FROM: SGHSA 2 January 1973

SUBJECT: PROPOSAL FOR CLINICAL INVESTIGATION

TO: SGS/Col McPhaul

1. TITLE: "Comparison of Continuous Catheter Spinal Anesthesia with Single Dose Spinal Anesthesia for Transurethral Resection of the Prostate."

2. PURPOSE: To confirm that increased safety to the patient accrues from continuous spinal anesthesia as compared with single dose spinal.

3. BACKGROUND: The group of patients who undergo transurethral resection of the prostate (TURP) are usually elderly males with either latent or manifest cardiovascular disease. The risk of myocardial infarction and cerebral thrombosis in this group is considerable in the presence of even transient hypotension. The prevention of hypotension at surgery and in the recovery room would minimize this complication of anesthesia.

Recently it has been shown that the dose of anesthetic necessary to obtain a given sensory level during spinal anesthesia varies markedly from individual to individual. Standard dosage charts suggest that factors such as increased intraabdominal pressure, position before and after block, coughing and straining etc. may modify level but it is impossible to predict with accuracy the requisite dose to achieve a certain dermatome level. Yet this is what one must do in a single shot spinal technic.

Because the patient should receive only the dose of anesthetic necessary to reach T_{10} (sensory) in order to avoid inordinately high sympathetic blockade, we have elected to compare single shot spinal with continuous spinal anesthesia where the medication is added in slow incremental doses and in the final operative position. The titration of spinal anesthetic dose should do much to prevent high sympathetic blockade and to eliminate the pressure falls that attend change of position in the already sympathectomized patient.

4. BIBLIOGRAPHY:

Underwood, R J : Experiences with Continuous Spinal Anesthesia in Physical Status Group IV Patients. Anesth & Analg, 47: 18-26, 1968.

Madsen, R E and Madsen, P O : Influence of Anesthesia on Blood Loss in Transurethral Prostatectomy. Anesth & Analg 46: 330-332, 1967.

Redick, L F and Walton, K N : Physiological Changes during Transurethral Resection of the Prostate. Anesth & Analg. 46: 618-23, 1967.

Bibliography (cont'd)

Winnie, Alon P : Spinal Anesthesia for Hip Pinning given with the Patient Supine. J.A.M.A. 207:1663-1666, 1969.

See also: Letter to the Editor: Winnie, Alon P. JAMA 208:1192, 1969.

Kallos, T. and Smith, T. C.: Continuous Spinal Anesthesia with Hypobaric Tetracaine for Hip Surgery in Lateral Decubitus. Anesth. & Analg. 51: 766-73, 1972.

Lemmon, W T : A Method for Continuous Spinal Anesthesia. Annals of Surgery, 3: 141-144, 1940.

5. TECHNICAL APPROACH:

a. Twenty (20) patients will be initially studied. Informed consent will be obtained from each. No patient will be less than 45 years old (since the incidence of cephalgia is greater in younger individuals given continuous spinal anesthesia). No premedication will be given. In all patients, an attempt at placement of a central venous pressure line will be made as the preferred site for IV medication and hydration. All patients will receive 500 cc D_5R/L in the 30 minutes preceding the block. Thereafter fluid administration will be governed by preoperative CVP - fluid will be administered to maintain the preoperative CVP.

b. Hypotension will be defined as a 25% fall in systolic pressure at which time fluids and 12.5 mg ephedrine will be given. In the absence of a response appropriate medications may be added to the above as indicated.

c. Alternate patients will receive either:

(1) A single-dose spinal in lateral decubitus position using a 25 Ga. needle at L_{3-4} dose to be that suggested by Dripps, Eckenhoff, and Vandam: "Introduction to Anesthesia. Ed. 4 for a T_{10} level. 60" = 10 mg 66" = 12 mg 72" = 14 mg of tetracaine 1% in $D_{10}W$ diluted with an equal volume of CSF. The patient will be passively moved to the supine and lithotomy position after block. 0.2 cc of epinephrine 1:1000 will be added to the single dose medication before injection.

(2) Continuous spinal anesthesia with a 19 Ga. Teflon catheter placed in the lateral decubitus position at L_{2-3} directed caudad 2 cm beyond the needle tip. Medication injected will be identical to the single dose technic except that no epinephrine will be added. The patient will be placed in the lithotomy position before medication is injected. At that time 3 mg increments of medication will be given q.5minutes until a T_{12} sensory level is reached wi

1 mg q.3 min. increments thereafter to reach a T_{10} sensory level. Increments will then be given for discomfort only.

d. All patients will have sensory levels monitored q.5 minutes until stable with CVP monitored q.15 minutes. Blood pressure will be checked as frequently as possible until the block is stable and at least q.5 minutes thereafter.

e. Results will be compared for mean sensory levels of anesthesia with standard deviations, incidence of hypotension requiring therapy, and dosage requirements to complete the procedure in the continuous spinal group.

6. EQUIPMENT: No nonstandard items will be required for the investigation.

7. INVESTIGATION SCHEDULE: Investigation will begin with approval of the protocol and will continue approximately four months.

8. EXPERIMENTAL SUBJECTS:

9. USE OF DRUGS: No non-standard drug usage will be performed.

10. PERSONNEL DATA:

a. Medical Facility Commander: PAUL W. MYERS, Brig.Gen., USAF, MC

b. Investigators: LOUIS A. MITCHELL, Capt, USAF, MC
Resident in Anesthesiology

FRANCIS J. DANNEMILLER, COL, USAF, MC
Chief, Anesthesiology Service

11. MANPOWER:

One (1) Captain, AFSC 9561, 100 hours duty time; 50 hours off-duty time.

One (1) Colonel, AFSC 9566, 20 hours duty time; 10 hours off-duty time.

One (1) Civilian Secretary, GS-5, 10 hours duty time.

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