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Is Positive Communication Sufficient to Modulate Procedural Pain and Anxiety in the Emergency Department? A Randomized Controlled Trial

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ABSTRACT

Objective: Research suggests that therapeutic communication could enhance patient comfort during medical procedures. Few studies have been conducted in clinical settings, with adequate blinding. Our hypothesis was that a positive message could lead to analgesia and anxiolysis, and that this effect would be enhanced by an empathetic interaction with the nurse performing the procedure, compared with an audio-taped message. This study aimed to modulate the contents and delivery vector of a message regarding peripheral intravenous catheter (PIC) placement in the emergency department (ED).

Methods: This study was a 2 + 2 randomized controlled trial registered on ClinicalTrials.gov (NCT03502655). A positive versus standard message was delivered through audio tape (double-blind) in the first phase ($N = 131$) and through the nurse placing the catheter (single-blind) in the second phase ($N = 120$).

Results: By design, low practitioner empathic behavior was observed in the first phase (median, 1 of 5 points). In the second phase, higher empathic behavior was observed in the positive than in the standard message (median, 2 versus 3, $p < .001$). Contrary to our hypothesis, the intervention did not affect pain or anxiety reports due to PIC placement in either phase (all p values > .2).

Conclusions: The positive communication intervention did not impact pain or anxiety reports after PIC. There might have been a floor effect, with low PIC pain ratings in a context of moderate pain due to the presenting condition. Hence, such a therapeutic communication intervention might not be sufficient to modulate a mild procedural pain in the ED.

Key words: therapeutic communication, hypnosis, acute pain modulation, empathy, emergency department, peripheral catheterization, adult, procedural pain.

INTRODUCTION

Acute pain is a frequent occurrence in hospital care and particularly in the emergency department (ED), due to the presenting condition as well as the investigative or therapeutic procedures. Optimizing its management in this setting is a constant endeavor (1). Although pharmacological management is standard of care, enhancing nonspecific aspects of treatment is also recommended (2). Nurses are in general especially aware of nonspecific aspects of care and use them (3). Communication is a key component that can elicit possible placebo or nocebo effects, especially during critical time points of care, such as procedural information (4,5). Positive suggestions can be introduced into this communication and have the potential to alleviate acute pain perception (6–8).

Using positive verbal communication or suggestions is rich in promises for this clinical context. However, in a number of prior studies with positive outcomes, research team members delivering the suggestions were aware of the hypotheses and their behavior was not monitored (9–11), which could have led to biases and misattribution of the effects. Indeed, suggestions are a verbal part of communication, yet nonverbal aspects are important contributors to nonspecific treatment effects (12). In fact, a recent study of positive suggestions conducted with stringent methods shows limited effects and reveals the complexities of the clinical setting (13).

ED = emergency department, **PIC** = peripheral intravenous catheter, **VAS** =visual analog scale

SDC Supplemental Digital Content

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Article Editor: Daryl O'Connor

DOI: 10.1097/PSY.0000000000001246

This study was designed to test whether positive suggestions compared with usual communication could attenuate pain and anxiety perceived during the placement of a peripheral intravenous catheter (PIC) in the ED, and if these suggestions needed to be made by the nurse in charge of the procedure to be effective. To this aim, a modulation of the communication was implemented: patients who underwent PIC placement were randomly attributed to a positive versus standard (negative) message. A first phase of the study delivered the message through an audio recording via a headset, and the nurse was asked to remain silent during the procedure. In the second phase, a trained nurse who was performing the procedure delivered the message. It was predicted that the nurses would have a more empathic behavior when delivering the positive than the standard message or when silent. The hypotheses were that a positive message provided through an audio recording would lead to less pain and anxiety than the usual one, and it would have an enhanced analgesic and anxiolytic effect if delivered by a person in charge of care (with empathic behavior).

METHODS

Study Design

This was a randomized, controlled, sequential group, monocentric trial with a 2 + 2 design: positive versus standard message; phase 1: audio taped–phase 2: nurse delivered. The first phase was double-blind, testing a positive versus standard information provided through a headset. The nurse performing the PIC placement was asked to have minimal interaction with patients during the procedure. The second phase was single-blind, performed by three nurses trained to deliver both intervention messages. The sequential design was chosen to guarantee that the large ED clinical nursing team would not be confused as to their role in the study. The first phase took place between October 2017 and October 2018, followed by the second phase in October 2019, at a teaching hospital ED with ~45,000 consultations a year. The study was approved by the Cantonal Ethics Committee for Vaud (CER-VD-2017-01505) and registered on ClincalTrials.gov (NCT03502655).

