Attitudes of Mexican family doctors regarding the use of placebos in clinical practice

*Issa Gil-Alfaro[1], Gad Gamed Zavala-Cruz[2], Azucena Maribel Rodríguez-González[3] and José Manuel Ramírez-Aranda[4]**

[1]Instituto Mexicano del Seguro Social, Family Medicine Unit 66, Xalapa, Veracruz; [2]Instituto Mexicano del Seguro Social, Family Medicine Unit 47, San Luis Potosí; [3]Universidad de Monterrey, Nuevo León; [4]Universidad Autónoma de Nuevo León, Hospital Universitario "Dr. José Eleuterio González", Nuevo León. Mexico

Abstract

Introduction: *The use of placebo has spread in clinical practice despite being controversial. In Mexico, the practice of family medicine is predominantly institutional and works with an essential medications list.* **Objective:** *To determine the frequency and family doctor attitude regarding the use of placebos in clinical practice.* **Method:** *Cross-sectional, observational, multicenter study of 307 family doctors with active practice in 27 states of the Mexican Republic. A questionnaire was used with sociodemographic data and consensus-developed questions about frequency of use and attitudes. For analysis, the square-chi test was used.* **Results:** *75 % used placebos (95 % CI=69.7-79.4%); 122 (39.7%) used pure placebos, mainly water ($p < 0.05$), and 220 (71.6%), impure placebos, mainly vitamins and laboratory tests. They were used more in patients with medically unexplained physical symptoms (178, 45.5%), including 122 (31.2%) "healthy worried" patients, or who had chronic conditions (40, 12.5%). Reasons for prescription: 249 (81%) for the psychological effect, when they showed benefit (176, 57%), even when it implied deceiving (78, 25%) or insufficient evidence of efficacy (57, 19%). The main reason was because of patient insistence.* **Conclusions:** *More impure placebos were used, mainly in healthy worried patients and in those with chronic conditions.*

KEY WORDS: *Placebos. Placebo effect. Family medicine. Community-based medicine. Primary health care.*

Introduction

Consciously or not, placebos have been used since ancient times.[1] Currently, their use is very extended in clinical practice:[2] only 28 % of Swiss doctors have never used interventions with placebo.[3]

The use of placebo in research is a controversial issue, since some consider that in randomized clinical trials it is unfair, although it has been documented that, with its use, results are obtained that are methodologically more reliable.[1,2] In addition, the Declaration of Helsinki (2013) states that "in the absence of existing proven intervention, the use of placebo or no intervention is acceptable".[2,4]

There are various definitions of the placebo effect in medical care, for example: "diverse non-specific, desired or undesired effects of substances or procedures and interactions between the patient and the therapist".[5] Initially, it was thought to be subjective, transient and of low in intensity; however, later it was shown to be objective.[6-8]

There are two types of placebos:[9,10]

- Pure: inert substances or procedures that have no pharmacological effect.
- Impure, substances with pharmacological effect, although not specific to the condition or situation they are being prescribed for.

Generally, the term placebo is used for pure or inert and the impure ones are ignored, even when the latter

Correspondence:
*José Manuel Ramírez-Aranda
E-mail: sersabe2010@gmail.com

Date of reception: 08-09-2018
Date of acceptance: 15-02-2019
DOI: 10.24875/GMM.M19000299

Gac Med Mex. 2019;155:335-340
Contents available at PubMed
www.gacetamedicademexico.com

are more commonly used in daily practice.[9,11] The percentages of placebo use worldwide have a fairly wide range: 17 to 80 % for pure placebos, 54 to 57 % for impure, and if both are considered, 41 to 99 %,[11] or lower, as in Denmark.[12]

Among the reasons for health professionals to prescribe placebos in clinical practice, the following are adduced: their psychological effect, to calm down the patient, to "do something" for them, to avoid more harmful medications,[13,14] to avoid confrontation with patients, as a complementary treatment,[15] as analgesics; they are even used in phytotherapy or homeopathy, with good results being attributed to trust in the doctor.[16]

In Mexico, the practice of family medicine is based on the institutional setting, which is governed by a predetermined list of essential medicines that does not include placebos as such. However, the effect of placebos in family doctors clinical practice and their attitude regarding their use are unknown. Therefore, determining the frequency of placebo use and its relationship with pathologies, identifying the patients in whom it is employed and exploring the attitudes of family doctors towards its use was proposed.

