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An Observational Study of Selected Agents and Intracranial Pressure Readings: In Adult Patients with Ladd Epidural Monitoring

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AN OBSERVATIONAL STUDY
OF SELECTED AGENTS AND
INTRACRANIAL PRESSURE READINGS
IN ADULT PATIENTS WITH
LADD EPIDURAL MONITORING

by

Amy Perrin

A Thesis Submitted to the Faculty of the Graduate School
of Loyola University of Chicago in Partial Fulfillment
of the Requirements for the Degree of
Master of Science in Nursing

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1981

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VITA

The author of this publication is Amy Perrin, R.N. She was born June 22, 1955, in Oak Park, Illinois.

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CHAPTER I

INTRODUCTION

Increased intracranial pressure can be a life threatening problem. Close, constant monitoring of intracranial pressure is a vital importance. The aim of intensive monitoring is to detect variations in intracranial pressure and in turn provide intervention before the situation becomes life threatening for the patient. Many factors such as physical, visual and auditory stimulation are thought to affect intracranial pressure (Mauss, 1978). Often there are no written guidelines for the nursing care of these patients.

The purpose of this study was to observe and describe selected procedures or agents and intracranial pressure readings. This information may be used to provide guidelines for the type and frequency of nursing care interventions for patients with increased intracranial pressure. Such information could be helpful in the development and testing of models of care in neurological and neurosurgical units.

Statement of Research Purpose

In this study selected agents which were present in the environment of and had an affect on adult patients with Ladd Epidural intracranial pressure monitoring were identified and recorded.

Conceptual Framework

The concept chosen to formulate a framework for this study are the physiology of increased intracranial pressure, stress and adaptation. Normal intracranial pressure ranges from 0-15 mm/Hg. The spinal fluid is continuously secreted by the choroid plexuses in the cranial ventricles and absorbed into the circulatory system through the villi in the arachnoid spaces. There are approximately 150 ml. of spinal fluid present in the body at any one time, with 400-500 ml. secreted and reabsorbed daily. The fluid moves from the ventricles, where it is secreted, into the subarachnoid spaces, filling the cisterns around the base of the brain and the spaces around the spinal cord. The fluid then diffuses over the convexities to the arachnoid villi in the sagittal sinus, where it is absorbed into the venous bloodstream.

The cranial contents are contained in a virtually nondistensible structure and any increase in the volume of the contents is reflected in an increase in pressure. In the adult, the rigid skull that encases the brain allows only minimal room for expansion of its contents: the nervous tissue, cerebrospinal fluid, and blood volume. An increase in any one of these elements will compromise the others. Momentary changes in intracranial pressure can be rapidly accommodated by the brain under normal circumstances. Pressure variables can be compensated for by redistribution

of the intracranial fluid volume.

Intracranial volume is composed of the volume of brain tissue, the cerebral blood volume and cerebrospinal fluid. The Monroe Kellie Hypothesis states that an increase in the volume of any one of the components of the cranium is usually accompanied by reciprocal change in the volume of the others.

The hazards of increased intracranial pressure are related to decreased cerebral perfusion and cerebral hypoxia. The intravascular blood volume is modified by a variety of autoregulatory mechanisms, including changes in carbon dioxide (PCO_2) levels. The degree of compensation or stretch within the system is referred to as compliance (Langfit, 1975). Compliance is determined by the volume and rate of displacement of brain tissue, intravascular blood and cerebrospinal fluid. It is also influenced by the rate at which the volume expands within the intracranial space.

Though sparse, there is some evidence that nursing measures may contribute to the fluctuations of intracranial pressure (Bell, 1975). If these measures are viewed as stressors that may in some way decrease cerebral perfusion and increase cerebral hypoxia. Other measures may have some as yet unknown, physiological impact on intracranial pressure.

Selye, (1966) integrates the concepts of stress and

adaptation. He refers to them as the stress syndrome or the general adaptation syndrome, (G.A.S.). From his observations he concluded that stress plays a role in every disease process regardless of causation. Selye defined stress as "the state manifested by specific syndrome which consists of all nonspecifically induced changes within the biological system" (p. 64). The G.A.S. appears whenever an organism is subjected to long, continued stress. The stressors that may induce the G.A.S. may be any common, non-specific events such as trauma, colds, infection or emotional upsets.