Participants

All patients 18 years or older who were admitted to the ED for a nonvital emergency and clinically stable, were requiring a PIC on the upper limb, able to interact in French, and give informed consent were invited to participate on the active study days. All participants gave an oral consent to the study before participation, based on partial information that omitted the randomization to different communication contents, to prevent expectation effects. Full written informed consent was obtained after collecting all outcomes. Participants were free to retract their participation at any stage.

Procedure

Eligible patients were approached in the ED by a study team member and given an information sheet, which described an observational study aiming to improve care in the ED (no mention of communication or randomization). After preliminary oral consent, randomization was performed by opening sequentially sealed, numbered opaque envelopes, which contained a code based on a computer-generated random 1:1 allocation (variable block sizes of two, four, and six; separate coding system for each study phase). The opening date was noted on the envelope, and the opening sequence was regularly checked by the lead investigator.

The *standard message* was based on usual communication observed in the study ED (pilot phase where warnings of pain, clinical terms, etc., were transcribed) consistent with previously published findings (14) ("You may feel the *tourniquet* placed on your arm, it *gets tight*, maybe it *tingles*. The *sting of the inserted needle can be painful*, but *don't move at all* during the procedure. When this message stops, raise a finger with the other hand, and the caregiver *will sting* you.").

The *positive message* was based on the literature and positive communication scripts (15) ("Your arm may begin to feel a certain *numbness*, like a kind of *heaviness*, or *warmth*, as if it were *asleep* for the duration of the procedure. Now that you've heard this message, *as soon as you're ready*, you can signal this to the caregiver by raising a finger with the other hand.").

Phase 1

The randomization code corresponded to the numerical identity of prerecorded messages held on an MP3 reader. Both the study team members and the nursing team were blind to the message. The patient was provided with a Bluetooth-connected headset, and when the nurse prepared for the PIC (disinfection etc.), the prerecorded message was played. Patients who revealed contents of the message to the study team or to whom the nurse talked between preparation of PIC placement and outcome measures were excluded.

Phase 2

The randomization envelope indicated which message (positive or standard) was to be delivered by the nurse (single-blind). While preparing and inserting the PIC, the nurse delivered the allocated message. A study team member checked compliance with the attributed message (requirement of 4/5 elements underlined in the scripted message and no contradictory elements to maintain inclusion of patient).

After the observation phase of the PIC placement and study-related outcome collection, complete written information regarding the study was provided, and written consent was collected.

Measures

Main Outcomes

Anxiety and pain intensity were collected through self-reported visual analog scales (VAS) with anchors 0 = not at all and 100 = extremely, after PIC placement.

Secondary Outcomes

Secondary outcomes were pain and anxiety VAS at baseline (pre-PIC placement). The study team observed a) nonverbal expressions of pain (Algoplus scale) (16) and b) empathetic behavior in the patient-nurse interaction: behavior enhancing the clinical encounter according to placebo research using a purpose-built five-point scale (1 point for each behavior: "warm and friendly manner," "active listening," "verbal empathy," "thoughtful silence during 20 seconds," and "communication of confidence or positive expectations") (17).

Data Analysis

Primary Outcome Analyses

The study investigated the efficacy of the interventions, and we used a per-protocol analysis. A sample of 55 patients per group was calculated as necessary to detect clinically relevant changes in pain VAS in the ED (18), with a power of 80% and an α error at .05. Considering attrition of about 10%, inclusion of 65 patients per group was planned. Missing data were not imputed.

Patients' characteristics were compared between the four arms using two-tailed Pearson χ^2 tests for discrete variables and Kruskal-Wallis tests for continuous variables. All tests were two-tailed. Given the randomized design, to assess the average intervention effect, the outcome distributions were compared between the two study arms, separately for each phase, using the Wilcoxon-Mann-Whitney test. Given the 2 + 2 design, no statistical comparisons of outcomes were conducted between phases.