Method

A cross-sectional, observational, descriptive, multicenter study was conducted in family doctors assigned to primary care offices of 27 states of the Mexican Republic, who were members of some medical society or college of the specialty and who signed the informed consent; those without clinical practice were excluded, and those who did not fully answer the surveys or who submitted them out of time were censored.

After authorization by an institutional ethics committee (State of Nuevo León Ministry of Health), with registry code DEISC-19 01 15 05, data were directly collected from the interviewed subjects during their attendance to the 17th Family Medicine National Congress on May 2015 in Tuxtla Gutiérrez, Chiapas, Mexico, or at their offices, with the data being sent by certified mail or electronically scanned.

In a non-probabilistic convenience sampling, the sample size was calculated using a formula for estimating proportions for finite populations with the Pan American Health Organization Epidat 4.0 program, with an accuracy of 5 % and 95 % reliability; considering a total population approximate of 2000 subjects and an expected proportion of the phenomenon of 0.48, a sample size of 323 was obtained.

Those who met the selection criteria were handed a self-applied questionnaire that included:

- Sociodemographic characteristics.
- Professional data.
- Labor data.
- Type of placebos, and relationship with the frequency and pathologies they were used for.
- Attitude of the physician towards the use of placebo.

This section was structured through two rounds of experts, members of the Mexican Network of Family Medicine Researchers, NPO, where the clarity of the questions, the context of participants and bias were assessed.

Data were analyzed using central tendency and dispersion measures for quantitative variables, as well as absolute and relative frequencies for qualitative variables. In addition, an inferential analysis was carried out with chi-square tests, with significance being set at a p-value <0.05 to find a cross-association with categorical variables.

Results

Three-hundred and seven family doctors were included (95 % of the calculated sample; 16 questionnaires were censored due to incomplete data). Women aged 36 to 45 years, married, with postgraduate degree in family medicine, who had worked in an institution for six to 10 years were predominant.

Of the participating physicians, 229 (74.5 %; 95 % CI = 69.7-79.4 %) accepted having used placebos within the previous month (most of them two or more placebo types); 122 (39.7 %) used some pure placebo and 220 (71.6 %), impure placebos. Among the latter, vitamins, procedures (laboratory tests and others) predominated, and the least used were pure or inert placebos: water, inert pastes and saline (Table 1).

The pathologies placebos were used for were quite varied, predominantly mental disorders (64, 19.9 %) and chronic conditions (40, 12.4 %); in most cases, impure placebo was used (234, 72.8 %; $p < 0.001$), as observed in Table 2.

The individuals in whom placebos were most commonly used were healthy worried subjects (31.2 %) and individuals with not medically explained physical symptoms (14.3 %). If we consider patients with medically unexplained mild physical symptoms as "healthy, worried subjects", we conclude that this type of patients constitute almost half of those in whom placebo is used, followed by those cataloged as "difficult subjects", with 13.2 %.

Table 1. Frequency and type of placebos used in clinical practice

Type of placebo	Doctors who use them		Use last month (times)				
	n = 307	%	1-10	11-20	21-50	≥ 51	Not specified
Pure or inert placebos	122	39.7	39				
Water	78	25.4	34	7	17	4	11
Inert pastes	45	14.6	0	4	2	0	5
Lactose	1	0.3	3	1	0	0	0
Starch	3	0.9	33	0	0	0	0
Saline	44	14.3		4	2	1	4
Impure placebos	220	71.6					
Vitamins	220	71.6	149	25	22	3	21
Dietary supplements	58	18.8	39	6	9	2	2
Topical agents	76	24.7	58	8	6	0	4
Alternative medicine	62	20.1	48	1	5	0	8
Others (omega 3, folic acid, hydroxyzine, oral rehydration solutions, arnica, calcarea carbonica pellets)	11	3.5	4	2	2	0	3
Procedures							
Laboratory tests	145	47.2	122	16	4	0	3
Imaging studies	89	28.9	76	8	1	0	4
Medical devices	7	2.2	5	0	0	0	2
Rituals	7	2.2	6	1	0	0	0
Others (verbal communication, meditation, yoga and tai chi exercises, detections, simple micronebulizations)	7	2.28	4	0	0	0	3

($p < 0.05$). Statistical analysis with Chi-square test.
Most surveyed subjects used two or more types of placebo.

The most common reasons for placebo to be indicated were insistence of the patient for being prescribed some treatment (159, 51.7 %) and failure to obtain response to usual treatment (98, 31.9 %). In these cases, the most commonly used were impure placebos (249, 81.1 %).

