

OPEN VERSUS HIDDEN MEDICAL INTERVENTIONS: THE ROLE OF PATIENT'S KNOWLEDGE IN THEIR TREATMENT OUTCOMES

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ABSTRACT

Objectives: This study was intended to find out the placebo effect on the patient's knowledge about a treatment.

Study Design: This study employed the quasi experimental approach.

Place and Duration: The study was carried out in different hospitals of Multan from May to September 2018.

Subjects and Method: A sample of 88 patients with postoperative pain participated in administration and interruption treatment with two conditions; open and hidden treatments. In open condition, patients were openly informed that the treatment is being done or stopped, and in hidden condition patients were kept uninformed about the giving and suspension of treatment. In administration of treatment, 44 patients received the treatment in actual wherein 22 patients were informed about the treatment (open condition) while 22 patients were kept uninformed about the fact that the treatment is being on (hidden condition). In interruption of treatment, the treatment for 44 patients was stopped in actual but 22 patients were known that their treatment has been stopped (open condition) while 22 patients were kept blind about this interruption of treatment (hidden condition). Though the actual effects of the administration and interruption of treatment were there, only the patient's knowledge that the treatment is being done or not was taken as independent variable.

Results and conclusion: Results demonstrated that patients in open administration of treatment reported low pain compared to those who were not known of actual administration of treatment. Further the results showed that the patients in open interruption of treatment reported high levels of pain than those who were kept blind about the interruption of treatment.

Keywords: Patients' Knowledge; Placebo Effect; Pain Severity; Medical Treatment

INTRODUCTION

When a physician prescribes a medicine and recommend it to a patient, the prescribed drug may have several impacts. Some of the impacts are directly linked to the pharmacological activity of the drug and some of them though are not linked to the drug's pharmacology but are related to drugs with no effect. The later effects are not related to actual drug's pharmacology but in fact are coming from inactive or dummy drug given to the patient. Indeed it is known as placebo effect (Sherman & Hickner, 2008). It is the most widely recognized phenomenon discussed in the field of medicine (Di Blasi, Harkness, Ernst, Georgiou, & Kleijnen, 2001). Placebo can be characterized as any treatment without particular action on the patient's illnesses that, some way or another, can result in an impact upon the patient (Amanzio, Pollo, Maggi, & Benedetti, 2001).

Placebos are grouped into two classifications; latent placebo and active placebo. Latent placebos are those truly without any activity, be it pharmacological and surgical. Active placebos are those that really have actions, despite the fact that these activities are not particular to the malady for which they are given (Barsky, Saintfort, Rogers, & Borus, 2002). Placebo is considered purely psychological because of a confidence in the treatment or to a subjective experience of improvement in health. A man's faith and trust for a therapy, together with their suggestibility, may have a substantial biochemical impact. Sometimes clinicians do not perform actual surgery but pretend that an actual treatment has been done. The dummy medical treatment is basically done just for the satisfaction of patient by giving them such inactive medicines which have no effects in real (Ballantyne, et al., 1993).

An individual's confident behavior and trust may be significant to their physical health (Hróbjartsson, 2002). A couple of efforts have been made to dispose of the patient's knowledge that a treatment is being done (Benedetti, et al. 2003). The difference between informed and uninformed treatment has been considered due to placebo effect or most probably the actual form of placebo links to the patient's knowledge of the treatment by physicians (Price, 2001). Consequently this placebo effect can be evaluated without actual treatment (Benedetti, 2002). Based on this conceptual explanation of placebo effect, the present study aimed to explore the effects of patient's knowledge that a treatment is being administered on treatment outcomes. To do this, the examiners have analyzed open and hidden medical interventions in patients undergoing thoracotomy and were with postoperative pain of thoracotomy. A thoracotomy is

a surgical procedure in which a cut is made between the ribs to see and reach the lungs or other organs in the chest or thorax to treat or diagnose the problems (Rogers, & Duffy, 2000).

