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INTERVIEW / BOLGAN

“Aggravation and resistance, the unknown risks of the vaccine”

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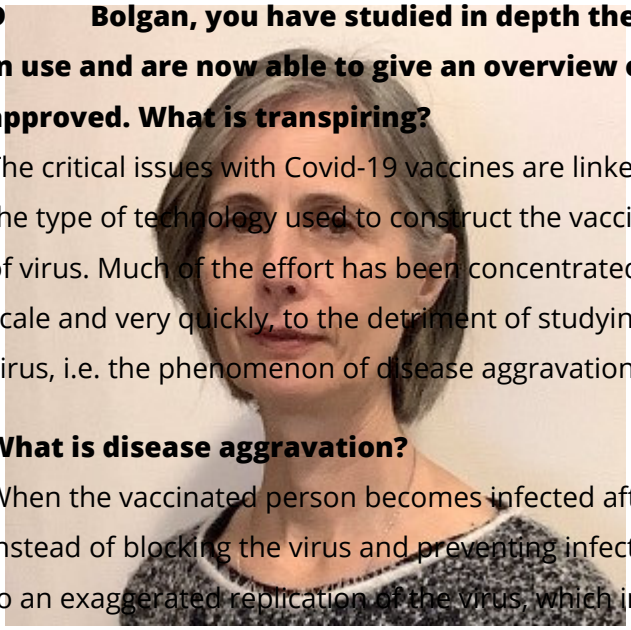
There are still many aspects that we don't know about the Covid vaccines, whose worldwide campaign is being carried out on a massive scale. First and foremost, there are several health risks that have not been entirely ruled out by the pharmaceutical

companies, such as disease aggravation and vaccine resistance.

The Daily Compass spoke to Loretta Bolgan (in the photo), Scientific Advisor for *Rinascimento Italia,* and a pharmaceutical chemist.



D Bolgan, you have studied in depth the main vaccine platforms currently in use and are now able to give an overview of the antidotes currently being approved. What is transpiring?

The critical issues with Covid-19 vaccines are linked to two factors, one dependent on the type of technology used to construct the vaccine antigen and the other on the type of virus. Much of the effort has been concentrated on producing the vaccines on a large scale and very quickly, to the detriment of studying the risks associated with the type of virus, i.e. the phenomenon of disease aggravation.

What is disease aggravation?

When the vaccinated person becomes infected after vaccination, the vaccine antibodies, instead of blocking the virus and preventing infection of the cells, facilitate it. This leads to an exaggerated replication of the virus, which in turn leads to a triggering of the disease. The risk is that Covid in that person develops into severe fatal pneumonia.

Do you have any evidence of this?

Yes, it is a real risk. I have studied and am still studying the mechanism of damage induction caused by SAR-Cov-2 and related vaccines, and it is documented that there are vaccines against SARS that have not been registered for this very reason. In preclinical animal studies, the vaccinated group developed the fatal severe complication, and these types of studies are still ongoing for SARS-Cov-2 vaccines despite the fact that some are already on the market.

When should we expect this?

I am personally receiving several reports from family members and healthcare workers of people vaccinated with both the flu vaccine and the COVID-19 vaccine, who shortly after the vaccine became positive in the molecular test and then developed symptoms of the disease. This could be explained in two ways: either the person already had the disease which then manifested itself at the same time as the vaccination, or the vaccine exacerbated a previous SARS-Cov-2 infection. There are now studies showing that the virus is able to infect intestinal bacteria and remain in the microbiota for a long time, supporting the chronic infection hypothesis. For those who have never been infected, the aggravation could occur on reinfection during the epidemic peak.

What evidence do we have on the risk of aggravation?

Animal studies do not yet allow us to answer this question, despite the fact that the Europe Medicines Agency (EMA) has expressly requested that this risk be assessed before marketing. Unfortunately, it will be necessary to wait for vaccinated people to become infected in order to know the incidence, because in the clinical studies carried out so far, most people, whether vaccinated or not, have not become infected.