Exploratory Analysis

In a recent publication on the effect of 3D virtual reality on procedural pain, we showed a potential heterogeneous differential analgesic and anxiolytic effect of virtual reality based on preprocedural anxiety level (19). The randomized clinical trial presented here was also designed to assess the average effect of positive communication on procedural pain and anxiety. Because randomized clinical trials are not designed to assess the heterogeneity of treatment effects across individuals (20), we conducted post hoc exploratory analyses using linear multivariate regression analyses to detect a possible heterogeneous effect of the intervention (i.e., positive versus standard communication) (21,22).

The analyses were performed with STATA, version 16.1 (StataCorp, College Station, Texas) by a research collaborator blinded to the study groups.

The data that support the findings of this study are openly available in Zenodo at http://zenodo.org (reference number 10.5281/zenodo.7534606).

RESULTS

The patient flowchart is presented in Figure S1, Supplemental Digital Content, http://links.lww.com/PSYMED/A966. The baseline characteristics (Table 1) show that randomization in each phase was successful, with well-matched characteristics. There were significant differences in the population's characteristics between study phases, with patients in the second phase less likely to have a surgical condition, chronic pain and to be chronically on analgesics.

There was a significant difference between the nurses' empathic behavior score when delivering the positive versus control message, interpreted as a positive manipulation check: as expected, the empathic behavior was less in phase 1 than 2, because

TABLE 1. Patient Baseline Characteristics, Showing the Control and Intervention Groups for Both Study Phases

	Phase 1 Audio-Recorded Message		Phase 2 Nurse Delivered Message		
	Control (n = 56)	Intervention (n = 57)	Control (n = 54)	Intervention (n = 58)	p (Phase 1 Versus Phase 2)
Age, median (IQR), y	43 (33–56)	51 (34–66)	53.5 (34–68)	47 (36–63)	.48
Female, n (%)	32 (57)	30 (53)	21 (39)	30 (52)	.26
Highest education level, n (%)					.93
Primary/Preprimary	14 (25)	10 (18)	14 (26)	11 (19)	
Postsecondary nontertiary/upper secondary/lower secondary	23 (41)	27 (47)	22 (41)	25 (43)	
Tertiary	19 (34)	20 (35)	18 (33)	22 (38)	
Type of admission, n (%)					<.001
Medicine	33 (59)	34 (60)	47 (87)	52 (90)	
Surgery/trauma	23 (41)	23 (40)	7 (13)	6 (10)	
Trypanophobia, n (%)	10 (18)	14 (25)	13 (24)	15 (26)	.75
Chronic pain, n (%)	25 (45)	23 (40)	14 (26)	12 (21)	.02
Chronic treatment with analgesics, n (%)	17 (30)	19 (33)	7 (13)	7 (12)	.01
Pain intensity by VAS on arrival, median (IQR), mm	35.5 (13–68)	35 (18–60)	40 (12–70)	39.5 (10–65)	.89
Pain discomfort by VAS on arrival, median (IQR), mm	53.5 (20.5–75)	51 (34–73)	61.5 (17–76)	52.5 (36–73)	.90
Anxiety by VAS on arrival, median (IQR), mm	45.5 (18–67.5)	47 (20–72)	36 (12–67)	37 (18–65)	.50
Analgesics before PIC, n (%)	35 (63)	35 (61)	31 (58)	34 (59)	.94

IQR = interquartile range; VAS = visual analog scale; PIC = peripheral intravenous catheter.

p Values are presented for the comparison between the two phases. Statistics: two-tailed Pearson χ^2 tests for discrete variables and Kruskal-Wallis tests for continuous variables.