Pain as an organic function indicates the existence of harm or infection inside the body (Colloca, & Benedetti, 2009). A pain following the surgery is called postoperative pain. Relief from postoperative pain must ponder the demands of every patient and a definitive factor of the pain release will be the patient's own understanding of pain (Kirsch, Moore, Scoboria, & Nicholls, 2002). The patient's body organ where the operation is performed affects significantly the level of postoperative distress that a patient may experience (Kaptchuk et al., 2008). Though it might be conceivable to anticipate the level of postoperative pain after recognizing the body location and type of operation may change the degree of pain. And when the outcome of surgery is not obvious to the patient, the patients' anxiety and apprehension may contribute in higher degree of postoperative pain being experienced by patient (Schug & Torrie, 1993; Colloca, & Benedetti, 2007).

Any medical treatment holds two dimensions; the first that the treatment itself has its particular effects and the second, the knowledge that the treatment is being carried on. The latter one is called as the placebo effect. Keeping in mind the importance of placebo effect, the present study was designed to study the placebo effects in a way that how patient's knowledge about the treatment will affect the treatment outcomes. Following hypotheses were formulated to achieve the objective of this study.

1. The hidden medical treatment will be less effective than the open one.
2. The degree of pain will be low in the open administration of medical treatment than in the hidden one.

METHOD

Participants

A sample of 88 male patients experiencing postoperative pain of thoracotomy surgery with age range between 30 and over 50 years was taken through purposive sampling technique from four major hospitals of Multan i.e., Azeem Hospital, City Hospital, Khurshid Rafique Hospital, and Institute of

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Cardiology. Participants' demographic characteristics are presented in Table 1. The inclusion criteria of taking only male patients were to generalize the findings to this kind of population because female patients are more vulnerable to experience pain as compared to male patients.

Measures

A 10-point Numerical Rating Scale developed by Northeast Health Care Quality Foundation (2003) was used to assess the degree of postoperative pain experienced by thoracotomy patients after major surgery. This scale has 10 ratings for pain which are categorized into six levels; no pain (0-1), mild pain (2-3), moderate pain (4-5), severe pain (6-7), very severe pain (8-9), worst possible (10). The test-retest reliability of this scale has been found with alpha reliability coefficient of .96.

Procedure

This study was completed with 88 patients undergoing thoracotomy surgery and experiencing postoperative severe pain. The study was approved by the Ethical Research Committee of Bahauddin Zakariya University, Multan. All the ethical standards were followed while conducting this research and informed consent was obtained from the caregiver of every patient. However, patients' participation in this study was voluntarily. Patients' demographic characteristics were noted from their hospital treatment files maintained by hospital administration. By employing a design of quasi experiment, 88 patients were randomly and equally categorized into two conditions of treatments; administration and interruption of treatment. These two conditions were further categorized into two situations of open and hidden treatments. In first condition of administration of treatment, patients ($n = 44$) were given a 0.14 mg/kg dose of morphine sulfate after one hour recovery from anesthesia. It means 44 patients were receiving medication by the doctor or nurse. Then these patients were examined with further two conditions; open and hidden administrations of morphine. Of this sample of 44 patients, 22 patients were given open infusion by doctor while the other 22 patients were given a hidden infusion with a preprogrammed infusion machine. The open administration of treatment was executed directly by the doctor or nurse who clearly explained the patients that the medicines given to them are the effective painkillers. Simply stated, the patients were kept aware of the treatment and were told that their pain will be decreased in a few minutes. By contrast, the hidden administration of treatment

was performed with the help of preprogrammed machine in the absence of doctor or nurse in the patient room. It means that the patients were kept completely unaware that painkillers were being given to them. Hence, the patients' knowledge that a treatment was given to them was basically the main distinction between open and hidden medications. The open and hidden groups provided the ratings of their pain by themselves on a numerical rating scale at one hour just after morphine infusion.

In the second phase of interruption of treatment, another sample of 44 thoracotomy patients was examined with open and hidden interruption after taking morphine for 72 hrs. In open condition, 22 patients were openly briefed that the treatment had been terminated and no painkillers were given to them. In hidden condition, the treatment was stopped for 22 patients without informing them. Patients were directed to take the painkillers only on request from doctor if needed. Patients of open and hidden interruption of treatment were then instructed to report about the degree of their pain on rating scale.

