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Widespread use of pure and impure placebo interventions by GPs in Germany

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Aim. To collect data on the use of placebo interventions by GPs in Germany.

Methods. A questionnaire was mailed to 400 randomly selected GPs in Bavaria. Non-responders were reminded by telephone after 4 weeks and were given a second copy of the questionnaire after a further 3 weeks.

Results. In all, 208 completed questionnaires were returned. The majority of GPs (88%) have used a placebo at least once in their practice; 45% have used pure placebos, such as saline injections and sugar pills, at least once last year; the median frequency of use was 5 [interquartile range (IQR), 2–10]. The use of impure placebos during the past year was more common: 76% of GPs have used impure placebos, i.e. medical interventions that have pharmacological or physical activity but have no intrinsic effect (e.g. pharmacological or physical action) on the patient's disease or its symptoms, with a median frequency of 20 times per year (IQR, 10–50). The main reason for the use of placebo was a possible psychological effect, followed by the expectation of patients to receive a treatment. For the majority of GPs placebo interventions were ethically justified if they were used for a possible psychological effect.

Conclusions. Placebo interventions are a widely accepted part of medical treatment in German general practices and are used primarily for their psychological effects. Impure placebos are used much more frequently than pure placebos.

Keywords. Medical ethics, placebo effect, placebos/therapeutic use, primary health care, professional–patient relations, questionnaires.

Introduction

In the past decade, numerous studies have shown that placebo interventions can improve the health and well-being of patients. The deliberate use of placebos in practice, however, remains problematic for ethical reasons. At the same time, surveys in various countries have shown that physicians use placebos regularly in their practice.[1] For example, a recent survey of internists and rheumatologists in the United States showed that 80% of them prescribe placebo treatments to their patients, 46% at least once a month.[2]

The frequency of placebo administration differs between hospital and outpatient setting: According to a Danish study 86% of GPs confirmed the use of placebo interventions in the past year in contrast to only 54% of physicians in hospital.[3] Furthermore, the frequency of use of placebo seems to vary with the type of placebo: A Swiss survey showed that impure placebos are used more often than pure placebos.[4] Impure placebos are defined as medical interventions that have a pharmacological or physical activity, but not for the actual disease or its symptoms (e.g. antibiotics for viral infections, vitamin supplements without vitamin deficiency), while pure placebos are inert treatments, such as sugar tablets and saline injections.

The present study aimed to investigate the frequencies and motivations for the use of pure and impure placebos in German practices of general medicine. We were also interested in the attitudes towards placebo use, and what GPs tell their patients if they want to administer a placebo. Since the use of placebos probably depends on what the person knows about placebo effects, we also posed questions about the assumed mechanisms of placebo analgesia and the potential impact of positive expectations on health.

Methods

Questionnaire and procedure

A pilot version of the questionnaire was sent to 20 GPs in Bavaria. A further five GPs were interviewed after

filling out the pilot version in order to assure the clarity of questions. The final questionnaire consisted of seven questions focusing on pure placebos, eight questions on impure placebos and seven questions on demographic data (Appendix). Questions about impure placebos were posed without using the term 'placebo'. Instead, they were described as drugs and other therapies with no intrinsic effects (e.g. pharmacological or physical activity) on the current patient's symptoms.

The questionnaire was sent to 400 GPs. This was a random selection from the 6700 GPs in the database of the Bavarian Medical Association. Data collection was conducted from November 2009 to February 2010. A package containing a letter explaining the purpose of the study, a numbered questionnaire, a stamped return envelope and a small gift was sent to each doctor. The letter promised a lottery drawing of €100 among the responders. After identifying the non-responders, the questionnaires were renumbered to ensure anonymity. Non-responders were reminded by telephone to complete the questionnaire after 4 weeks and were given a second questionnaire copy after a further 3 weeks.

Data analysis

We used descriptive statistics to summarize the results. Subgroup comparisons were done with Chi-square test. Statistical analysis was performed with SPSS (version 18). A P-value $\leqslant 0.05$ was considered significant.