Doctors considered acceptable using placebos in their practice mainly because of their psychological effect and when clinical experience had demonstrated some benefit, even when it involved deception or their effectiveness was insufficient, with statistically significant differences being found (Table 3). Cronbach's alpha for all nine items to explore family doctors attitudes regarding the use of placebo was 0.726.

Younger professionals, those with updated certification and with one to 10 years of service used placebo more often ($p < 0.05$), while there was no statistically significant association with regard to gender and highest academic degree.

Discussion

In this study there was a predominance of the female gender, which was similar to observations in the United Kingdom;[13] other studies refer a higher proportion of males.[10,14,17,18] Regarding the use of placebos, three out of every four doctors acknowledged using them in their practice, unlike the trends observed in general practitioners in Germany (88 %),[14] Denmark (86 %),[12] India (89 %)[18] and Poland (80 %),[16] and in family doctors of the United States (56 %).[19] However, when general practitioners and specialists were included, this figure varied from 60 to 86 %,[18,20] probably due to the tendency for primary care doctors to use them more often in comparison with physicians who serve in hospitals and private specialists.[11]

Considering the type of placebo, pure types are less employed in the office and more in the hospital area;[11] however, in our study, 40 % of doctors had used some type of pure placebo in the preceding month, which is a higher figure than that observed in the United States (3 and 11 %),[17,19] the United Kingdom (12 %),[13,21] Switzerland (17 %)[3] and Germany (12 to 45%).[14,22]

Regarding impure placebos, 71.6 % of professionals had employed them, which is a higher figure than that reported in Switzerland for general practitioners and pediatricians (57 %),[3] although there are countries with higher values such as Germany, with 76 to 84 %,[10,14] and the United Kingdom, with 97 %.[18] This may be due to the tendency to use this type of placebos in the primary care setting.[10]

In this study, the most commonly used impure placebos were vitamins (71.6 %), which is the same that has been documented in Denmark[12] and Poland.[16] It is important highlighting that in no case were antibiotics mentioned, which in many countries are at top

Table 2. **Type of placebo used by family doctors in various pathologies**

Pathologies placebos are used for	Pure placebo		Impure placebo		Procedure		Total
	n	%	n	%	n	%	
Anxiety, depression, hysteria, hypochondria, anxiety, stress, emotional fragility	2	3.2	58	90.6	4	6.2	64
Diabetes, high blood pressure/chronic-degenerative conditions	7	17.5	29	72.5	4	10	40
Depressive disorder, dysthymia, depressive neurosis	2	5.1	33	84.6	4	10.3	39
Osteoarthrosis, gonarthrosis, musculoskeletal disorders	0	0	14	58.3	10	41.7	24
Neurodermatitis, herpes, warts, sunburn	6	25	16	66.6	2	8.4	24
Headache, tension headache, migraine, headache with vertigo, vertigo	1	4.5	14	63.6	7	31.8	22
Chronic fatigue syndrome, asthenia, weakness, adynamia	0	0	21	95.5	1	4.5	22
Somatoform disorders, psychosomatic disorders, unexplainable specific symptoms	4	19	11	52.5	6	28.5	21
Healthy, no pathology	0	0	8	53.4	7	45.6	15
Senility, tiredness, old age	1	9.1	8	72.8	2	18.1	11
Pain	4	36.4	4	36.4	3	27.2	11
Digestive pathology, gastritis, irritable colon	4	40	6	60	0	0	10
Conversion disorder	4	100	0	0	0	0	4
Fibromyalgia	0	0	4	100	0	0	4
Climaterium	0	0	4	100	0	0	4
Psychiatric disorders, bipolar	1	50	1	50	0	0	2
Urinary disorders, urinary tract infection	1	50	1	50	0	0	2
Cancer	0	0	2	100	0	0	2
Total	37		234		50		321

p = 0.0000, Chi-square test.

