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A RANDOMISED CONTROLLED STUDY OF PATIENT-CONTROLLED SEDATION WITH PROPOFOL ONLY OR PROPOFOL AND ALFENTANIL IN OUTPATIENT UROGYNECOLOGICAL SURGERY-THE SURGEONS´ VIEW.

Hypothesis / aims of study
Local anaesthesia combined with patient-controlled sedation with propofol and alfentanil is better than only propofol because it makes urogenital surgery quicker and easier for the surgeon.
Study design, materials and methods
A prospective randomised controlled double blind study. All patients eligible for outpatient surgery for incontinence, secondary reconstruction after delivery or genital prolapse during 2009 at a tertiary hospital were approached for participation. Written consent was obtained. One hundred and fifty five out of 185 eligible patients completed the study. The fifteen patients who did not wish to participate were operated on with local anaesthesia and nurse-controlled sedation. Another fifteen patients were excluded after randomisation, three due to language-difficulties, two due to changes in medical status and ten due to additional sedative doses given by the nurse anaesthetist. Patients were operated on in an office setting with a standardized dose of local anestesthetic with epinephrine and mepivacaine in combination with a self-administration-system for small i.v. doses of propofol only or propofol mixed with alfentanyl. Pre-packaged code-labelled syringes with a random allocation of either propofol only or propofol and alfentanyl were supplied by the hospital pharmacy. The code was broken after all patients had been operated. The patient received a pre-set small dose from a syringe-pump by pressing a button on a hand control. A six-second pre-set minimum latency-time between doses ensured that the patient could not exceed a safe dosage.
Patients were monitored for consciousness (BIS), carbon dioxide elimination, respiratory frequency, oxygen saturation and subjective wellbeing at baseline and at every five minutes during surgery. The six different surgeonsinvolved were asked to rate their subjective assessment of surgical access. Operating time was measured from the start of administration of the local anaesthetic to the last suture. Patient satisfaction of the surgical experience, the perioperative biochemical results, peri- and postoperative complication rate, subjective outcome of surgery at 8 weeks and 1 year are being recorded and will be presented later.
Results: Values are given as mean (SD). Probabilities of less than 0.05 were accepted as significant.

Demographic data	All	Propofol	Propofol+alfentanyl
Age, years	57 (13,3)	57 (13,8) [1]	56 (12,8) [1]
Weight, kg	71 (13,9)	70 (13,7) [2]	72 (14,1) [2]
ASA physical status I/II/III	98/55/2	51/25/0	47/30/2

[1] P = 0.68 [2] P = 0.29

Procedure characteristics

	All	Propofol	Propofol+alfentanyl
Surgical procedure, n			
TVT	58	27	31
Anterior colporraphy	37	15	22
Posterior repair	30	15	15
Ant. and post. repair	30	18	12
	155	75	80
Excluded after rarandomisation	15	9	6
Procedure time, minutes			
TVT	23 (9,1)	25 (10,1) [1]	21 (8,0) [1]
Anterior colporraphy	24 (6,0)	25 (7,0) [2]	26 (12,0) [2]
Posterior repair	36 (9,8)	36 (10,5) [3]	35 (9,4) [3]
Ant. and post. repair	50 (19,7)	48 (15,5) [4]	56 (24,7) [4]
Assessment of procedure access			
Good	146	69	77
Somewhat limited but not influencing quality or speed	8	6¤	2¤
Limited, influencing quality and/or speed	1	1¤	0¤

[1] P =0.13 [2] P = 0.40 [3] P = 0.65 [4] P = 0.29 ¤P=0.06

Ninety-two percent of TVT-patients and 80% of prolapse or delivery injury-patients went home the same day. Six percent of TVT-patients and 12% of prolapse patients went home the next day. No differences were seen between types of sedation

Interpretation of results

There was no significant difference in the surgeons´ subjective assessment of procdure access or operating time between patient-controlled sedation with propofol only and propofol and alfentanil.

Concluding message

Patient-controlled sedation combined with local anaesthesia provides good surgical access in surgery for incontinence, secondary repair of delivery injuries and genital prolapse. The addition of alfentanil to propofol in patient-controlled sedation does not significantly improve operation speed or surgeon-percieved access and our hypothesis could not be supported.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Regionala etikprövningsnämnden i Linköping**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**