Results

Study population

In all, 219 of 400 questionnaires (55%) were returned. Eleven physicians, who worked exclusively as a psychotherapist, were excluded. Thus, we analysed 208 of 389 questionnaires, representing a response rate of 53%. Demographic characteristics of responders are summarized in Table 1.

Frequencies of placebo use

Eighty-eight per cent of GPs confirmed that they have used pure and/or impure placebos at least once in their practice. Of the 208 physicians, 101 (49%) reported that they have used pure placebos outside of clinical trials, and 94 (45%) have done so at least once during the last year. The median frequency of use per year was 5 [interquartile range (IQR), 2–10]. Forty-one GPs (21%) had placebo tablets in their practice in stock. The use of drugs and other therapies with no intrinsic activity (e.g. pharmacological or physical activity) for the patient's current symptoms (so-called 'impure placebos') was confirmed by 175 of the 208 physicians (84%). One hundred and fifty-seven GPs (76%) reported that they have used impure placebos at least once during the last year, with a median frequency of 20 times per year (IQR, 10–50). Most often, herbal remedies were used as impure placebos (73%), followed by homeopathic remedies (62%), vitamin preparations (62%), minerals and micronutrients (58%), mild sedatives (30%), massages (30%), acupuncture (21%) and antibiotics (20%).

Using a case example, we asked the doctors how they would treat a patient with cold and cough, when the patient insisted on antibiotics, but there was no evidence of a bacterial aetiology of his symptoms. In such a situation, 25% of surveyed GPs would prescribe antibiotics.

Table 1 *Demographic characteristics of respondents*

Variable	n	
- Age, mean ± SD	204	52.8 ± 7.6
- Males/females, n (%)	208	139 (67%)/69 (33%)
- Certified specialization for general practice or internal medicine, n (%)	208	181 (87%)
- Years in practice, mean (SD)	208	17.1 (9%)

Reasons for the use of placebo

In all, 78 of the 101 (77%) doctors, who gave pure placebos, used them because of their psychological effect, followed by the expectation of the patient to receive a treatment (57%), the impression of GPs that the patient wanted more drugs than necessary (47%), the handling of a difficult treatment situation (46%) and non-specific complaints (31%). A quarter of GPs (25%) reported the use of pure placebos for diagnostic reasons. Other reasons were the prevention of drug dependence (22%), and use as an additional treatment option (19%).

The most common reason for the use of impure placebos was a possible psychological effect (79%), followed by the expectation of the patient to receive a treatment (52%), the use as an additional treatment option (47%), the handling of a difficult treatment situation (47%) and non-specific complaints (42%).

We conducted exploratory analysis in order to learn more about the possible motives of the 25% of GPs, who would prescribe antibiotics for non-bacterial infections, if the patient insists. Among all users of impure placebos, this subgroup used impure placebos more frequently because the patient expected a treatment (68% versus 46%; $P = 0.011$), in order to deal with a difficult treatment situation (62% versus 41%; $P = 0.026$), or as a further treatment option (62% versus 41%; $P = 0.026$).

Patient information

The ways in which GPs inform their patients during the administration of pure and impure placebos is summarized in Table 2. Only a few doctors informed their patients that the treatment itself had no intrinsic effect on the current health complaints.

TABLE 2 *Information of patients by GPs when giving out pure placebos (n = 101) and impure placebos (n = 175)*

Information	Pure placebos, *n* (%)	Impure placebos, *n* (%)
- Treatment stimulates self-healing powers	49 (49%)	136 (78%)
- Treatment is highly effective	46 (46%)	49 (28%)
- Treatment has helped other patients	44 (44%)	65 (37%)
- Description of expected effects	12 (12%)	57 (33%)
- No information	11 (11%)	8 (5%)
- Treatment itself actually is not effective	2 (2%)	10 (6%)

Attitudes

The attitudes towards the placebos were different for users and non-users of both pure placebos (Table 3) and impure placebos (Table 4). The most frequent justification for the use of placebo was a possible psychological effect.