Table 3. **Family doctors attitudes regarding the use of placebos in their clinical practice (n = 307)**

Variable	Yes		No		Don't know/no data		Total	
	n	%	n	%	n	%	n	%
The use of placebo is acceptable when								
Used for a psychological effect*	249	81.0	28	9	30	9	307	100
All other treatments have been used up*	130	42	113	37	64	21	307	100
The patient wants or expects this therapy*	134	44	105	34	68	22	307	100
Clinical experience has shown some benefit*	176	57	45	15	86	28	307	100
The use of placebo is acceptable even when								
It implies deception*	78	25	163	53	66	22	307	100
It jeopardizes trust between patient and doctor*	24	8	204	66	79	25	307	100
Its efficacy is insufficient*	57	19	172	56	78	25	307	100
It can be the cause of legal problems*	26	8	197	64	84	27	307	100
It has possible adverse effects*	16	5	217	71	74	24	307	100

*p ≤ 0.05, Chi-square test.

places as impure placebos.[12,17] This could be attributed to the fact that doctors do not consider them impure placebos or want to avoid being questioned about their use.

In this investigation, procedures such as laboratory tests were used as placebos with a frequency of 47.0 % (145), which after vitamins were the most commonly used. In the United Kingdom, the former are

much more commonly used than the latter.[21] Paraclinical studies deserve separate attention, since they are generally used to "buy time" while clinical diagnosis is established, although this has a clear impact on the cost of health services. Therefore, it would be important including this item in the primary care research agenda.

Due to the frequency in the use of placebo, a wide variability was shown in this study (range from one to ≥ 50 times a month). Lower ranges have been reported in Germany, with an average of 20 times a year,[14] whereas in the UK, 77 % used impure placebos once a week or daily,[21] in India, daily,[18] in Poland, 12 % used them daily, 30 % once a week and 26 % once a month;[16] in Israel, general practitioners indicated them in 62 % once or more times per month.[20]

The pathologies doctors used placebos for were highly diverse, with the most common being those related to mental or psychological problems. In the UK, doctors considered that patients with mental disorders were the ones who could benefit most from the use of placebos.[13] In India, 61.1 % use them in patients with unspecific symptoms.[18] The main reasons to indicate placebos comprised patient insistence, no response to treatment, as a last option, to buy time, and a combination thereof, which is similar to observations reported in other studies.[11,13,19]

Regarding doctors' attitudes towards the use of placebos, it was acceptable mainly when their psychological effect was sought (81 %, 249), although acceptance of their use even when on the other hand it involved deception (78, 25 %) or their efficacy might be insufficient (57, 19 %) draws the attention. There were statistically significant differences between doctors regarding these issues. In other investigations, professionals also sought the psychological effect[14,21] and gave more value to previous experience than to scientifically proven efficacy,[11] and it is even adduced that many treatments used in the primary care setting don't have enough scientific evidence.[13] This opens a window of opportunity for research in the ethical field of family medicine practice.

The fact that placebos were effective for a large percentage of the participating professionals (69 %) explains that a large part of them use them in their daily practice. In previous investigations, the belief in the effectiveness of placebo is also widespread (50 to 94 %),[16,20] and there is even the belief that there are not only psychological changes but also objective and physiological changes.[11,12,19]

In India, as in many other countries, placebos are covertly prescribed, labeling them as medications (60 %) or without mentioning it to the patient (39 %),[18] while in others there is open indication when prescribing them, with symptom improvement also being observed.[22]

In this study, the consulted doctors referred that the existence of a good doctor-patient relationship is key to placebo effectiveness, which has already been demonstrated in previous investigations.[22] Patients' relief expectations, their beliefs, the experience of benefits in other people, together with doctors' verbal suggestions about therapeutic benefits, ritual and behavioral aspects, will trigger the mechanism of placebo's positive effect.[19,22]

Although other investigations refer differences between doctors who used various placebos,[19,21] in our case, it was only possible finding a significant association between some of doctors' sociodemographic (age) or professional characteristics (seniority, certification) and the use or not of placebos, as well as between the type of placebo and the pathology it is used for.

Currently, there is the knowledge that the maximum therapeutic benefits for patients will be achieved if there is a combination of circumstances, including a social support network (family, friends, support groups, school, work, community), the so-called "therapeutic alliance", which is the clinical encounter (social and psychological) between the therapist and the patient, as well as the environmental context, both physical and behavioral (nature, art, color, sound, music, rituals, etc.). If the clinician strives and manages to know the patient and his/her context, he will be able to assemble the necessary individual components and optimize the chances of improving the patient.[23,24]

Conclusions

In the Mexican context, the use of placebos is more common in patients with mental disorders, in "healthy worried subjects" and in those with chronic conditions, to improve their psychological state.

The use of placebos in the family medicine specialty is a significant issue because it plays a relevant role in the management of patients in the primary care setting that has an impact on symptom improvement, on doctor-patient relationship, on therapeutic adherence, even more so when doctors' own variables such as current certification, seniority and clinical practice in public institutions have a relationship with their use.