In addition to the general systemic responses, the body can also adapt to local stressors. Selye called this process of local response which takes place within a specific single organ system, the local adaptation syndrome (L.A.S.). He suggests that both the L.A.S. and G.A.S. develop in three distinct stages: (1) alarm reaction; (2) stage of resistance; and (3) the stage of exhaustion. The alarm reaction is the stage in which the body's defences against any non-specific stressor is activated. Individual homeostatic mechanisms are activated and coordinated to meet the stressor. The effects are generalized to the whole body because at this time no one specific system is equipped to deal with it. Here the body's resistance falls below normal initially but then increase sharply. The next stage, that of resistance, also known

as the stage of adaptation, follows. During this stage the body attempts to adapt to the stressor to limit the effects to a localized area that is appropriate for dealing with the stressor. The final stage is that of exhaustion. The level of adaptation can no longer be maintained and once again falls below normal. Consequently, the effects of stress can no longer be contained and again generalize to the whole body. Most often the exhaustion is temporary and the individual will return to normal. With continued, multiple and prolonged stress, it becomes increasingly difficult to recover to the former level of function.

Figure A. shows the level of normal resistance during the three stages.

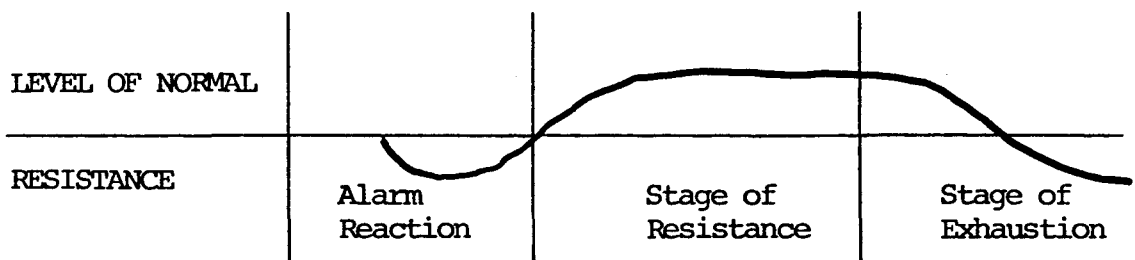


FIGURE A. adapted from the Stress of Life, Selye, (1956) p. 64.

Selye stated that many organs and systems contribute to the regulation of these stress syndromes; the most important are the brain, the nervous system, the pituitary and adrenal glands. The generalized response to stress is

the result of two coordinating systems: the endocrine system and the nervous system.

In the nervous system, mediation of the stress reaction is an important role played by the reticular formation is well developed in the brain and spinal cord. The main function appears to be one of correlation among the various parts of the nervous system and thus it has an important role in the adaptation to the most diverse stressors.

The adrenal and pituitary glands are also very important to the adaptation process. They release hormones that specifically combat stress and inhibit or stimulate the body's defense mechanisms. Selye calls these the adaptive hormones. The group of hormones that inhibit the defensive activities are called glucocorticoids. The group that stimulate the body's defenses are known as the mineralocorticoids. Usually, adaptation to stressors involves a balanced blend of defense and submission on the the part of the body. Selye also states that faulty adaptation in itself can cause disease, which he calls diseases of adaptation.

Selye describes some general characteristics of stress. First, stressors affect people differently. These differences in reaction may depend on two factors. The first is the stressor itself, how suddenly, forcefully and long it endures. Often a short stressful situation

is better tolerated than a chronic stressor which requires continuous adaptation. Secondly, the reaction to a stressor depends on the limitations and potential of the individual dealing with the stress. The effect of the stressor is always relative to the individual and his adaptive capabilities. Another characteristic is that whenever a person encounters stress, he attempts to adapt to it. Stress of whatever nature, if too prolonged or severe, can eventually overwhelm the person no matter how well he has developed his adaptive capabilities.

Selye has listed many types of stressors that can elicit an alarm reaction and subsequent adaptive activity. Some of these include hereditary, physiological, cultural and physical factors are represented in figure B.