Placebo-related beliefs

The first question with respect to pure placebos presented the case of a chronic pain patient who received a saline injection instead of his usual analgesics and reported pain relief thereafter. The GPs were asked about their beliefs regarding the reasons for this improvement. The answers are displayed in Figure 1.

When asked about possible effects of expectations, 197 doctors (95%) answered that subjective symptoms such as stress could be relieved; 184 doctors (89%) deemed possible that disease-related subjective symptoms, as pain or itching, would improve; 159 GPs (76%) expected that bodily functions, such as autonomic and immunological processes, would improve. Only three doctors (1%) did not expect any improvements by expectations.

Discussion

This is the first survey on the use of placebo interventions in outpatients in Germany. In all, 88% of respondents had administered either a pure or an impure placebo at least once in their practice. Impure placebos were used much more frequently than pure placebos: They were administered by more physicians (76% versus 45% in the preceding year) and more often (median 20 versus 5 times in the preceding year). For both pure and impure placebos, the most frequently reported reason for use was a possible psychological effect. The majority of GPs believed that expectations can improve subjective and objective symptoms. Both pure and impure placebos were usually administered without informing the patient that the treatment had no intrinsic effect on the current health complaints.

The response rate of 55% in our survey is acceptable but not high. Our sample consisted only of GPs from Bavaria, and we cannot rule out that the results may be different in other states of Germany. A major problem in any survey on placebo use is the concept of impure placebo. The decision whether an intervention is still an active treatment or a placebo depends on personal attitudes and situational factors. If physicians are asked to define placebo they generally describe

TABLE 3 *Attitudes towards the use of pure placebos by users (n = 101) and non-users (n = 107)*

Item	User, *n* (%)	Non-user, *n* (%)	Chi-quadrat *P*-value
Acceptable, ...			
- when used for their psychological effect	94 (93.1)	67 (62.6)	<0.001
- when used for diagnostic reasons	62 (61.4)	36 (33.6)	<0.001
- because they do not harm	50 (49.5)	40 (37.4)	0.052
- when all other treatment options are exhausted	36 (35.6)	34 (31.8)	0.329
Not acceptable, because of ...			
- threatening the doctor–patient relationship	2 (2.0)	30 (28.0)	<0.001
- decepting the patient	3 (3.0)	25 (23.4)	<0.001
- lack of efficacy	0 (0.0)	5 (4.7)	0.034
- legal problems	1 (1.0)	5 (4.7)	0.213

TABLE 4 *Attitudes towards the use of impure placebos by users (n = 175) and non-users (n = 33)*

Item	User, *n* (%)	Non-user, *n* (%)	Chi-quadrat *P*-value
Acceptable, ...			
- when used for their psychological effect	144 (82.3)	14 (42.4)	<0.001
- when clinical experience showed usefulness	113 (64.6)	18 (54.5)	0.327
- when all other treatment options are exhausted	110 (62.9)	9 (27.3)	<0.001
- when patient's demand	95 (54.3)	6 (18.2)	<0.001
Not acceptable, because of ...			
- decepting the patient	2 (1.1)	9 (27.3)	<0.001
- threatening the doctor–patient relationship	6 (3.4)	8 (24.2)	<0.001
- lack of efficacy	1 (0.6)	3 (9.1)	0.013
- legal problems	6 (3.4)	1 (3.0)	1.000