Acknowledgements

To the Red Mexicana de Investigadores en Medicina Familiar A. C. members.

References

1. Macedo A, Farre M, Baños JE. Placebo effect and placebos: what are we talking about? Some conceptual and historical considerations. Eur J Clin Pharmacol. 2003;59:337-342.
2. Hernández A, Baños JE, Llop C, Farré M. The definition of placebo in the informed consent forms of clinical trials. PLoS One. 2014;9:e113654.
3. Fassler M, Gnadinger M, Rosemann T, Biller-Andorno N. Use of placebo interventions among Swiss primary care providers. BMC Health Serv Res. 2009;9:144.
4. Millum J, Wendler D, Emanuel EJ. The 50th Anniversary of the Declaration of Helsinki. Progress but many remaining challenges. JAMA. 2013; 310:2143-2144.
5. De Deyn PP, D'Hooge R. Placebos in clinical practice and research. J Med Ethics. 1996;22:140-146.
6. Meissner K, Kohls N, Colloca L. Introduction to placebo effects in medicine: mechanism and clinical implications. Phil Trans R Soc B Biol Sci. 2011;366:1783-189.
7. Finniss DG, Kaptchuk TJ, Miller F, Benedetti F. Biological, clinical, and ethical advances of placebo effects. Lancet. 2010;375:686-695.
8. Papakostas YG, Daras MD. Placebos, placebo effect, and the response to the healing situation: the evolution of a concept. Epilepsia. 2001; 42:1614-1625.
9. Fent R, Rosemann T, Fässler M, Senn O, Huber CA. The use of pure and impure placebo interventions in primary care. A qualitative approach. BMC Fam Pract. 2011;12:11.
10. Fässler M, Gnädinger M, Rosemann T, Biller-Andorno N. Placebo interventions in practice: a questionnaire survey on the attitudes of patients and physicians. Br J Gen Pract. 2011;61:101-107.
11. Fässler M, Meissner K, Schneider A, Linde K. Frequency and circumstances of placebo use in clinical practice. A systematic review of empirical studies. BMC Med. 2010;8:15.
12. Hróbjartsson A, Norup M. The use of placebo interventions in medical practice: a national questionnaire survey of Danish clinicians. Eval Health Prof. 2003;26:153-165.
13. Bishop FL, Howick J, Heneghan C, Stevens S, Hobbs FD, Lewith G. Placebo use in the UK: a qualitative study exploring GPs' views on placebo effects in clinical practice. Fam Pract. 2014;31:357-363.
14. Meissner K, Höfner L, Fässler M, Linde K. Widespread use of pure and impure placebo interventions by GPs in Germany. Fam Pract. 2012; 29:79-85.
15. Sherman R, Hickner JJ. Academic physicians use placebos in clinical practice and believe in the mind-body connection. J Gen Intern Med. 2008;23:7-10.
16. Babel P. Use of placebo interventions in primary care in Poland. Med Princ Pract. 2013;22:484-488.
17. Tilburt JC, Emanuel EJ, Kaptchuk TJ, Curlin FA, Miller FG. Prescribing "placebo treatments": results of national survey of US internists and rheumatologists. BMJ. 2008;337:1938.
18. Shah KN, Panchal DJ, Vyas BM, Patel VJ. Use of placebo: knowledge, attitude and practice among medical practitioners. Indian J Med Sci. 2009;63:472-473.
19. Kermen R, Hickner J, Brody H, Hasham I. Family physicians believe the placebo effect is therapeutic but often use real drugs as placebos. Fam Med. 2010:42:636-642.
20. Nitzan U, Lichtenberg P. Questionnaire survey on use of placebo. BMJ. 2004;329:944-946.
21. Howick J, Bishop FL, Heneghan C, Wolstenholme J, Stevens S, Hobbs R, et al. Placebo use in the United Kingdom: results from a National survey of primary care practitioners. PLOS One. 2013;8:e58247.
22. Colloca L, Jonas WB, Killen J, Miller FG, Shurtleff D. Reevaluating the placebo effect in medical practice. Z Psychol. 2014;222:124-127.
23. Jonas WB. Reframing placebo in research and practice. Phil Trans R Soc B Biol Sci. 2011;366:1896-904.
24. Blease C. The principle of parity: the "placebo effect" and physician communication. J Med Ethics. 2012;38:199-203.