

Placebo in Proving

Exclusion or Inclusion Criteria? A Paradigm Shift due to Observations

Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Placebo = I will please ≠ deceit (informed consent)

- A placebo reaction is a reaction to any therapeutic or proving situation, and is not related to the active drug component.

Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Placebo = I will please ≠ deceit (informed consent)

- The incidence of placebo symptoms is high in general (about 30 % in some studies) and their origin is still speculative.

Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Placebo = I will please ≠ deceit (informed consent)

- In homeopathic proving remedies (C 30) we don't have an active „drug component“
 - Don't mind microbubbles, nanospheres or photon theories at this point of the considerations!



Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Placebo = I will please ≠ deceit (informed consent)

- A proving study about Okoubaka showed no difference between placebo and verum symptoms (Teut et al. Homeopathic drug proving of Okoubaka aubrevillei: a randomised placebo-controlled trial. *Trials*. 2013; 14: 96)
- Conclusion? Are proving symptoms mere placebo or are placebo symptoms already a proving?

Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Placebo paradoxon

- Several clinical trials showed a significant placebo effect, sometimes higher than the drug effect of already proven beneficial drugs or operations.
- In hom. provings we often see proving symptoms (= changes from normal equilibrium) in the placebo group, that are specific to the remedy. (double blind)
 - These symptoms are cured by the remedy and therefore verified.
- In blinded trituration provings we often see remedy symptoms without remedy intake (unless by smelling?)
 - These triturations showed a compatibility with traditional provings, as high as two standard provings compared together. (Hildebrandt 2013, Pele's hair)

Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Hypothesis

- We don't prove a pharmacon against a specific proving situation (= placebo), BUT:
- We compare a specific proving situation against the individual normality



Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Hypothesis argumentation

- Therefore placebo group is **not an adequate means** of differentiation neither in quality (exclusion) nor in quantity between the symptoms
- it is important to have an „attention“ prephase to differentiate equilibrium phase from intake phase.

Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Hypothesis argumentation

- This, in turn, does in no way mean that a remedy is a placebo, or a deceit.
- We just refer to the *proving situation*, which is the opposite of the *treatment situation*. (similia similibus!)
- In a treatment we match the patient's symptoms with the symptoms induced by the remedy in the proving situation. These symptoms are not inducible by the placebo.

Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Reinhard how often could you see valid placebo symptoms in your numerous provings? Can you give examples?



China off. tree in Peru

- Flick: in 7 of my 14 provings a placebo prover returned a protocol.
- 4 of these 7 placebo provers showed obvious reactions to the placebo.
- Hildebrandt: in 6 of 7 placebo controlled provings I had symptoms in the placebo group

Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Reinhard : are these symptomes just surprisingly new symptoms, or are they related to the specific remedy?

- Natrum phosphoricum in 1999
- Magnesia iodata in 2003
- **prover 5:** Twitching of left upper lid for 8 days
- **placebo prover:** His own symptom of twitching of the left upper lid disappeared for 7 weeks (and his palpitations!)
- Placebo prover 3 reacted with numerous symptoms:
- Her mental symptoms were clearly "magnesia" whereas her cough-symptoms << in warmth and better outside fitted perfectly to the iodium-modalities.

Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Jörg: have you ever seen symptoms that originated only in the placebo group, but cured in the therapeutic situation?



- Aqua St. Leonhard (enteisent = from bottle)
- A hyperreaction to a mosquito bite twice and several itching eruptions in a placebo.
- Two patients with urticaria cured.
- No generalized skin symptoms in verum

Flick Reinhard MD, Hildebrandt Jörg MD
Austria

Jörg: have you seen symptoms in the placebo group, which turned out to show the specific traits of a remedy?

Toxopneustes pileolus

- I use it with succes in orbital /periorbital pain, either referred pain from neck, or myositis /skleritis.

- The placebo showed:

- Sticking behind right eye around opticus
- Sticking right eye laterally, several times, followed by heat.



Flick Reinhard MD, Hildebrandt Jörg MD Austria

Acanthaster planci

- A remedy for influenza with extreme weariness.

- The placebo showed

- weariness with and without common cold symptoms and shivering



Reinhard: If we accept the coincidence of placebo and verum symptoms – What are the reasons?

- Remedies influence each other by:

- Being stored together
- Intake at the same time
- Intake in a close distance
- Not any influence?
- Not even necessary?



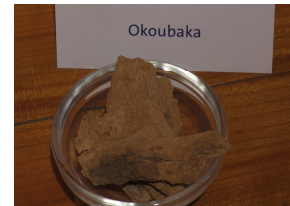
Flick Reinhard MD, Hildebrandt Jörg MD Austria

Okoubaka proving Flick

- 10 +10 verum, 10 placebo,
 - prepared at different times by Remedy company
 - never stored together in the same room and
 - sent per mail to one of the three proving-coordinators at different times.
 - handed out to the provers without contact to one another

Okoubaka proving Flick

- Finally included: 8 verum, 5 placebo
- All 5 placebo showed specific smptoms,
- 2 showed a strong reaction



Conclusion

- It is unlikely to be a sort of „contamination“ between verum and pacebo probes
- Placebo group in hom. proving is essential for psychological reasons (less pressure to succeed).
- Placebo symptoms should not be excluded, but included.

Flick Reinhard MD, Hildebrandt Jörg MD Austria

Conclusion

- Further studies are needed to evaluate the intrinsic nature of proving symptoms.
- Neither photons nor microbubbles may explain these „pseudo contaminations“
- whatever this intrinsic nature of the proving effect is, it does have the effects we observe since hundreds of years!

Flick Reinhard MD, Hildebrandt Jörg MD Austria

Conclusion

- To get closer to the understanding of proving effects we must stop to think we do drug trials –
- On the opposite: we suggest, that rare side-effects of drugs are proving effects of their homeopathic nature

Reinhard Fick MD, Hildebrandt Jörg MD
Austria

Now let's have a verum break!



Flick Reinhard MD, Hildebrandt Jörg MD
Austria