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Statistical aspects on the usage of some dermatological creams with metallic nanoparticles

Ioana Chiorean

Abstract. The main purpose of the present paper is to emphasize, by statistical studies, the anti-inflammatory effect of some new prepared nanomaterials on skin diseases (psoriasis). These new materials are based on silver and gold nanoparticles and natural compounds extracted from native plants of *Adoxaceae* family (European Cranberry Bush - *Viburnum opulus L.*, European black Elderberry - *Sambucus nigra L.* and *Cornus mas*), which grow in our country and possess a known anti-inflammatory activity mainly due to their high content of anthocyanins and other polyphenols.

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1. Introduction

In the 21-st century, the scientists from different domain of activity, all over the world, find more and more attractive the idea of "back to nature". Mainly in Medicine, many researchers try to discover new products, based on natural extract, to cure all kind of diseases, because it is known that the antocyanins obtained from plants are organic colorants which have good results in this. In order to get a better penetration of these products into the human body, the nanotechnology became "a great help", by new metallic (gold/silver) nanomaterials. For the moment, few studies have been made directly on human subjects, due to the fact that the toxicity of these metallic nanoproducts has to be carefully determined. For each case, and for each material, *in vitro* and *in vivo* studies have to be performed. Only then, if the results indicate the non-citotoxicity of the material, they may be used on humans.

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In paper [1], [2], the effect of the natural extract made from the different fruits of *Adoxaceae* family found in Romania has been studied. We are talking about *Călin* (*Viburnum opulus L.*), *Soc* (*Sambucus nigra, L.*) and *Corn* (*Cornus mas*).

The natural extracts of these fruits have been functionalized with metallic ions of gold/silver (more precisely the metallic ions have been reduced in the presence of natural extracts) and some new nanomaterials have been obtained. Their physical characteristics have been studied in [1] and [2].

In vitro and *in vivo* studies have been made (see also [1] and [2]). It has been found that our products are non-toxic. Their benefits on skin diseases have been also emphasized. Some dermatological creams have been produced with our nanomaterials and have been tested on a sample of patients with psoriatic lesions.

The histograms of the subjects' skin thickness presented an involution of diseases after treatment, fact that indicates, from medical point of view, the very good anti-inflammatory effect of all our nanomaterials. But, in order to state a final conclusion, the data has to be statistically interpreted.

2. Statistical studies

The data have been collected from a total sample of 45 subjects, all aged between 35-63 years old, with clinical diagnosis of psoriasis. Patients enrolled in the study signed an informed consent forms. The study has been approved by the Ethical Committee of the University of Medicine and Pharmacy "Iuliu Haţieganu" Cluj-Napoca, Romania. All subjects have been submitted to an ultrasonographic evaluation, images from different areas of the skin being taken and analyzed in the Dermavision software. The ultrasound evaluation allowed the acquirement of cross-sectional images of the skin up to a depth of 2.5 cm as well as the assessment of the echogenicity variation, by comparing the number of pixels (with different echogenicity levels) before and after therapy.

2.1. Study for the cream with gold nanoparticles functionalized with *Călin* (*Viburnum opulus L.*)

The pictures in Figure 1 indicates the skin lesions before and after treatment with this cream.

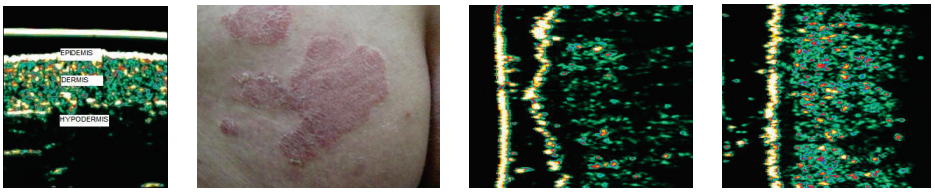

Figure 1. Anti-inflammatory effect on skin lesions; (a): normal skin, (b) psoriasis vulgaris, (c): histogram before treatment, (d) histogram after treatment

The cream has been used by 8 patients have used the cream, for two weeks, twice a day.

According with [1], the mean value of our data is $M = 3437.75$ before treatment, and $M = 983$, after treatment, which indicates that the cream has a very good anti-inflammatory effect. From statistical point of view, the two tailed Student test has been used. The correlation coefficient is $R = 0.874$ and $p = 0.005 < 0.05$, which means that this result is statistically significant.

2.2. Study for the cream with silver nanoparticles functionalized with *Călin* (*Viburnum opulus L.*)

In this case, 7 patients have used the cream, for two weeks, twice a day. The graphic in Figure 2 indicates the variations of psoriatic lesions skin thickness before and after the treatment with this cream.