TABLE 2. Main Study Outcomes by Phase and Intervention Group

	Phase 1 Audio-Recorded Message			Phase 2 Nurse Delivered Message		
	Control (n = 56)	Intervention (n = 57)	p	Control (n = 54)	Intervention (n = 58)	p
Pain intensity by VAS during PIC insertion, median (IQR)	16 (2.5–27.5)	9 (2–30)	.72	17 (4–46)	22 (11–42)	.23
Pain discomfort by VAS during PIC insertion, median (IQR)	14 (1.5–43)	15 (4–45)	.88	28.5 (7–45)	30 (11–50)	.47
Anxiety by VAS during PIC insertion, median (IQR)	21.5 (0–51)	20 (0,57)	.87	26 (3–59)	29 (4–57)	.85
Algoplus score, median (IQR), points	1 (0–3)	1 (0–3)	.18	0.5 (0–2)	1 (0–2)	.94
Nurses' empathic behavior score, median (IQR)	1 (1–2)	1 (1–2)	.09	2 (1–2)	3 (2–3)	<.001
PIC insertion site, n (%)						
Cubital fossa	26 (46)	34 (60)	.35	17 (31)	25 (43)	
Forearm	20 (36)	17 (30)		31 (57)	33 (57)	.02
Hand	10 (18)	6 (11)		6 (11)	0	
Catheter gauge, n (%)						
18G	29 (52)	24 (42)	.35	14 (26)	17 (29)	.83
≥20G	27 (48)	33 (58)		40 (74)	41 (71)	
Attempt at PIC insertion, n (%)						
1	56 (100)	56 (98)	.99	36 (67)	48 (83)	.08
2	0	1 (1.8)		18 (33)	10 (17)	

VAS = visual analog scale; PIC = peripheral intravenous catheter; IQR = interquartile range.

Statistics: two-tailed Pearson χ^2 tests for discrete variables and Kruskal-Wallis tests for continuous variables.

nurses were asked to communicate minimally with patients in phase 1, whereas in phase 2, they were more empathic in the positive than the standard message group (Table 2).

There were no statistically significant differences in patients' reported pain and anxiety during PIC insertion between communication groups, whether in phase 1 or 2 (Table 2). There was no effect of the message on pain behavior (as measured with Algoplus).

In addition, patients in phase 2 were more likely than in phase 1 to need two attempts at catheter placement (phase 2: n = 28; phase 1: n = 1). There was a trend toward more catheter placement attempts in the standard message group compared with the intervention in phase 2 (Table 2).

The heterogeneity analysis, controlling for different patient characteristics, did not show significant effects of our positive communication during either phase on pain intensity or pain unpleasantness during PIC placement (Supplemental Digital Content, Tables S1–S4, http://links.lww.com/PSYMED/A966). There was a borderline significant effect of the communication (β coefficient = 9.2 mm, 95% confidence interval = 0.3 to 18.1, p = .044) on anxiety during PIC placement in phase 2 (Supplemental Digital Content, Table S6), but not in phase 1 (β coefficient = 1.6, 95% confidence interval = −6.8 to 10, p = .7; Supplemental Digital Content, Table S5). Patients with baseline anxiety greater than 30/100 mm, with pain 50/100 mm and greater, and having trypanophobia (fear of needles) had greater procedural anxiety, accounting for the intervention (Supplemental Digital Content, Table S6). The multivariable linear regression analyses showed some other interesting findings regarding heterogeneity of intervention effect. Severe preprocedural pain contributed to an increased pain intensity during the procedure, but not pain unpleasantness. Trypanophobia significantly increased pain intensity, pain unpleasantness, and anxiety during both phases and types of communication. Interestingly, preprocedural anxiety did not impact procedural pain intensity or unpleasantness. Preprocedural anxiety was associated with greater procedural anxiety. Nurses' empathy had a different impact during phase 1 and 2. During phase 1, when nurses were minimally interactive and responsive, greater empathy tended to be associated with lower procedural pain intensity and unpleasantness, whereas the opposite was found when nurses interacted with patients in phase 2. Nevertheless, given the lack of significance of most of the models, they cannot be interpreted as evidence that the intervention had a positive effect on certain patients. This conclusion would require multiple interaction analyses, which our study was not powered to conduct. The details of these analyses are presented in Tables S1 to S6, Supplemental Digital Content, http://links.lww.com/PSYMED/A966.

DISCUSSION

In this real-life study in a tertiary hospital ED, a positive message was delivered through a prerecorded audio or by the nurse in charge of the procedure. Contrary to our hypothesis, this positive communication did not result in lower levels of procedural pain or anxiety during a PIC placement, compared with a standard message. No effects were obtained whether this positive message was delivered through audio recordings or trained nurses despite higher observed empathy scores in nurses delivering a positive message.