Data collected on pain rating scale from patients were then statistically analyzed using SPSS-20. To study the significance of differences between open versus hidden conditions of administration and interruption of treatment, non-parametric tests (Mann-Whitney U test Table 1 & 2) were performed because the data did not fulfill the assumptions of normal distribution. Level of significance was set at 0.05 to check the hypotheses.

RESULTS

Table 1
Sample Characteristics

Characteristics	Status	Frequency	%
Gender	Male	88	100
Age	30-40	30	34.05
	40-50	30	34.05
	Above 50	28	31.90
Education	Intermediate	39	44.32
	Graduation	28	31.82
	Post-graduation	21	23.86

Marital Status	Married	88	100
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Table 2
Comparison of Pain Experienced by Patients between Open and Hidden Administration of Treatment (N = 44)

Conditions of Treatment	<i>N</i>	<i>Median</i>	<i>IQ R</i>	<i>Mann-Whitney U test</i>	<i>p</i>
Open Administration	22	5	4		
Hidden Administration	22	8	2.75	85.50	.000*

*df = 42, *P<.001*

Table 2 reveals the significant difference between open and hidden conditions of administrations of treatment (Mann-Whitney U test = 85.50, *p* < 0.001). Findings indicate that patients in condition of open administration of treatment reported less pain than that of patients from hidden condition.

Table 3
Comparison of Pain Experienced by Patients between Open and Hidden Interruption of Treatment (N = 44)

Conditions of Treatment	<i>N</i>	<i>Median</i>	<i>IQR</i>	<i>Mann-Whitney U test</i>	<i>P</i>
Open Interruption	22	3.5	0.5		
Hidden Interruption	22	2	1	93.50	.000*

*df=42, *P<.001*

As to the interruption of morphine, table 2 indicates the significant results (Mann-Whitney U test = 93.50, *p* < 0.001). Findings indicate that the pain reported by the patients in the open interruption of treatment is higher compared to that of patients from hidden interruption of treatment.

DISCUSSION

This study was conducted to find out the effect of patient's knowledge on their treatment outcomes. To study this empirically it was expected that patient's awareness that the treatment is or is not being performed itself has effect on the efficiency of medication. Several studies conducted in Pakistan examining the impact of patients' beliefs and knowledge on recovery from disease indicated the significant findings in this regard (Malik, 1997; Kumar, Shaikh, Khalid, Masood, 2010). Malik (1997) explored from his study conducted on Pakistani cancer patients that communication with the patient and the knowledge about disease and its treatment affected their treatment outcomes. Similarly Kumar, Shaikh, Khalid, and Masood, (2010) also found that patient's perceptions, beliefs and knowledge about cancer influence the better treatment decision making and successful treatment in Pakistan

Findings significantly supported the hypothesis that the patients who were informed (open condition) that their treatment is under process, reported less complaints about their pains after surgery than those who were kept uninformed but their treatment was in actual carried on (hidden condition). The present study findings are in consistent with the studies conducted by Wampold, Minami, Tierney, Baskin & Bhati (2005); Scott et al. (2007); Sherman and Hickner (2008) exhibited that the medicines investigated are more powerful just if the patients realize that they are being done. The knowledge about the treatment administration or interruption provided by physicians or their staff in any hospital setting enhances the efficiency of treatment. Hence, in this way the patient knew the subtle elements of the treatment, why it was being done, and what results to anticipate (Jacobs, 2001).

In contrast to open intervention, a hidden treatment that the treatment was being given or stopped also affected the treatment outcomes. In this hidden condition, no specialists or medical caretakers were in the room, and the treatment was begun by a prearranged machine. Findings showed that after the suspension of treatment, the degree of pain is greater in the open condition of stopping the intervention after two hours as compared to that of hidden condition. These findings are in line with the work of Rizwi and Hussain (2001) who reported from their survey conducted on tuberculosis patients that knowledge of termination of treatment developed serious issues among patients and they complained more about symptoms of their problems than that when were under treatment.

