

RETRO PUBIC TAPE INSERTION: SEDATION OR SPINAL? THE PATIENT'S PERCEPTION – A PILOT STUDY

Hypothesis / aims of study

Retropubic sling insertions were introduced as an ambulatory day case procedure. It was initially performed under local anaesthesia (with sedation) but subsequently performed under spinal anaesthesia. To date no study has compared the results of different anaesthesia techniques.

The aim of this study was to do a pilot study to look at the feasibility of a RCT and for power calculation. Our aim was to determine the patient's satisfaction and to assess success of spinal anaesthesia and sedation following retro pubic tape insertion.

Study design, materials and methods

Ethics approval was granted

This is a pilot studies (double blinded randomised controlled trial) in which 38 patients were recruited. Randomisation was done by opaque envelope, to low dose spinal anaesthesia (LDS) or to propofol-controlled sedation (TCI). Both groups received local anaesthesia by infiltration to the operative field. One patient had to be withdrawn from each group.

Patients undergoing a primary retro pubic tape insertion were eligible for the study.

Exclusion criteria were any contraindication to spinal anaesthesia, patients unable/unwilling to give consent, the presence of significant respiratory/cardiovascular disease/ epilepsy allergies to propofol, Opioids, local anaesthetics and a history of previous pelvic floor repair.

Patients were asked to fill out a visual analogue score (VAS) looking at various perceptions of the anaesthesia received. Hospital records were examined to assess recurrence of stress incontinence.

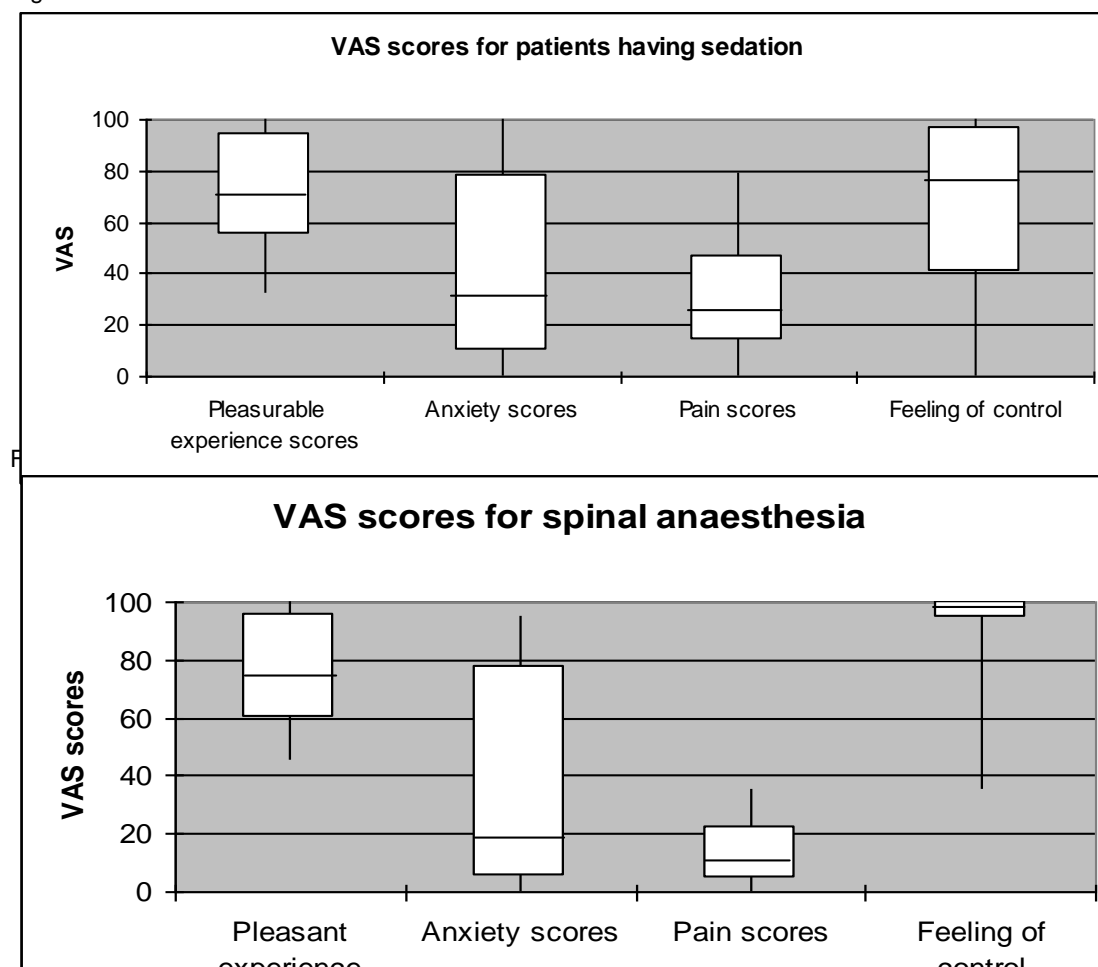
Results

Table 1: A table showing the number of patients with VAS > 80% for various parameters of surgeon's assessment and patient satisfaction

	Sedation (VAS scores > 80) N= 18	Spinal (VAS scores > 80) N = 18
Patient's cooperation	8 (44%)	14 (78%)
Good surgical conditions	8 (44%)	12 (67%)
Pleasurable experience	10 (56%)	11 (61%)
Anxiety	4 (22 %)	4 (22 %)
Pain	2 (11%)	0
Feeling of in control	12 (68%)	14 (78%)

There was 1 patient in each group returned to the clinic with recurrence of their stress incontinence thus indicating a 94% success rate for both spinal anaesthesia and sedation in the short –term period.

Figure 1



Interpretation of results

There is a similar success rate in the insertion of Retropubic tapes under spinal anaesthesia and sedation. There is also similar patient's satisfaction with both forms of anaesthesia/ analgesia but there is a preference for spinal anaesthesia amongst the surgeons.

Concluding message

Sedation provides a suitable option for analgesia for patients undergoing the insertion of a retro pubic tape with no difference in recurrence of stress incontinence. Evidence from previous studies suggests that good short term success rates are likely to be maintained and our initial success rates are equally acceptable. Larger studies would be required to make a significant conclusion but based on this small pilot study and we would suggest that such a study is not practically worthwhile. We will continue to use both techniques based on patient choice and physician recommendation.

<i>Specify source of funding or grant</i>	Birmingham Women's Health NHS Trust
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	South Birmingham Research Ethics Committee
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes