Study protocol

Does investigator gender has an impact on patients perceived pain intensity after surgery?

Aim

The objective of this study is to investigate whether the gender of the investigator has an impact on patients reported levels of pain intensity after acute or scheduled surgery.

Background

Postoperative pain is a common problem after surgical procedures with many patients afflicted worldwide. Fundamental challenges are the complexity of measuring pain appropriately, and the many associated possible confounders. Over the last decades, gender of the investigator has been identified as a conceivable bias in the assessment and management of pain in experimental, as well as, clinical research. However, to our knowledge this issue has not so far been systematically investigated in a postoperative setting.

In a preclinical setting Levine et al. showed that male subjects reported less pain when evaluated by a female than by a male investigator, and this was followed by other similar studies indicating that the gender of the investigator may have an impact on the pain report Kallai et al. 2004, Gijsbers et al. 2005, Aslaksen et al. 2007 and Vigil et al. 2014. In a recent review Chapman et al. 2018 emphasize that it may have significant impact on experiments and clinical trials.

Methods

In this prospective paired cross-over study, two investigators of opposite gender independently obtain individually reported pain intensity levels in each study patient based on three different methods of pain assessment the Visual Analogue Scale (VAS), the Numeric Rating Scale (NRS), and the Painmatcher® (PM) technique based on electrical stimulation, at Malmö University hospital in Sweden.

Inclusion criteria is ongoing PACU care after recent surgery, age ≥18 years, cognitive and linguistic abilities to understand instructions and participate in the study, and perceived postoperative pain. All study participants receive oral and written study information and sign an informed consent form.

We have estimated to include around 50 patients per week, corresponding to around 600 patients in total, which we value to be enough margin verifying or rejecting the primary hypothesis of our study.

In each study session – from arrival at the PACU until approximately 15-minutes after arrival – the patients shortly describe, in words of their own, the main character of their postoperative pain. Afterwards they rate their current pain intensity level with the three different study techniques (VAS, PM and NRS in mentioned order). The investigators inform the patients equally verbally on how to carry out the pain measurements and the patients were blinded to the study aim of evaluating potential impact of investigator gender. Additional information on surgical and anaesthetic procedures, including current analgesic medication, is obtained from the peri-operative database of the hospital, and from individual patient records.

Study value

To further improve the postoperative care and pain relieve after acute and scheduled surgery it is of great importance to study biological, psychological and social factors affecting patients pain perception. More knowledge and awareness of investigator gender would possibly encourage caretaking and treatment of patients with pain and further on improved pain relief.

Statistical analysis plan

Study data is recorded in a Microsoft Excel spreadsheet. Non-parametric statistical tests will be used to evaluate study data reflecting pain intensity due to Visual Analogue Scale (VAS), the Numeric Rating Scale (NRS) and the Painmatcher®. With the Painmatcher® we obtained three values at each evaluation and the mean of these will be used for comparison. Pain intensity levels will be evaluated with respect to influence of investigator gender with the Wilcoxon signed-ranked test for dependent samples. Pain intensity levels will be compared between female and male study participants with the Mann-Whitney *U*-test. Reported pain descriptors will be analysed with qualitative methods. As is common in statistical practice we will adopt a significance level of $P < 0.05$.