PHYSICAL STRESSORS

<u>EXTERNAL FACTORS</u>	<u>INTERNAL FACTORS</u>	<u>INSUFFICIENT FACTORS</u>
Mechanical forces poison and drugs heat and cold radiation temporary blood vessel occlusion	Bodily secretions and products: insulin cholesterol gastric juice	Oxygen deprivation Vitamin and Mineral deficiencies Dehydration Electrolyte loss
Extent of possible injury depends on:	These factors produce injury by:	Factors produce injury by:
Individual ability to adapt Psychological and social factors Virulence of factor	Being excessive Contracting organs particularly sensitive to them	Production of a deficiency

Note. Adapted from Luckman and Sorensen Medical-Surgical Nursing, 1974 p. 43.

The concept of adaptation is the other important part of Selye's theory. This concept includes the whole range of protective adjustments from a simple motor action to a complex interaction between humans. Man does not react to his environment, instead he responds to it with its multiple stressors. Selye noted that adaptation is always a concentration of effort at the site of demand. Human adaptation may be divided into three levels: (1) physiologic or biologic; (2) psychologic; and (3) sociocultural. In terms of human adaptation these levels are fully interrelated.

To further illustrate these levels, some characteristics common to all levels can be summarized. First, all adaptive mechanisms are attempts to maintain within the individual optimum physical and chemical conditions. This is referred to as the concept of homeostasis.

Adaptation is a dynamic and active process that can be viewed in relationship to time. Adaptability varies from individual to individual however, when people adapt to stress they tend to adapt as total organisms. Adaptive responses may also be inadequate excessive or inappropriate. The process of adaptation may be simultaneously make us more sensitive to some stimuli and less

sensitive to others. Finally, though the adaptation process is helpful, the adaptive mechanisms in themselves may be stressful.

In an attempt to provide an integrated background, nursing theorists' views on stress and adaptation are also included. Sister Callista Roy has applied the concepts of stress and adaptation to nursing.

In Roy's (1976) adaptation model, man is viewed as a whole being in constant interaction with his environment. He is one who adapts to change through four adaptive modes: (1) physiological needs; (2) self-concept; (3) role function; and (4) interdependence. Roy states that man copes with environmental change through biopsychosocial adaptive mechanisms. The adaptation level of the person is his level of coping. The goal of nursing process activities is assessment and manipulation of stimuli so that the client's adaptation can occur.

King deals with the concept of adaptation in her theory. The central focus of King's framework (1981) is man. The first of her three basic premises is that man is a reacting being. Man as a reactor adapts. Adaptation occurs with positive response to change for the promotion of maximum potential for living.

Levine (1973) notes that the nurse is a participant in the patient's environment, supporting their adaptation.

Nursing intervention means that the nurse interposes knowledge and skills into the course of events affecting the patient, so that adaptation results. Nursing assessment implies an effort to recognize and understand the nature and quality of the adaptation taking place.

Using the conceptual framework of increased intracranial pressure, stress and adaptation as background, a review of related literature will be presented in Chapter three. In Chapter four the results of the data analysis is presented. In the final Chapter a summary, of the findings, conclusions and recommendations for future study will be discussed

CHAPTER II

REVIEW OF LITERATURE

The concept of intracranial pressure monitoring is a relatively new one. Research since the early 1960's has primarily focused on characteristics of intracranial pressure variations in specific pathologies and on mechanisms basic to increases in intracranial pressure rather than on the relationship between basic patient care activities such as moving the patient in bed, and variations in intracranial pressure. It has only been since 1975 that the concept of bedside procedures affecting intracranial pressure has been explored in medical and nursing literature.

Mauss and Mitchell (1978) studied increased intracranial pressure and concluded that persons with increased intracranial pressure from all causes are subject to periods of markedly increased pressure. The nine patients of the study were observed continuously for up to twenty-four hours, to determine what, if any patient-nurse activities were associated with transient or sustained increased intracranial pressure. These patients were monitored by using pressure controlled ventriculostomy drainage systems. Eight patients had greater than predicted amounts of ventricular fluid drainage associated with

activity. Although each patient displayed individual patterns of specific activity associated with ventricular fluid drainage, turning in bed was consistent among the sample.

