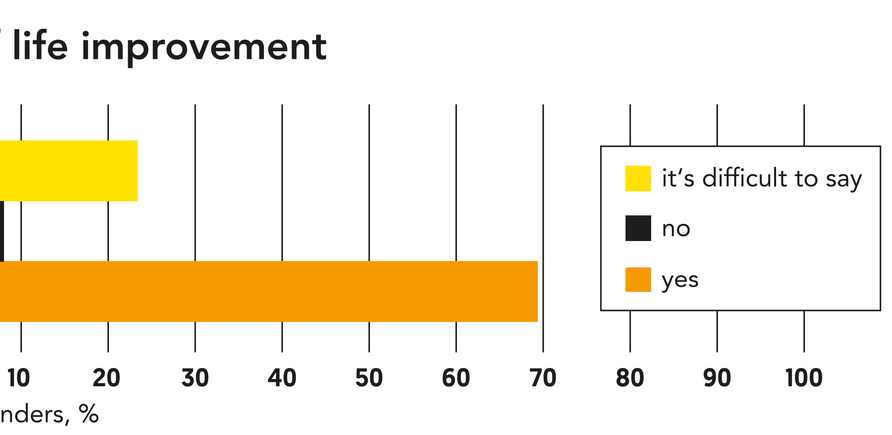

Fig. 7. Changes in quality of life after one month of "SmartHit^{IV} Curcumin".

CONFLICT OF INTEREST

D.D. is a part-time researcher in Valentis R&D department, **Z.S.** is a full-time researcher in Valentis R&D department.

Valentis had supplied reagents and different curcumin forms for the studies.

Valentis had in no way impacted the outcome of the results.

CONCLUSIONS

Arthritis stabilized after 10 days of "SmartHit^{IV} Curcumin" supplementation **(Fig. 2).**

- Pro-inflammatory cytokines (TNFα, IL-1, IL-6) reduced to a level of healthy control **(Fig. 3).**
- Number of leukocytes and neutrophils reduced **(Fig. 4).**

"SmartHit^{IV} Curcumin" reduced joint pain and stiffness, decreased use of NSAIDs and improved life quality of the patients suffering from arthritis **(Fig. 5-7).**

CONTACT

PhD candidate **Dominyka Dapkute**
Researcher at Valentis R&D department
Moletų road 11, Vilnius 08409, Lithuania
Mobile +370 677 05841
Phone +370 5 2701222
dapkute@valentis.lt