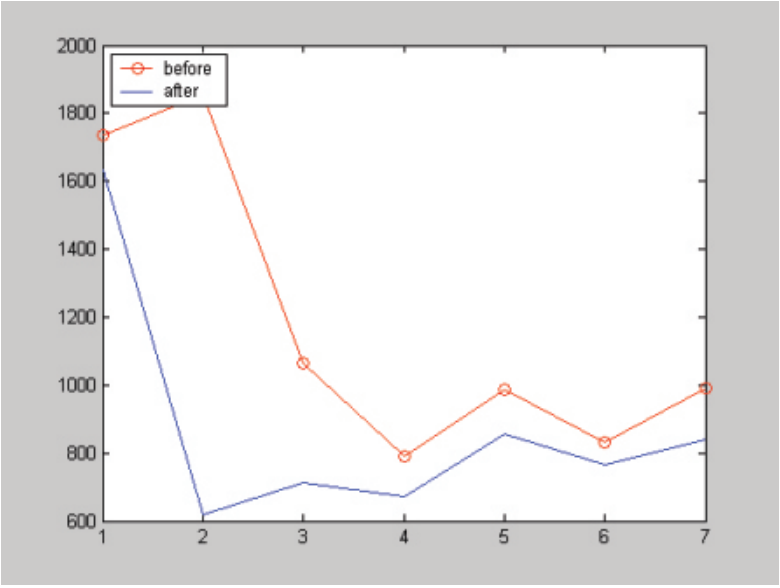

Figure 2. The skin thickness (in μm) before and after treatment with silver nanoparticles functionalized with *Călin* (*Viburnum opulus L.*) cream

In this situation, in spite of the fact that the values indicate a decrease in the thickness of the skin lesions, the data are not correlated, so the sample is too small to be statistical significant.

2.3. Study for the cream with gold nanoparticles functionalized with *Soc* (*Sambucus nigra, L.*)

In this case, also 7 patients have used the cream, for two weeks, twice a day.

Again, as in [1], in this situation, in spite of the fact that the values indicate a decrease in the thickness of the skin lesions, the data are not correlated, so the sample is too small to be statistical significant.

2.4. Study for the cream with silver nanoparticles functionalized with *Soc* (*Sambucus nigra, L.*)

In this case, the 7 patients have used also the cream, for two weeks, twice a day. The graphic in Figure 3 indicates the variations of psoriatic lesions skin thickness before and after the treatment with this cream.

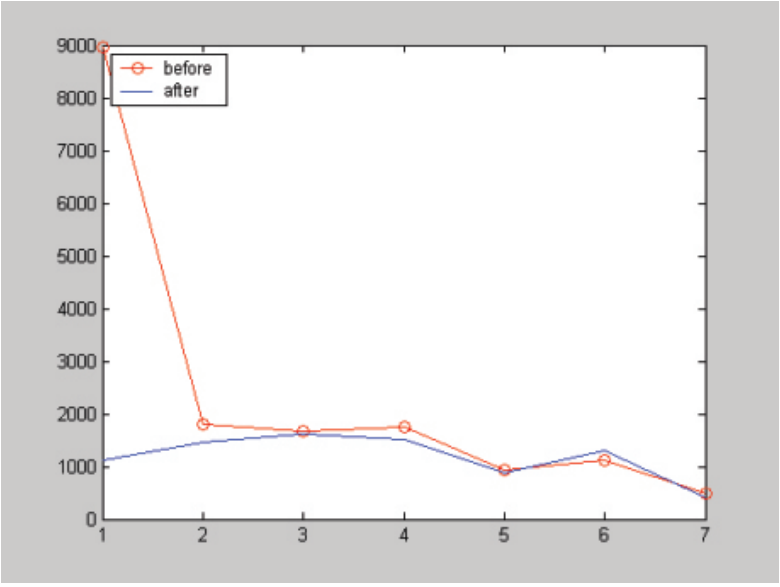

Figure 3. The skin thickness (in μm) before and after treatment with silver nanoparticles functionalized with *Soc* (*Sambucus nigra, L.*) cream

We note that we are in a situation similar with the previous two.

2.5. Study for the cream with gold nanoparticles functionalized with *Corn* (*Cornus mas*)

In this case, 8 patients have used the cream, for two weeks, twice a day. The graphic in Figure 4 indicates the variations of psoriatic lesions skin thickness before and after the treatment with this cream.