Shalit and Umanski (1977) investigated the effects on intracranial pressure of routine bedside procedures such as changing the patients position, suction, rotation, flexion or extension of the head in twenty one patients with brain edema. Simple maneuvers, which under normal physiological conditions have no effect on intracranial pressure, often led to significant changes in intracranial pressure in these patients.

According to Bell (1975), the character of the intracranial pressure is physiologically related to three other pressures: systemic arterial pressure, intrathoracic pressure and venous pressure. Another related concept is that of cerebral perfusion pressure. The perfusion of the brain, cerebral perfusion, depends on a favorable relationship between arterial blood pressure and intracranial pressure. Intracranial pressure is dynamically varying pressure and can change appropriately due to variations in respiratory patterns with concomitant blood gas alterations. Bell also noted that in some cases there was a marked rise in intracranial pressure related to the position of the head relative to the rest of the body. If the patients

head was not in line with the rest of the body, this resulted in muscular compression of the jugular veins with resultant compromise of venous drainage from the head.

The mechanisms underlying the frequent ventricular fluid drainage are less clear when associated with turning to any position as noted by Lundberg (1960). Neck rotation or flexion to 90 degrees was documented (Watson, 1974) as obstructing the ipsilateral internal jugular venous return. From this he further suggest that head rotation may cause intracranial venous stasis.

Becht (1920) was one of the first to attempt to demonstrate a relationship between ligation of the jugular veins and a proportional increase in intracranial pressure due to accumulation of venous blood in the cranium. He concluded that movements of the head probably blocked the jugular veins in the neck, thus raising the pressure. Hulme and Cooper (1976) studied intracranial pressure changes associated with different head positions and varying degrees of jugular vein compression. Maximal increases in pressure were associated with bilateral jugular vein compression and head flexion.

Liipe and Mitchell (1980) investigated how turning and head rotation affect the internal jugular vein. They concluded that head rotation of 90 degrees to either side partly or totally occludes the ipsilateral internal jugular

vein. They further suggest that from their results the risks should be weighed against the benefits when performing nursing procedures which require head flexion or rotation.

Nikas (1975) noted that poor ventilation which leads to carbon dioxide retention and/or inadequate oxygenation, causes the blood vessels to compensate by dilating and thus increases cerebral blood flow. This increased cerebral blood flow also increases the total intracranial volume. Consequently, the increased blood flow further aggravates increased intracranial pressure. The Valsalva maneuver may also be a component in increasing intracranial pressure. Perfusion of the brain tissue is vital for life. If the perfusion is decreased due to obstructing venous outlets, levels of PCO_2 will increase. Increased PCO_2 will lead to vasodilatation and thus, increase cerebral blood flow and, therefore, intracranial pressure.

In 1960, Lundberg performed a study measuring ventricular pressure. He suggested an apparent association between patient body activity i.e. nursing manipulation of the patient, and the onset of transient and sustained increases in ventricular fluid pressure. Lundberg also discussed the idea that suctioning has often been reported to precipitate increases in ventricular fluid pressure. The severe hypoxemia documented during suctioning has been postulated as the mechanism by which ventricular pressure is

increased. In the Shalit (1977) study, the effect of suctioning on intracranial pressure was studied 28 times in seven patients. In all cases in which the initial pressure had been high, the coughing which followed the tracheal suctioning was accompanied by an increase of intracranial pressure. In some cases, the increase was very high and prolonged.

Hip flexion, noted by Nores and Maganes (1971) to be a factor in increasing ventricular fluid pressure, may also contribute to increased intracranial volume during turning. The mechanism relating this flexion to increased intracranial blood volume is unexplained.

The effect of changes in position of the patient's body was studied in eleven patients by Shalit (1977). In seven patients, every change in body position was accompanied by a considerable increase in intracranial pressure. The result of the study suggests that proper positioning of the patient may be more effective in reducing intracranial pressure than the administration of drugs. Conversely improper positioning of the patient may lead to a marked and prolonged increase in intracranial pressure. It was also suggested that the cumulative effect of the increases in intracranial pressure which take place during routine bedside management of the patient may be a major factor in determining the outcome of the illness.

