Self hypnotic relaxation combined with structured attention reduced the discomfort of invasive medical procedures

Lang EV, Benotsch EG, Fick LJ, et al. *Adjunctive non-pharmacological analgesia for invasive medical procedures: a randomised trial. Lancet* 2000 Apr 29;355:1486-90.

QUESTION: Do self hypnotic relaxation and structured attention reduce discomfort and adverse effects in patients having percutaneous vascular and renal radiological procedures?

Design

Randomised [allocation concealed]*, unblinded, controlled trial.

Setting

An interventional radiology division of a university medical centre in the US.

Patients

241 patients who were 18-92 years of age (median age 56 y, 53% women) and were referred for percutaneous transcatheter diagnostic and therapeutic peripheral vascular and renal interventions. Exclusion criteria included severe chronic obstructive pulmonary disease, psychosis, intolerance of midazolam or fentanyl, and pregnancy. Follow up was complete.

Intervention

Patients were allocated to self hypnotic relaxation plus structured attention (n=82), structured attention alone (n=80), or standard treatment of intravenous conscious sedation (n=79). A manual was used to standardise treatment in each group. In the structured attention group and the self hypnosis group, an additional provider sat close to the patient's head and implemented structured attentive behaviour (8 key components). In the self hypnosis group, guidance to self hypnotic relaxation was also given (3 additional components). Patients were able to control within reasonable limits the amount of analgesia/sedation they received. Analgesia/sedation consisted of midazolam, 0.5 mg, plus fentanyl, 25 µg, per request for up to 4 times, with a lockout time of 5 minutes and then 15 minutes.

Main outcome measures

Total procedure duration, amount of medication requested and given, self reported pain and anxiety scores (minimum 0, maximum 10), and adverse effects.

Main results

The procedure duration was shorter in the hypnosis group than in the standard group (mean 61 v 78 min, $p=0.002$). Less analgesia was used in the hypnosis (0.9 units requested and received) and attention (0.8 units requested and received) groups than in the standard group (1.8 units requested, 1.9 units received) ($p<0.001$). Pain scores increased linearly with procedure time in the standard (slope 0.09 increase in pain score/15 min, $p<0.001$) and the attention (slope 0.04/15 min, $p=0.04$) groups but did not change in the hypnosis group. Anxiety scores decreased over time in all 3 groups. The hypnosis group reported a greater reduction in anxiety than the standard group ($p=0.002$) and less pain than the standard ($p<0.001$) and attention ($p=0.03$) groups. 1

patient in the hypnosis group showed haemodynamic instability compared with 10 in the attention group ($p=0.004$) and 12 in the standard group ($p<0.001$).

Conclusions

In patients having invasive medical procedures, structured attention combined with self hypnotic relaxation led to shorter procedure duration, reduced requests for analgesia, less self reported pain and anxiety, and less haemodynamic instability.

*Information provided by author.

COMMENTARY

A non-pharmacological intervention that can reduce both discomfort and adverse effects during invasive medical procedures will be welcomed by many healthcare professionals. The study by Lang *et al* supports previous research findings in this area. For example, Mandle *et al* found that relaxation reduced pain and anxiety associated with femoral angiography.¹

The strengths of the study by Lang *et al* include randomisation, intention to treat analysis, and careful attention to detail in most of the methodology, including training and monitoring the trainers. Limitations include no power calculations, lack of blinding in outcome assessments, and partial blinding of clinicians.

The interpretation of the results gives rise to my main concerns when considering implications for practice. The median number of pain ratings made by patients is 3 (ie, up to 45 minutes only), and the groups are very similar at this time. Beyond 75 minutes, each group has too few patients for meaningful analysis. At 75 minutes, the pain scores on 0-10 scales are 3.1 (standard care), 2.8 (attention control), and 2 (hypnosis); and anxiety scores are 2.5 (standard care), 2.9 (attention control), and 2 (hypnosis). (These figures are estimated from the graphs because raw scores were not included). These changes are small, and the clinical significance is not great. The data after 75 minutes, when the main differences between groups becomes apparent, are likely to be useful for generating further research hypotheses but not for making changes in clinical practice. The conclusions about haemodynamic stability are based on few adverse events, with no associated estimate of precision. The conclusions that self hypnotic relaxation has more pronounced effects on pain and anxiety and improves haemodynamic stability thus seem to go beyond the data and could be misleading in clinical practice. The most robust result seems to be the significantly shorter duration of the procedure for the self hypnotic relaxation group.

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1 Mandle CL, Domar AD, Harrington DP, et al. Relaxation response in femoral angiography. *Radiology* 1990;174:737-9.

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