By considering these contemplations, the open versus hidden intervention indicate an intriguing way to comprehend the complicated mental components that exist in any treatment (Benedetti et al., 2003), for example, the interaction between doctor and patient, and the knowledge the treatment is carried on. In particular, the reduced therapeutic effect after a hidden therapy shows that the patient's knowledge about the treatment and/or the doctor-patient relationship is of crucial importance. In the first case, the perception of receiving a treatment induces expectations of treatment benefit and hence the activation of a complex cascade of events, such as the release of endogenous opioids. In one case, the impression of getting a treatment instigates desired outcomes from medical treatment (Haour, 2005).

In the other case, the strong relationship between physician and his or her patient is probably to improve the perception of the medication that is being administered. Thus, a relationship of the physician with his or her client can add to build these endogenous systems that are activated by expected outcomes (Pollo et al., 2001). Despite the fact that doctor should endeavor to improve the client's information about treatment, from the present findings it is intriguing to note that this is favorable just when the treatment is being administered (Wampold et al., 2005).

Kaptchuk (1998) studied the effect of placebo on patients of irritable bowel syndrome who received no therapy by their doctor while were given a placebo treatment for acupuncture with support and without support of their physician. Both groups of these placebo treatment reported better and positive results as compared to that group of patients who didn't receive any treatment. It is pertinent to point out here that better results were observed in the patients who were given support and care by their doctors along with the placebo.

One another study (Fuente-Fernández, 2001) attempted to examine the effect of placebo in improving the symptoms of Parkinson's disease. Through PET scanning of patients who were on placebo, experts found that patients' brains produced dopamine in result of placebo, in spite of their neurological impairment engendered by the Parkinson's disease.

This approach shows that the placebo effect, or at least its major component deriving from the perception that a treatment is being administered, can be studied without placebo groups (Scott et al., 2007). This has been noted significantly that the aspect of placebo is a complex approach and very difficult

to examine its effects (Ballantyne et al., 1993; Kaptchuk et al., 2008). It is also important to note that placebo effects might be observed without the use of any placebo. So far, it could be better to restrict the follow the word of placebo to those conditions wherein fake or dummy treatment is administered.

Conclusion

The study has provided significant findings in the field of medicines to understand that not only the medicine itself but the patients' knowledge that the treatment is being performed is a key factor in the efficacy of treatment. The findings of present study have implications in terms of clinical treatment and bring the significant findings for physicians and surgeons to this point that not only the drug itself but the patient's knowledge that the treatment is being performed is also effective in the successful treatment. The patient's knowledge about the therapy can be effective for the desired outcomes of therapy.

Limitations of the Study

In spite of significant findings of the current study, few limitations are in worth consideration. One of these limitations is related to the open condition of treatment administration because some other variables can confound the exact effects of knowledge of treatment and it cannot be assured that in open administration of treatment which of the following was more effective in actual; the knowledge of the treatment itself, the close care of the doctor, and the anticipation of the result. In this way, the present study can't recognize which one of these components was the most pertinent.

In addition, the response bias is another limitation in the open settings. It must be noted that the biased subjective measures, such as pain and anxiety, are less conceivable than the objective assessment, for example, heart rate fluctuations and physical functioning. Moreover the medical severity of the pain was also not considered in the present study.

REFERENCES

Amanzio, M., Pollo, A., Maggi, G., & Benedetti, F. (2001). Response variability to analgesics: a role for non-specific activation of endogenous opioids. *Pain*, 90(3), 205-215.

Ballantyne, J. C., Carr, D. B., Chalmers, T. C., Dear, K. B., Angelillo, I. F., & Mosteller, F. (1993). Postoperative patient-controlled analgesia: meta-analyses of initial randomized control trials. *Journal of Clinical Anesthesia*, 5(3), 182-193.

Barsky, A. J., Saintfort, R., Rogers, M. P., & Borus, J. F. (2002). Nonspecific medication side effects and the placebo phenomenon. *Journal of American Medical Association*, 287(5), 622-627.

Benedetti, F. (2002). How the doctor's words affect the patient's brain. *Evaluation & the Health Professions*, 25(4), 369-386.

Benedetti, F., Pollo, A., Lopiano, L., Lanotte, M., Vighetti, S., & Rainero, I. (2003). Conscious expectation and unconscious conditioning in analgesic, motor, and hormonal placebo/nocebo responses. *Journal of Neuroscience*, 23(10), 4315-4323.