We will first discuss these negative results, with different hypotheses and suggestions for further work. The power question comes first. The study was carefully set up, with a conservative effect size calculation based on clinical relevance in the given context (18) and prior studies showing moderate effect sizes of verbal

suggestions on pain (23). To assess if certain patient characteristics lead to the null result, a heterogeneity analysis was conducted. When controlling for the baseline factors in the heterogeneity analysis, no effect of the intervention could be shown on pain in either phase. Nevertheless, about 25% of the patients declared having trypanophobia, and they reported significantly more pain. This study did not have sufficient power to conduct multiple interaction analyses examining potentially significant effects of the intervention specifically in this subgroup. Based on our findings, future research targeting patients with trypanophobia could be warranted.

The second question concerns the choice and delivery of the intervention messages. The messages were simple scripts taught in a 1-hour training. Our positive message was based on prior works (9–11) and corresponds to positive communication training recommendations (14,15). Hence, our findings raise the possibility that the positive effect of communication in prior studies was due to the delivery of the intervention by unblinded study staff (messenger effect) or other elements, rather than the scripted verbal message. The training was successful, without any exclusion due to a failure of message delivery.

Third, there could have been a floor effect on pain scores. The pain reported from the PIC procedure (i.e., <20/100 on average) was lower than reported in similar studies (9,11). An earlier study with positive suggestions regarding PIC also reported very low pain scores on average and limited results, that is, no analgesia but less frequent pain-related vocalizations (10). Furthermore, our study patients had on average moderate discomfort due to their underlying condition. Hence, the pain induced by the PIC procedure could have been perceived as relatively minor. Therefore, such an intervention on communication might be better suited for a patient population without underlying pain and/or undergoing a procedure that is more painful. Interestingly, a recent study of hypnotic communication during PIC insertion in the operating room in pain-free patients showed higher PIC pain ratings (mean in neutral group = 3.5/10), with positive effects of the intervention (mean pain in the hypnosis group = 1.5/10) (24). In addition to the absence of underlying pain, the anesthesiologists delivering the messages in that study were trained in hypnosis, a technique having shown reliable effects in the procedural context (25). The interactions between preprocedural pain, intensity of noxious input, and communication interventions with different levels of complexity deserve to be further tested.

Beyond the negative main results, two findings deserve a brief discussion. The heterogeneity analysis on anxiety in phase 2 showed a statistically significant effect of the positive message. In other words, when controlling for all baseline factors, the intervention increased anxiety by 9.2/100 mm, a statistically significant result but a clinically insignificant result (26). In addition, this effect was marginal compared with the impact of preprocedural anxiety: that is, highly anxious participants had higher anxiety by 62 points on the 100-mm VAS than those without anxiety. Future efforts in the ED should be focused on anxious patients, who might need specific interventions. In fact, we also showed that preprocedural anxiety >12 mm blocked the analgesic effect of virtual reality during minor procedures (19). Finally, when delivering standard messages including usual nocebo suggestions in that context (14), nurses tended to have more PIC failures than during a positive message/not having to deliver a message. This unexpected finding of a potential self-delivered nocebo effect of a standard, negatively laden message, on nurses trained in positive communication is worthy of further research.

One of the main limitations of our study is the sequential 2 + 2 rather than a 2 × 2 design. This was chosen to guarantee that there was no cross-contamination between the different nursing roles (silent role versus message delivery) given our setting with a large nursing staff and high turnover of personnel.

In conclusion, the positive communication intervention did not impact the pain and anxiety reports after a peripheral catheter placement in the ED, whether the communication was audio-taped or delivered by a trained nurse. There might have been a floor effect, with low procedural pain ratings in a context of moderate pain due to the presenting condition. Hence, such a simple therapeutic communication intervention might not be sufficient, especially to modulate a mildly painful input in the ED.

The study team thanks Marie-France Derkenne for her help with monitoring the study and all the patients who agreed to participate.

Author Contributions: C.B. and O.H. planned the study, supervised data collection, led the data interpretation, and wrote the manuscript. O.H. and P.T. led the analyses. A.B., A.F.B., N.G., H.G.-D. contributed to study planning, enrolled patients, and collected the data. A.G. contributed to study planning and data interpretation. All authors critically revised the manuscript.

Source of Funding and Conflicts of Interest: A.G. is part of the board of the Institute for Medical hypnosis for the French-speaking part of Switzerland. The authors have no other conflicts of interest to declare. C.B. was supported by the Foundation Mercier Pour la Science during the time of writing. The Foundation had no role in the study presented here.

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