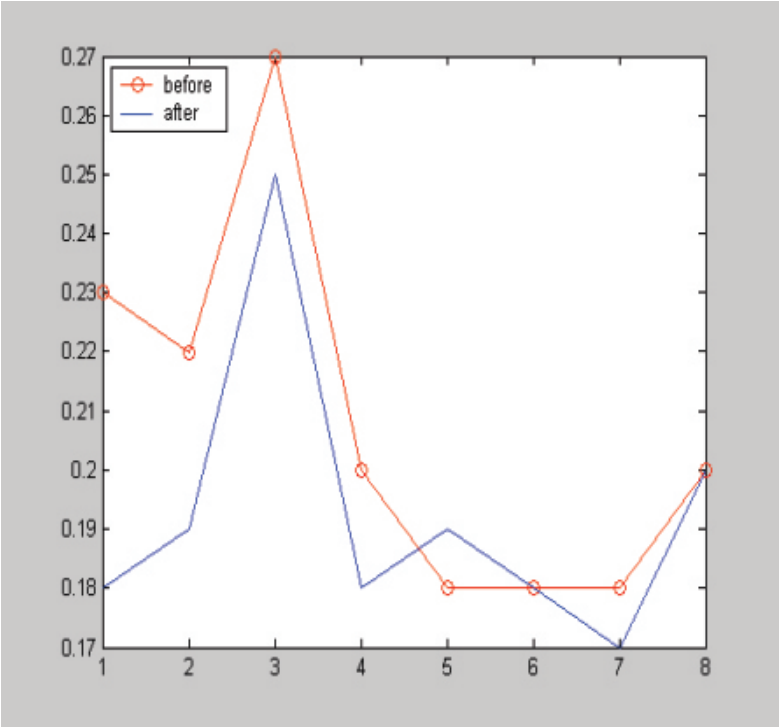

Figure 4. The skin thickness (in μm) before and after treatment with gold nanoparticles functionalized with *Corn* (*Cornus mas*) cream

From statistical point of view, the two tailed Student test has also been used. The mean value is $M = 0.2075$ before treatment, and $M = 0.1925$, after treatment. The diminishing of this value is small, but it is statistically significant, correlation coefficient being $R = 0.79$ and $p = 0.01 < 0.05$.

2.6. Study for the cream with silver nanoparticles functionalized with *Corn* (*Cornus mas*)

In this case, also 8 patients have used the cream, for two weeks, twice o day. The graphic in Figure 5 indicates the variations of psoriatic lesions skin thickness before and after the treatment with this cream.

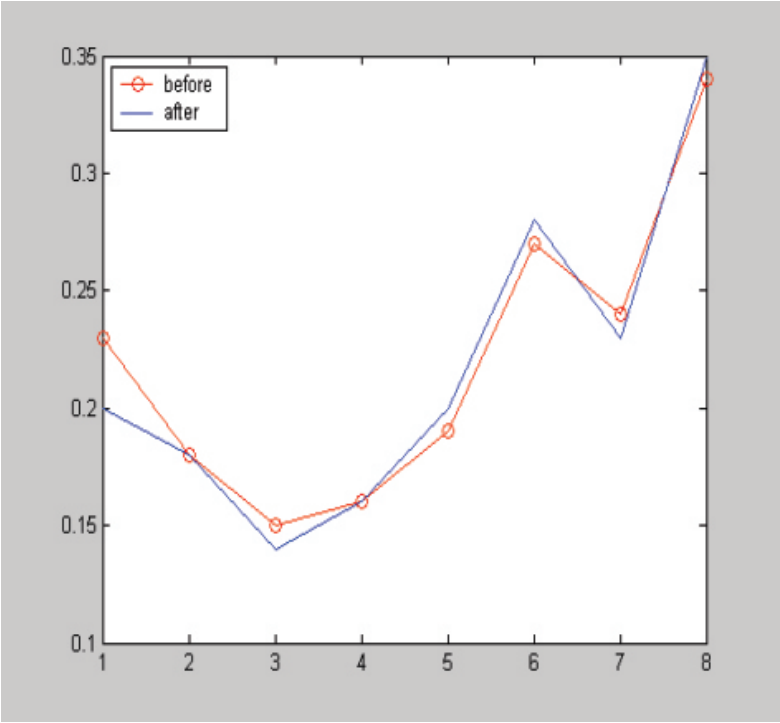

Figure 5. The skin thickness (in μm) before and after treatment with silver nanoparticles functionalized with *Corn* (*Cornus mas*) cream

The statistical study has revealed a very good correlation with $R = 0.98$ and $p < 0.00001$. The mean value of data before treatment has been $M = 0.22$, and $M = 0.2175$ after treatment, which indicates only a very slightly modification in the thickness of the skin. This permits us to state that, in spite of the good statistical results, this cream has not a very good anti-inflammatory effect.

Conclusion. Comparing from mathematically point of view our six creams, we may state that the cream with **gold nanoparticles functionalized with Călin** (*Viburnum opulus L.*) has the best anti-inflammatory effect. The second one is **the cream with gold nanoparticles functionalized with Corn** (*Cornus mas*) and the third is **the cream with silver nanoparticles functionalized with Corn** (*Cornus mas*). All the other may indicate some medical diminishing of the psoriatic skin lesions thickness, but they are not statistically significant.

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Ioana Chiorean
Department of Mathematics, Babeş-Bolyai University, Cluj-Napoca, Romania
e-mail: ioana@math.ubbcluj.ro