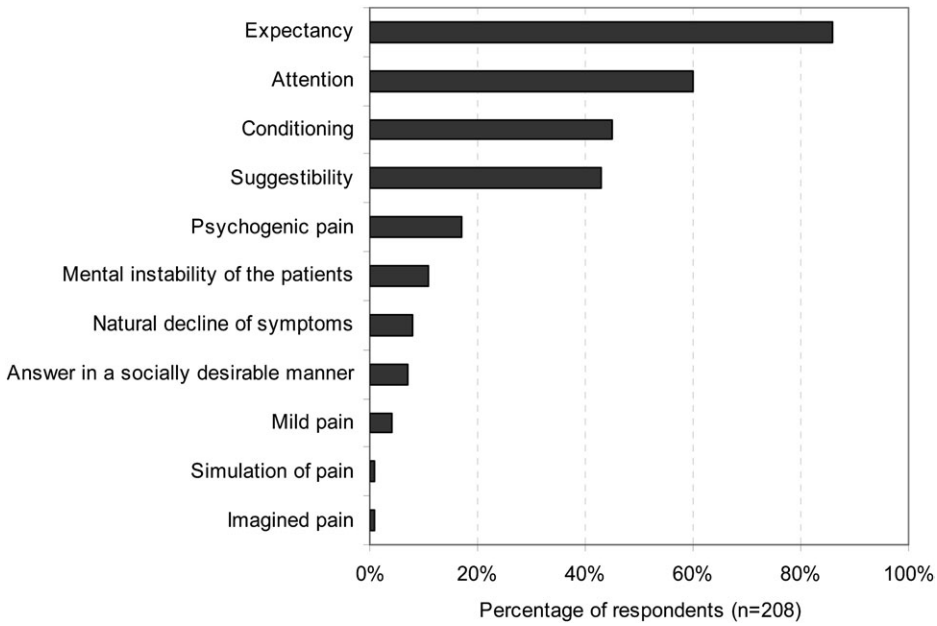

FIGURE 1 *GPs' beliefs regarding the reasons for pain relief by placebo*

pure placebos (5). Many physicians do not know the term impure placebo, and surveys either explain it in questionnaires or—as we did—use circumscriptions. The data on pure placebos are therefore more reliable than the data on impure placebos.

The frequency of placebo use in our study is comparable to data from Denmark and the United States, according to which 86% and 80% of GPs or internists give placebos.[2,3] Furthermore, the proportion of German physicians who use pure placebos in outpatients is similar to that in the hospital[6] and to respective data from Israel.[7] These data are contrasted by recent results from Switzerland, where only 17% of GPs confirmed the use of pure placebos.[4] Similarly, the use of impure placebos in the Swiss survey was lower than in ours (54% versus 84%, respectively). Whether these differences will be attributable to national differences or to different types of questions remains to be investigated.

Impure placebos seem to be used rather regularly by German GPs at a first glance (in median, 20 times per year). Although the true figure may even be higher, we want to emphasize that German GPs treat ~250 patients per week.[8] Thus, impure placebos appear to be prescribed more sporadically than regularly.

Our findings suggest that most GPs—possibly because of their own experiences—take placebo effects seriously. However, there were also more pragmatic reasons for the administration of placebos, such as the request for treatment of the patient, a difficult treatment situation, or non-specific complaints of the patients. Apparently, GPs feel sometimes under pressure to administer a treatment although there is no specific treatment for the current patients' symptoms. Then they resort to placebo interventions in order to meet the patients' needs.[9] Especially the deeper motivations of prescribing impure placebos could be even more complex. Qualitative studies suggest that a complex mixture of internalized role models, perceived patient expectations, fear of conflicts and lack of time play a major role.[9,10] Also the question of what exactly determines the choice of a pure or impure placebo remains unclear. These questions probably require qualitative approaches to be resolved.

Only a minority of physicians informed their patients that the treatment had no physical or pharmacological effect on the current condition. The most popular information during administration of placebos was the stimulation of self-healing powers (Table 2). This seems plausible since it is a popular concept to describe the effects of alternative treatments and placebo interventions.[11,12]

The GPs' ideas about the mechanisms of placebo analgesia (Fig. 1) fit well with the latest understanding of the psychological mechanisms of placebo effects.[13] Few doctors have argued that the pain was psychogenic, simulated or not real, or the patient was mentally unstable. This is in contrast to a survey of thirty years ago, when the majority of doctors still used placebos to determine whether pain was real.[14]