Mitchell and Ozuma (1981) studied moving the patient in bed and the effects on intracranial pressure. Mean ventricular fluid pressure increased in all patients after at least one of the four turns. Turning in all directions produced considerably more variability in ventricular fluid pressure than did passive range of motion or head rotation. A large increase in intracranial pressure occurred as a result of head rotation while there was minimal change with passive range of motion. A cumulative increase in intracranial pressure occurred with activities spaced 15 minutes apart, regardless of the nature of the activity. No cumulative increase in intracranial pressure was found with procedures spaced at least one hour apart.

The several studies cited indicate a relationship between activities and increases in intracranial pressure. However, the studies cited concentrate on limited variables such as turning or suctioning. It is important to observe and describe the effect of environmental factors on intracranial pressure. Such descriptive data should add to the body of knowledge used in the care of patients with increased intracranial pressure. As a result of this information, it is hoped that recommendations for future study of how nurses can facilitate the neurological patient's adaptation will be identified.

CHAPTER III

METHODOLOGY

Research Design

A descriptive design was utilized for this research. The main objective is the description of phenomena relating to the patient. Careful and deliberate descriptions are often essential for a foundation for the development of theories.

Dickoff and James (1968) note that various theories can be grouped into four levels. The first of these levels is factor isolating or naming theory. Each higher level of theory presupposes the existence of theories at lower levels. If it is agreed that to theorize is to invent a conceptual framework, then naming is a theoretical activity. Naming can be thought of as a counterpart of creativity. The need to identify or name factors that can later be conceptually related is often overlooked. The lack of factor isolating theory is particularly detrimental in areas such as this, where theory is being newly developed.

Since the concept of monitoring intracranial pressure is so new, there is very little research done in this area. When a field is new, such as this, it is difficult to provide adequate justification for the development of

a hypothesis. The descriptive study takes this into account and aims to describe phenomena rather than infer cause and effect relationships. In the present study then, selected agents and activities within the patient's environment were observed and described along with concurrent recordings of intracranial pressure readings.

definition of terms

Agents-Affecting Intracranial Pressure: persons, substances or forces affecting the patient that are identifiable within the patient's environment, such as loud noise and positioning.

Intracranial Pressure: compression or force exerted by cerebrospinal fluid in the subarachnoid space, cerebral blood flow and brain tissue. Normal intracranial pressure is 1-10mm/Hg.

Adult Neurological Patient: any person 16 years or older with a neurological disease or injury. The person must be in an intensive care unit and be monitored on a Ladd epidural monitor.

Ladd Epidural Monitor: a fiber-optic intracranial pressure sensor implanted in the epidural space of the patient for the purpose of observing variations in intracranial pressure.

Patient's Environment: all conditions, influences and circumstances surrounding and directly affecting a patient.

Glasgow Coma Scale: a rating scale designed to assess the level of consciousness in head injury patients.

Assumptions

The assumption basic to this study was: Ladd fiber-optic intracranial pressure monitors are valid and reliable tools for measuring intracranial pressure (Levin, 1977).

Setting

The setting was a neurosurgical intensive care unit at a large midwestern medical center. The hospital was a regional trauma center located in a large city surrounded by rural areas. The intensive care unit was a 12 bed trauma life support unit adjacent to the emergency room. There were 4 private rooms. The remaining beds were located along the periphery of one large room. Nursing station, supply area, pharmacy and respiratory therapy stations were located in the center of the room. Each bed was equipped with a cardiac, respiratory, and arterial swan-ganz monitor. The Ladd epidural monitor was placed at the head of the bed with one central trend recorder located along the wall in the back of the room. There were individual televisions and a radio speaker above every bed. There was soft background music present in every patient area.

Description of Sample

Patients who met the following criteria were eligible to participate in the study:

- (1) Sixteen years or older.
- (2) Those with a Ladd fiber-optic intracranial pressure sensor implanted in the epidural space of the cranium for any reason, for the purpose of monitoring intracranial pressure.
- (3) Those monitored in neurological and neurosurgical intensive care units.
- (4) Any level of consciousness.

