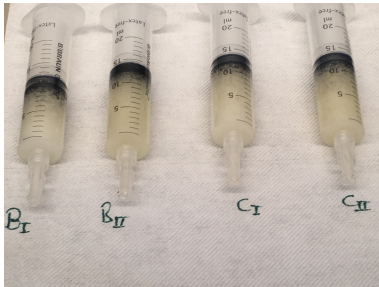


Bacteriophage Therapy

semi-solid, solid and release modified applications



source: S. F. Junghans

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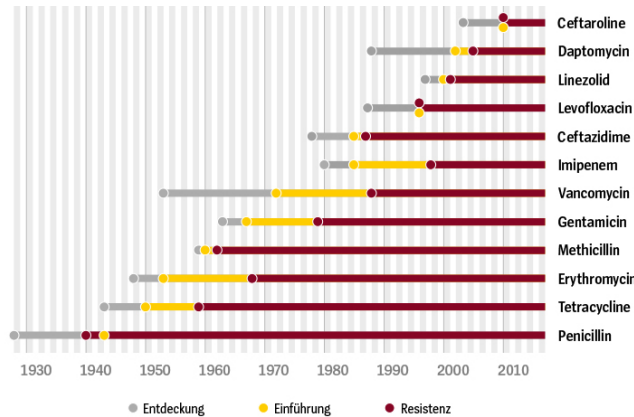
Overview

Therapy problems

Bacterial infections are still one of the leading causes of death worldwide. In addition, this situation is worsened by the increasingly development of nosocomial infections and antibiotic resistance.

According to figures published by the Robert Koch Institute, the number of nosocomial infections only in Germany is approximately 600,000 per year, of which about 20,000 die annually.

Times of Developing first resistances



source: Kupferschmidt, Kai (2016). Resistance fighters. Science 352 (6287): 758-761. DOI:10.1126/science.352.6287.758-759.

Latest studies

Current knowledge and studies, initiated by the frustrating, antibacterial therapy outcomes, resulting from the serious antibiotic resistance problem, show very good Results of bacteriophage-therapy and in addition no side effects.

Moreover, it has been shown that the bacteriophage solutions used can be produced in such a way that they meet the qualitative requirements of the European Pharmacopoeia.

Bacteriophages

... ad-on, or problem solving?

Bacteriophages are often described as the solution to the acute resistance problem. However, the impression must not be given that the antibiotics currently used will become less important due to the establishment of bacteriophage products. Bacteriophages offer the possibility of drastically reducing the use of antibiotics in all areas of application, can ensure therapeutic success and reduce therapeutic antibiotic doses by using synergy effects.

bacteriophages an safety

Bacteriophages (syn.: phages) are viruses with a special host specificity: A bacteriophage species has only one type of bacteria as its target, which is infected by the corresponding virus, so that the bacterial cell only produces clones of the infecting virus and is consequently destroyed, whereby the clones of the bacteriophage are released and infect further bacteria.

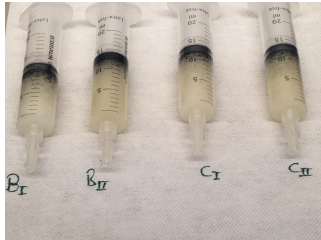
Host specificity has the advantage, that only the specific bacteria are attacked, which means that, on the one hand, bacteria that we need physiologically and which, like the intestinal microbiome, are currently the focus of much research, are not attacked. Patients therefore do not experience any weakening or other side effects from the therapy. Secondly, no human cells are attacked. Bacteriophages that do not find target bacteria are excreted from the body through urine and faeces.

Bacteriophage therapy is therefore a gentle, efficient antibacterial therapy for all patients, in particular for elderly and / or weakened patients, since no side effects or other physiological weaknesses are initiated.

Products

GEL

Sterile gels of different viscosities can be produced in which the phages, presented in the matrix, remain lytically active and are released by the action of body temperature, which lowers the viscosity of the gel.



source: S. F. Junghans
Bakteriophage-Gels: different viscosities

COMBINATIONS

By means of a two-injection-technique, the gels of different, final viscosities and the phage mixtures, which differ in the bacteriophages compiled according to indication, can be freely combined.

The product is sterile-packed with an application aid, so that the gel generation and thus the selection of the phage mixture can take place shortly before application e. g. on the operating table.

LYOPHILISATION

Freeze-drying is provided as a sponge-like, solid phage application. This product is used for the circular coating of e.g. anastomoses, for acute and persistent infection prophylaxis up to days after surgery.



source: S. F. Junghans
Bakteriophage-Lyophilisation



source: S. F. Junghans
Bakteriophage-Lyophilisation manually deformed

All products can be generated with different phage mixtures.

The contained phages of the finished products are compiled according to indication.

Quality

All application forms could be generated sterilely in all experiments under aseptic production.

Testing for sterility was performed using the direct loading method (Ph. Eur. 2.6.1) and was extended to nine days in order to increase the detection limit of bacteria contained in the final product.

Release Modification

The release of the phages contained in the respective product is controllable via the composition and proportions of the ingredients.

For the phage-gel, it is possible to proceed in such a way that the decision on release characteristics and phage mixture is made by the treating person shortly before application, so that the gel base and phage mixture can be prepared on the basis of the respective, individual requirements.

If the treating person decides against this option, at least the phage mixtures according to the given indication have to be selected.

OUTLOOK

Compared to the phage solutions currently used in research and clinical trials, the semi-solid and solid application forms, which additionally have the possibility of modified release, provide the prospect of a situationally appropriate and sufficient antibacterial therapy with regard to extra- and intra-corporal application.

In addition, a microbiological examination of the infectious bacteria prior to therapy is no longer obligatory, since the products contain the phage mixtures against the germs that statistically most frequently cause the corresponding infection on the basis of investigations and studies.

This is a revolution for the applicability of bacteriophage therapy!

The possibility of **semisolid and solid application of bacteriophages,** whose **composition based on scientific knowledge of the respective indication,** and the **modified release of the therapeutic agent,**

calls for a rethink and the rapid implementation of the therapeutic use of bacteriophages,

that can become reality with us and our possible products.



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