The attitude of GPs with respect to the administration of placebo interventions was surprisingly liberal. Both pure and impure placebos were regarded ethically justifiable for most of the GPs if used for a possible psychological treatment effect. Ethical concerns regarding the impairment of the doctor–patient relationship and deceptive behaviour were almost exclusively found among non-users (Tables 3 and 4). A disturbing finding

was that some of the GPs do not hesitate to give impure placebos, which are potentially harmful, such as antibiotics for common cold with no evidence for a bacterial genesis. Non-indicated prescription of antibiotics may be detrimental and clearly is in contrast with the ethical principle of 'nil nocere'. Also the use of 'harmless' placebos is ethically controversial.[15] The German Medical Association has recently defined a few situations in which placebos can be administered in an ethically acceptable way.[16] Following these recommendations, the physician can use placebos without mentioning the term placebo. In contrast, in the USA, the non-deceptive and transparent use of placebos is discussed as the only viable way to administer placebos.[17]

In conclusion, we found evidence for a widespread and liberal use of placebo interventions among German GPs. The proportion of GPs who confirmed the use of placebos was pretty similar to most available data from other countries. Placebo effects were perceived as real and serious phenomena. Qualitative studies are needed to better understand the GPs' motivations, especially for the use of impure placebos.

Declaration

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Appendix: English translation of the questionnaire

Questionnaire on the use of non-specific treatment effects in ambulatory health care

I. Questionnaire

1. A forty-year-old man, self-employed, visits you in your practice complaining of a cold and cough. He wants an antibiotic, so that he can work again as soon as possible. On examination, you can see no medical indication for an antibiotic. The patient insists, however, as antibiotics had helped him very well during the last cold. What would you do most likely in that situation? (multiple answers possible)

   ☐ Prescribe an antibiotic.
   ☐ Prescribe/recommend a drug or a treatment for symptoms of common cold.
   ☐ Offer a check-up in the next few days.
   ☐ Other:_____

2. Have you ever used medicine or therapies, even if you considered that they had **no intrinsic effect** (e.g. pharmacological or physical action) on the patient's disease or its symptoms?

   ☐ Yes
   ☐ No ☞ continue with question 7

3. Rough estimate, in how many patients in the last year?
   In approx. _____ patients in the last year.

4. What was your motivation? (multiple answers possible)

- ☐ Because the patient was expecting a therapy.
- ☐ Because of a possible psychological treatment effect.
- ☐ In patients with symptoms that could not be ascribed to any particular disease ('non-specific complaints').
- ☐ To be able to still offer a treatment option to patients with untreatable, incurable disease.
- ☐ For constantly complaining patients, to bridge a difficult treatment situation.
- ☐ For other reasons: _____

5. Which forms of drugs/therapies have you already used **for that purpose** (see question 2)? (multiple answers possible)
   (Here are just meant situations where you personally felt that the treatment has no intrinsic/specific effects on the actual symptoms; we do not mean the general use of these treatments).

   - ☐ Minerals and trace elements
   - ☐ Vitamins
   - ☐ Mild sedatives
   - ☐ Antibiotics
   - ☐ Homeopathic remedies
   - ☐ Phytotherapeutics
   - ☐ Acupuncture
   - ☐ Massages
   - ☐ Other: _____

6. How did you inform your patients? (multiple answers possible)

   - ☐ This is a highly effective drug/a highly effective therapy.
   - ☐ This therapy has helped many other patients.
   - ☐ This treatment promotes self-healing/the healing process.
   - ☐ This is a treatment without pharmacological or physical effect for your condition.
   - ☐ I said what effect is expected from the therapy.
   - ☐ I said nothing.
   - ☐ I said (*please add yourself*): _____

7. What is your opinion towards the use of drugs and other therapies that **do not have any intrinsic effect** (e.g. pharmacological or physical action) on the current disease of the patient or its symptoms? (multiple answers possible)

   - ☐ Are acceptable if they are used for their psychological effect.
   - ☐ Are acceptable when all other therapies have been exhausted.
   - ☐ Are acceptable when the patient wants this therapy.
   - ☐ Are acceptable if the clinical experience has shown a benefit.
   - ☐ Are not acceptable because they involve the deception of the patient.
   - ☐ Are not acceptable because they endanger the trust between doctor and patient.
   - ☐ Are not acceptable because the efficacy is insufficient.
   - ☐ Are not acceptable because of legal problems.