A non-probability sample of patients in an intensive care unit participated in the study. There were thirteen subjects; nine were males and four were females, who ranged in age from 45 to 76 years. All patients had continuous Ladd epidural monitors in place for the purpose of recording their intracranial pressure. All patients had a decreased level of consciousness ranging from "stuporous" to "deeply comatose." Medical diagnoses included: trauma, intracranial bleeding, subarachnoid hemorrhage, cerebral anoxia and space occupying lesions. All patients had received medication (Urea), at some point in their treatment prior to observation. No patient had received a dose within six hours of observation.

Protection of Human Subjects

Because the author was a student, it was necessary to obtain permission to conduct the study from the degree

granting institution. A proposal of the study, including a consent form (appendix B), was presented to the institutional review board of the medical center. In addition permission was obtained from appropriate personnel to conduct the study in the observational setting (see appendix A for letters). According to institutional protocol however, no consent was required to complete the data collection.

The patients participating in this study may not have benefited directly from their participation. The data gained from this study may provide nurses with further information that can be used to meet patient needs more effectively. The observation of the patient and recording of digital readouts by a non-participant observer has no known or anticipated risk. No pain, discomfort or psychological harm was rendered. Every attempt was made to protect the patient's privacy and confidentiality. All participants remained anonymous.

Data Collection

The data were collected solely by the principle investigator in the study. The data collector served as a non-participant observer recording the environmental conditions, selected agents and patient responses, including level of consciousness and intracranial pressure readings for a period of one hour for each subject.

The use of non-participant observation offers the

opportunity to obtain necessary information without restricting the mobility of the researcher. One limitation of non-participant observation is the possibility of interaction between the researcher and the subject thus altering the subject's behavior. This did not seem to be a factor in this study since the observer had no direct contact with the patient. All subjects in the study had a Glasgow Coma Scale rating of 8 or less and had no verbal or visual contact with the observer.

The sample for this study was a non-probability sample of convenience. Thirteen patients who were presently monitored for intracranial pressure by means of a Ladd epidural monitor were selected for this descriptive study. Each subject was observed for a one hour time period. Observations were made between 10 am. and 4 pm. This time period was one of heightened activity for the patients. The principle investigator was constantly present at the bedside for that hour, sitting in an unobtrusive place. By using non-participant observation, the principle investigator was able to observe and record the stimuli in the patient's environment and simultaneously record the patient's intracranial pressure response. No attempts were made by the investigator to manipulate any of the circumstances or current procedures. The data collector had no direct patient contact. Activity continued as "normal" included family visits, testing and pro-

cedures. Observations and recordings were taken of all agents affecting the patient during the hour observation.

Instrument Selection

The Ladd fiber-optic intracranial pressure monitor is an automatic system designed for accurate and safe monitoring of intracranial pressure. The clinical value of this fiber-optic method had been documented in the treatment of patients with intracranial hypertension (Levin, 1977). The central part of the monitor is the fiber-optic sensor. This device employs light to sense or indicate the position of a diaphragm that moves in response to external pressure and air. The sensor is normally implanted in the epidural space. The instrument measures absolute pressures from 37 to +185 mm/Hg with 99% accuracy. The reliability and validity are reported to be statistically significant $\pm .37$ mm/Hg. The patients in this study had Ladd epidural monitors in place for the purpose of monitoring fluctuations in intracranial pressure.

Reliability of Observations

The principle investigator was the only data collector. She had been taught by a representative of the Ladd Research Industries company to read and calibrate the monitors. Reliability coefficients of her accuracy in recording were established at the .9 level.

Summary

The research design for this study was a descrip-

tive design. The principle investigator collected all data as a non-participant observer. The instrument used was the Ladd epidural monitor which is assumed to be a valid and reliable tool for recording intracranial pressure. The subjects were adult males and females in a university medical center intensive care setting. With this information as background the results of the data collection will be presented in Chapter IV.

CHAPTER IV

RESULTS OF THE STUDY

This chapter includes the findings from the analysis of the data.