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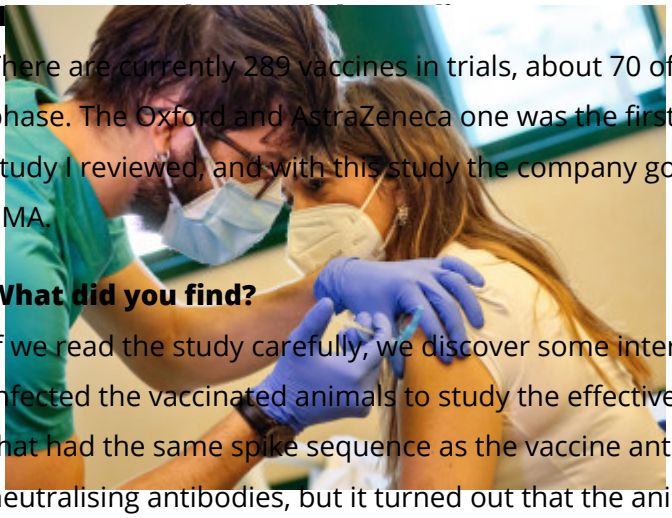

There are currently 289 vaccines in trials, about 70 of which are in an advanced clinical phase. The Oxford and AstraZeneca one was the first one whose preclinical animal study I reviewed, and with this study the company got fast-track authorisation from the EMA.

What did you find?

If we read the study carefully, we discover some interesting things: for example, they infected the vaccinated animals to study the effectiveness of the vaccine with a virus that had the same spike sequence as the vaccine antigen, so that they could obtain neutralising antibodies, but it turned out that the animal became infected anyway and could therefore transmit the virus, i.e. the vaccine was not sterilising, which is necessary to stop contagion. The animals were therefore not infected with the circulating virus, which was and is now even more mutated than the virus in the vaccine. This made it impossible to assess the efficacy and danger of the vaccine, as was done for the SARS vaccines. In addition, they used primates, which do not develop the fatal complication.

But regulatory agencies are accepting these studies....

They're accepting studies that to date have inconclusive results; they can't say that it's been proven that they don't develop aggravation of the disease because it hasn't yet been studied properly.

So why do they talk about 95% efficacy for the Pfizer-Biontech vaccine and even higher for the Moderna vaccine?

The 95% efficacy relates to the protection of a very small number of people who developed the disease in the two groups, vaccinated and unvaccinated, but if you calculate the risk reduction values, in particular the absolute risk, it turns out that to protect 13 people from the disease we have to vaccinate 1000. So in fact the effectiveness is not yet known because the vaccines were tested mainly in the summer, i.e. at a time when the epidemic was already over and therefore the vaccinated were no longer exposed to the virus.

Why has this been accepted by agencies?

Because they reason according to the criterion of risk-benefit assessment, i.e. they compare how many people die of Covid and how many die from an adverse reaction. Suffice it to say that more and more people die of Covid. But the number of people who die of Covid is not a true figure because we know very well that many deaths, exactly how many we do not know, due to complications from other diseases have also been grouped together in Covid deaths. So we cannot use it for risk-benefit assessment.

What are the main findings of your study?

I am studying the various vaccine platforms in depth, although not exhaustively, because of the exceptional number of vaccines being studied.

Do they include new technology vaccines that use mRNA?

There are not very many. Most of them are inactivated virus vaccines that use adjuvants or protein subunits, i.e. the classic vaccines. And then there are nanoparticle vaccines. We are facing something unprecedented; for no other disease have we had such an investment in the development of vaccine platforms for a single virus.

What do you think?

My impression is that the mRNA vaccine has issues that do not allow it to be used on a large scale. The need to respect the cold chain with such a low temperature, -80°C, an expiry time of only 6 months makes it a very difficult commercial product to manage.

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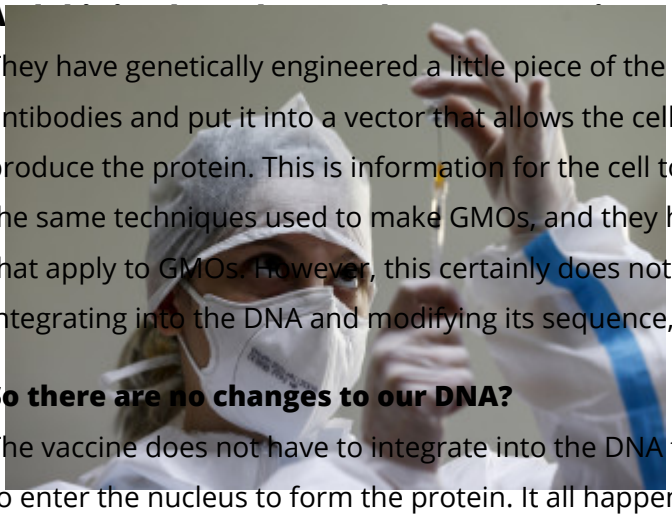

They have genetically engineered a little piece of the virus that is capable of forming antibodies and put it into a vector that allows the cell to recognise it so that it can produce the protein. This is information for the cell to produce the antibodies. These are the same techniques used to make GMOs, and they have to comply with the regulations that apply to GMOs. However, this certainly does not mean that the vaccine acts by integrating into the DNA and modifying its sequence, i.e. it is not a gene therapy.