Colloca, L., & Benedetti, F. (2007). Nocebo hyperalgesia: how anxiety is turned into pain. *Current Opinion in Anesthesiology*, 20(5), 435-439.

Colloca, L., & Benedetti, F. (2009). Placebo analgesia induced by social observational learning. *Pain*, 144(1), 28-34.

Di Blasi, Z., Harkness, E., Ernst, E., Georgiou, A., & Kleijnen, J. (2001). Influence of context effects on health outcomes: a systematic review. *The Lancet*, 357(9258), 757-762.

Fuente-Fernández, R., Ruth, T. H., Sossi, V., & Schulzer, M. (2001). Expectation and Dopamine Release: Mechanism of the Placebo Effect in Parkinson's Disease. *Science*, 293(5532), 1164 -1166.

Haour F. (2005). Mechanisms of the placebo effect and of conditioning. *Neuroimmunomodulation*, 12(4), 195-200.

Hróbjartsson, A. (2002). What are the main methodological problems in the estimation of placebo effects?. *Journal of clinical epidemiology*, 55(5), 430-435.

Jacobs, G. D. (2001). Clinical applications of the relaxation response and mind–body interventions. *The Journal of Alternative & Complementary Medicine*, 7(1), 93-101.

Kaptchuk, T. J., (1998). Powerful placebo: the dark side of the randomized controlled trial. *Lancet*, 351, 722-5.

Kaptchuk, T. J., Kelley, J. M., Conboy, L. A., Davis, R. B., Kerr, C. E., Jacobson, E. E., ... & Park, M. (2008). Components of placebo effect: randomised controlled trial in patients with irritable bowel syndrome. *British Medical Journal*, 336(7651), 999-1003.

Kirsch, I., Moore, T. J., Scoboria, A., & Nicholls, S. S. (2002). The emperor's new drugs: an analysis of antidepressant medication data submitted to the US Food and Drug Administration.

Kumar, S., Shaikh, A. J., Khalid, S., & Masood, N. (2010). Influence of Patient's Perceptions, Beliefs and Knowledge about Cancer on Treatment Decision Making in Pakistan. *Asian Pacific Journal of Cancer Prevention*, 11, 251-255.

Malik, I. (1997). *QACwcp, experience in Pakistan. Communication with the cancer patient, information and the truth*. A Surbone and M. Zwitter. New York. The New York Academy of Sciences: New York: 300-308.

Northeast Health Care Quality Foundation. (2003). *Thermometer Pain Scale, Medicare Quality Improvement Organization for Maine*, New Hampshire and Vermont, Department of Health and Human. U.S. 0305-86.

Pollo, A., Amanzio, M., Arslanian, A., Casadio, C., Maggi, G., & Benedetti, F. (2001). Response expectancies in placebo analgesia and their clinical relevance. *Pain*, 93(1), 77-84.

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Price, D. D. (2001). Assessing placebo effects without placebo groups: an untapped possibility. *Pain*, 90(3), 201-3.

Rizwi, N., & Hussain, M. (2001). Survey of knowledge about tuberculosis amongst family physicians. *Journal of Pakistan Medical Association*, 51(9), 333-7.

Rogers, M.L. & Duffy, J.P. (2000). Surgical aspects of chronic post-thoracotomy pain. *European Journal of Cardio-Thoracic Surgery*, 18, 711-716

Schug, S. A., & Torrie, J. J. (1993). Safety assessment of postoperative pain management by an acute pain service. *Pain*, 55(3), 387-391.

Scott, D. J., Stohler, C. S., Egnatuk, C. M., Wang, H., Koeppe, R. A., & Zubieta, J. K. (2007). Individual differences in reward responding explain placebo-induced expectations and effects. *Neuron*, 55(2), 325-336.

Sherman, R., & Hickner, J. (2008). Academic physicians use placebos in clinical practice and believe in the mind-body connection. *Journal of general Internal Medicine*, 23(1), 7-10.

Wampold, B. E., Minami, T., Tierney, S. C., Baskin, T. W., & Bhati, K. S. (2005). The placebo is powerful: estimating placebo effects in medicine and psychotherapy from randomized clinical trials. *Journal of Clinical Psychology*, 61(7), 835-854.