Table I describes the sample according to age, sex, medical diagnosis and Glasgow Coma Scale. The sample consisted of thirteen patients, nine males, and four females. Patients ranged in age from 45 to 76 years, with a mean age of 63.5 years and a median age of 65 years. Among the categories of medical diagnosis were 3 incidences of trauma, 3 cases of subarachnoid hemorrhage, 3 incidences of space occupying lesions 2 cases of intracerebral bleeding and 2 incidences of cerebral anoxia post cardiac arrest. Previously documented complicating conditions included 6 incidences of hypertension, 4 incidences of coronary artery disease, 2 cardiac arrhythmias, 1 incidence of cerebrovascular disease, cancer of the breast and asthma. The mean length of time the Ladd Epidural monitor was in place at the time of the observation was 3.8 days, with a range of 1 to 10 days. The range of Glasgow Coma Scale scores were 3 to 8 with a mean rating of 4.8.

TABLE I

FREQUENCY DISTRIBUTION OF AGE, SEX, AND GLASGOW COMA SCALE
BY MEDICAL DIAGNOSIS

Age	DIAGNOSIS				
	Trauma	Subarachnoid hemorrhage	Space Occ. Lesion	Intracranial Bleeding	Cerebral Anoxia
40-50	2	0	0	0	0
51-60	0	1	0	1	1
61-70	0	2	0	1	0
71-80	1	0	3	0	1
Total	n=3	n=3	n=3	n=2	n=2
Sex					
Male	3	1	3	0	2
Female	0	2	0	2	0
Total	n=3	n=3	n=3	n=2	n=2
Glasgow Coma Scale					
3	1	1	0	0	2
4	2	0	0	2	0
5	0	1	0	0	0
6	0	0	2	0	0
7	0	0	1	0	0
8	0	1	0	0	0
Total	n=3	n=3	n=3	n=2	n=2

Descriptive data were collected using the data sheet (Appendix C). The investigator recorded environmental events such as suctioning and voices and concurrent intracranial pressure readings were taken. The data was reviewed for patterns and clusterings of events which produced changes in intracranial pressure. The following agents were identified as increasing intracranial pressure. They are described in the following sections and are listed according to increasing values of mean pressure readings.

Functional Touch: any physical stimuli given to the patient for the purpose of performing nursing care. Agents identified here were taping of equipment such as IV tubing, reinforcement of dressings and body alignment of limbs.

Therapeutic Touch: any non-painful stimuli given to the patient by nurses, family or friends, that may be perceived as soothing. Agents identified in this study included, back rubs, stroking of arms, legs and face.

Professional Verbal Stimuli: voices, male or female, of hospital personnel directed to the patient.

Painful Touch: any agent other than an invasive procedure which may be perceived as pain producing such as sternal rubs, nail bed compression and pinching.

Passive Range of Motion: flexion and extension of the patient's limbs done by nurses without assistance from the patient.

Environmental Noise: any auditory stimuli which is louder than normal background noise. Agents identified here were chairs banging, books falling, doors slamming, and portable X-ray machines grinding by the patients bed.

Suctioning: any mechanical removal of secretions from endotracheal tube or tracheostomy tube using a wall vacume on a low setting.

Turning: any change in body position to the right, left or supine that is performed by nurses.

Oral Stimulation: the introduction of any object into the oral cavity for any purpose. The agents identified here were swabbing of the mouth with a mouthwash soaked swab and the use of oral suction catheters.

Cough: a forceful expiratory effort, preceded by inspiration during which air is expelled.

Head of Bed Lowering: any increase in the angle of the top of the bed measured with a protractor.

Spontaneous Movement: any purposeful physical movement initiated and carried out by the patient without assistance or command. Agents identified in this study were, sitting up in bed, moving about in bed, pulling at dressings and equipment.

Invasive Procedure: any activity which is performed on the patient which breaks the body's first line of defense, the integumentary system. Included as elements of observation from this study were such activities as veinpuncture,

removal and reinsertion of an intraventricular catheter through a previously placed burr hole and the placement of sutures.

Manual ventilation: administration of 100% oxygen to the patient by a nurse or respiratory therapist using an Ambu bag.

Neck Hyperextension: any extention of the head beyond the normal allignment.

The following agents were identified as decreasing intracranial pressure and are listed according to decreasing values of mean pressure.

