

Does Hypnosis Relieve Pain and Anxiety During Conscious Sedation?

Lang EV, Benotsch EG, Fick LJ, Lutgendorf S, Berbaum ML, Berbaum KS, et al. Adjunctive non-pharmacological analgesia for invasive medical procedures: a randomised trial. *Lancet* 2000;355:1486–90.

Study Overview

Objective. To determine if structured attention or hypnosis improves outcomes for patients undergoing conscious sedation.

Design. Randomized controlled trial without a sham procedure.

Setting and participants. 366 consecutive patients scheduled for vascular or renal procedures at a single interventional radiology unit. Patients with severe chronic obstructive pulmonary disease, psychosis, intolerance of midazolam or fentanyl, or pregnancy or who were unable to hear or understand English were excluded. 96 patients (26%) declined to participate, 13 failed the Mini-Mental State test (cutoff not specified) and were therefore excluded, and 16 did not participate because their procedures were canceled. The median age of study subjects was 54 to 57 years (range, 18 to 92 years); of these individuals, nearly half were men and three quarters were white. Most had mild, benign diseases.

Intervention. 241 patients were randomized to receive standard care ($n = 79$), structured attention ($n = 80$), or hypnotic relaxation ($n = 82$). Patients in all groups were put under conscious sedation with fentanyl or midazolam. During the procedure, all patients were able to request medication, which was administered based on a protocol similar to that used with patient-controlled analgesia machines. For procedures involving attention- or hypnosis-group patients, an additional staff member dressed like the rest of the operative team sat at the patient's head. The structured attention intervention included 8 key components intended to create a positive psychological environment and to ascertain and meet the patient's needs. Hypnosis-group patients received the attention intervention plus a scripted hypnosis procedure. The staff administering the interventions received approximately 1 week's training but otherwise did not have expertise in either method.

Main outcome measures. Pain and anxiety levels were measured on a 0-to-10 verbal scale, ranging from "no pain" to

"worst imaginable pain," and from "no anxiety" to "terrified," respectively. These measures were recorded before the procedure and at 15-minute intervals throughout the procedure. Researchers also measured medication usage, adverse events during the procedures, and the length of time to complete each procedure. Analysis was performed using an intention-to-treat model.

Main results. Patients receiving standard care experienced more pain than those receiving structured attention ($P = 0.0681$). Pain scores remained constant among patients in the hypnosis group, compared with the standard ($P < 0.0001$) and attention groups ($P = 0.0259$), respectively. Although all 3 groups experienced slightly decreased anxiety scores, only the hypnosis group's scores were significantly lower ($P = 0.0022$). Differences started to appear after 45 minutes into the procedures.

On average, procedures performed on hypnosis-group patients were 17 minutes shorter ($P = 0.0016$) than those performed on standard-group patients. The attention group's procedures were of intermediate length, not significantly different from either group. Patients in both intervention groups received about half the amount of medication as did standard-group patients and had significantly fewer adverse events involving oxygen desaturation. Patients receiving hypnosis also experienced significantly less hemodynamic instability.

Conclusion

There was a trend toward a "dose-response" effect involving the attention intervention and the hypnosis intervention.

Commentary

This is the largest study of its kind published in a MEDLINE-indexed journal. The researchers designed the study very well and carefully monitored the work of research assistants who delivered the intervention. A small weakness is that the standard-care group did not have a sham procedure. Because patients in both intervention groups had 2 staff members seated by the head throughout the procedure, one could hypothesize that the second person introduced a placebo effect regardless of the actions taken.

The researchers wisely chose to use nonexperts, who received little training, to deliver the interventions. This decision greatly enhances the generalizability of this study. Each intervention was videotaped, which may diminish the generalizability somewhat since such monitoring will probably not be used in nonresearch settings.

Applications for Clinical Practice

This intriguing area of behavioral medicine is ripe for exploration. Certainly, researchers should seek to reproduce this

study's results with large randomized controlled trials examining a wider array of procedures (eg, endoscopy, day surgery). While it seems unlikely that these interventions will have important negative effects, the cost-benefit ratio is unknown. Instituting these interventions requires an extra staff member at each procedure. The question of whether the extra costs will be borne through a combination of decreased procedure costs (operating room time, drug administration, adverse events requiring additional care) and increased patient satisfaction is left for future research.

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