So there are no changes to our DNA?

The vaccine does not have to integrate into the DNA to work. The mRNA does not need to enter the nucleus to form the protein. It all happens in the cytoplasm where the ribosomes are.

What could happen?

One event, albeit unlikely, that could happen and that has not been ruled out by studies is that this mRNA could be retrotranscribed and could still integrate to produce an adverse reaction. Retrotranscription and integration into the DNA of RNA viruses is well

described in the literature, and SARS-Cov-2 has also been shown to have virus fragments integrated into its DNA in the cells of people who have developed Covid.

So it doesn't work by mutating genetics, but it could still get in?

Yes, unfortunately there is a lack of studies carried out to accurately verify the incidence of this potential adverse reaction. The most serious risk in my opinion is the modification of gene expression, i.e. epigenetic alteration. If the nucleic acid vector, particularly the adenovirus vector, enters the nucleus, although it does not integrate, it can interact in the DNA and affect its ability to express itself. This is an epigenetic modification, which does not change the DNA sequence, but this is potentially more likely than integration.

What can be the consequences of this change in DNA expression capacity?

The consequence is the development of new autoimmune or degenerative diseases because defective proteins may be produced or they may not be produced at all. If the expression of a gene that is essential for the life of the cell is blocked, it is obvious that there will be damage.

What reasons did the EMA give for not requiring these tests?

That the vaccine is administered once, with at most one or two booster shots, and is not able to cause cancer, for example, because it is assumed that cancer must have continuous exposure in the body in order to develop, but this must be demonstrated with appropriate studies on the ability to cause mutations and induce tumours, i.e. with oncogenicity studies. We do not really know how long these vaccines are able to remain in the body and whether they distribute themselves in the various organs.

What is the time frame for protection against infection?

For protection, the problem is twofold: from what we have seen, the antibodies are short-lived. They seem to last two or three months and tend to decay over time. But then: what kind of antibody is formed? If these antibodies are weak, it is very risky, because it favours the strengthening of the disease, especially if one is vaccinated close to the infection. But as I explained earlier, we do not yet have this information.

It is said, however, that substantiation of effectiveness will inevitably occur in the post-marketing phase...

Yes, that's true, and this applies to all vaccines. Even the flu vaccine has an accelerated authorisation every year and with a very short clinical trial. However, post-marketing has a problem: adverse reactions are collected by passive reporting. This means that either the vaccinated person reports them of his or her own free will, or he or she tells the

doctor, who in turn reports to AIFA (Italian Medicines Agency) and regulatory bodies such as EMA. Unfortunately, doctors who pass on to the agencies adverse reactions reported by their patients are 1 in 10, or even fewer, which means that we have an underestimation of 90% of adverse reaction reports.

Let's move on to virus mutations. Can they affect the efficacy of the vaccine?

Yes. They affect it for two reasons: the first is that they are mutations that occur in the area of the spike, the protein used by the immune system to produce antibodies. If my protein has a different conformation because of the mutations, there is a change in the way the antibody binds to the protein and therefore it binds in a much weaker way. Secondly, there is already a lot of literature on the fact that RNA viruses such as SARS-Cov-2 are able to form mutant populations. Vaccine antibodies produced by nucleic acid vaccines (mRNA and adenovirus) are very specific and therefore those mutants that do not bind to the antibody will be favoured in replication. This risks vaccine resistance.

Is this the case in England?

The fact that the English mutant appeared after the start of the vaccination campaign could be vaccine resistance. This phenomenon is very similar to antibiotic resistance, because the RNA viruses form a population of mutants in the body of the infected person that compete with each other and those that do not bind to the vaccine antibodies will be favoured. This can lead to the development of mutants that may even be more contagious and aggressive. Mass vaccination of the entire population, in this case instead of leading to the herd effect, risks leading to the opposite effect, i.e. rapid vaccine resistance.