8. Maybe you know the following case: A hospital patient with severe pain receives a painkiller iv 3 times a day and on demand. On days with very high needs the painkiller is occasionally replaced by saline injections. Upon request, the patient reported in each case that the 'painkiller' worked well. What conclusions can you draw from the effectiveness of the saline injection? (Multiple answers possible)

   - ☐ The pain had not organic cause, but was psychogenic.
   - ☐ The pain was not particularly strong.
   - ☐ The pain was imagined.
   - ☐ The patient is very suggestible.
   - ☐ The patient is mentally unstable.
   - ☐ The patient has simulated the pain.
   - ☐ The intensity of pain decreased naturally.
   - ☐ The patient has given a favour answer.
   - ☐ The pain reduction was conditioned (learned).
   - ☐ The expectation of pain reduction has led to the decrease in pain.
   - ☐ The positive attention by the nursing staff has led to a decrease in pain.
   - ☐ Other:_____

9. Do you have pre-fabricated placebo preparations (e.g. placebo tablets, injections with saline solution, artificial sweetener pills, etc.) in stock in your practice?

   - ☐ Yes
   - ☐ No

10. Did you ever use in your practice placebos (e.g. placebo pills, saline injections, sweeteners, etc.) outside of clinical trials?

    - ☐ No ☞ continue with question 14
    - ☐ Yes

11. Rough estimate, in how many patients in the last year?

    In approx. _____ patients in the last year

12. What was your motivation? (multiple answers possible)

☐ Because the patient was expecting a therapy.
☐ Because of a possible psychological treatment effect.
☐ In patients with symptoms that could not be ascribed to any particular disease ('non-specific complaints').
☐ To be able to still offer a treatment option to patients with untreatable, incurable disease.
☐ For constantly complaining patients, to bridge a difficult treatment situation.
☐ If a patient asked for more drugs than you thought necessary.
☐ As a test of whether symptoms were psychogenic or organic (differential diagnosis).
☐ To prevent drug dependence.
☐ For other reasons: _____

13. What did you tell your patient? (multiple answers possible)

☐ This is a highly effective drug or a highly effective therapy.
☐ This treatment has helped many other patients.
☐ This treatment promotes self-healing/the healing process.
☐ This is a treatment without pharmacological or physical effect.
☐ I said what effect is expected from the therapy.
☐ I said nothing.
☐ I said: (*Please add yourself*) _____

14. What is your attitude towards the use of placebos? (multiple answers possible)

☐ Are acceptable if they are used for their psychological effect.
☐ Are acceptable when all other therapies have been exhausted.
☐ Are acceptable if they are used as a diagnostic.
☐ Are acceptable because they do not harm.
☐ Are not acceptable because they involve the deception of the patient.
☐ Are not acceptable because they endanger the trust between doctor and patient.
☐ Are not acceptable because the efficacy is insufficient.
☐ Are not acceptable because of legal problems.

15. The placebo effect is often defined the proportion of improvement, which goes back to a positive expectation of the patient and not to the specific effect factors of treatment (e.g. their pharmacological ingredients). What kinds of improvements can have positive expectations of the patient you think? (multiple answers possible)

☐ Positive influence on general subjective symptoms, e.g. stress reduction, relaxation.
☐ Positive influence on **disease-relevant subjective symptoms**, e.g. decrease of pain, itch, tinnitus.
☐ Positive influence on **bodily functions**, e.g. improvement of vegetative, biochemical or immunological functions.
☐ Positive expectations do not produce **any improvement**.

II. Background information

1. Your age: _____

2. Your sex:
☐ female
☐ male

3. Are you a specialist?
☐ No
☐ yes, namely for _____

4. How many years have you been in your practice? For approx. _____ years

5. In which area the practice is specialized? _____

6. How many patients do you treat on average per week? approx. _____ patients per week

7. Would you be prepared for a personal interview on the subject?

☐ Yes
☐ Possibly
☐ No

Thank for your help!