Personal Verbal Stimuli: voices, male or female, or persons familiar to the patient.

Head of Bed Elevation: any decrease in the angle of the top of the bed as measured with a protractor.

Therapeutic touch which was previously defined was also noted to decrease intracranial pressure.

The agents were then reviewed for commonalities and placed into five catagories which included touch, invasive procedures, auditory stimuli, movement and airway stimulation. The next section identified the agents within the catagories along with mean pressure readings and ranges.

Touch

Variations in intracranial pressure with touch in-

cluded funtional touch, painful touch and therapetic touch.

Functional touch: The mean increase in intracranial pressure was 3.8 mm/Hg for nine patients. The range for this catagory was 2 to 6 mm/Hg.

Painful touch: This catagory showed a mean increase of 4.4 mm/Hg for five patients. Here also there was a wide range of 2 to 7 mm/Hg.

Therapeutic touch: Therapeutic touch produced multidimensional results. Of seven patients observed, two had a mean increase of 4.0 mm/Hg in intracranial pressure. In the other five patients there was a mean decrease of 3.0 mm/Hg with a range of 2 to 4 mm/Hg.

The catagory of touch showed the least amount of change in intracranial pressure of the five catagories.

Invasive Procedure

Variations in intracranial pressure with invasive procedures were also seen.

Invasive procedures: There was a mean increase of 8.0 mm/Hg with both of the patients in the sample.

Variations in intracranial pressure with auditory stimuli included professional verbal stimuli, environmental noise, and personal verbal stimuli.

TABLE II

MEAN INTRACRANIAL PRESSURE INCREASES AND RANGES ACCORDING
TO DIAGNOSIS

Agent	Number in Sample	Mean Pressure Increases	Range
Functional			
Touch	9	3.8	1-6
Therapeutic			
Touch	7	4.0	-4-
Professional			
Verbal Stimuli	7	4.0	1-7
Painful			
Touch	5	4.4	2-7
Passive Range of Motion	3	4.7	4-5
Environmental			
Noise	6	5.0	3-7
Suctioning	5	5.2	5-6
Turning	5	5.4	4-6
Oral			
Stimulation	3	5.7	5-6
Cough	7	5.7	4-10
Head of Bed			
Lowering	5	6.2	5-7
Spontaneous			
Movement	4	6.5	5-10
Invasive			
Procedure	2	8.0	-8-
Manual			
Ventilation	5	9.0	4-11
Neck			
Hyperextention	5	10.4	7-15

TABLE III

MEAN INTRACRANIAL PRESSURE DECREASES AND RANGES ACCORDING TO DIAGNOSIS

Agent	Number in Sample	Mean Pressure Increases	Range
Therapeutic Touch	7	3.0	2-4
Personal Verbal Stimuli	3	3.0	1-2
Head of Bed Elevation	6	6.7	4-9

Professional verbal stimuli: This agent showed a mean increase in pressure of 4.0 mm/Hg with a range of 1 to 7 mm/Hg for seven patients. Most of the patients here had an increase of 4 to 5 mm/Hg.

Environmental noise: Here the mean increase was 5.0 mm/Hg for six patients. The range was from 3 to 7 mm/Hg with most patients showing an increase of 5 to 6 mm/Hg.

Personal verbal stimuli: For this agent, there was a mean decrease in pressure of 3.0 mm/Hg with a range of 1 to 4 mm/Hg for three patients.

Movement

Variations in intracranial pressure with movement included passive range of motion, turning, head of bed lowering, spontaneous movement, neck hyperextension and head of bed elevation.

Passive range of motion: This agent has shown a 4.7 mm/Hg increase with a narrow range of 4 to 5 mm/Hg for three patients.

Turning: In this study, turning to any position showed a 5.4 mm/Hg increase in pressure with a narrow range of 4 to 6 mm/Hg for five patients.

Head of bed lowering: This agent resulted in a narrow range of 5 to 7 mm/Hg with a mean increase of 6.2 mm/Hg for five patients.

Spontaneous movement: In four patients there was a 6.5 mm/Hg increase with a wide range of 5 to 10 mm/Hg.

Neck hyperextension: This agent also showed a wide range of 7 to 15 mm/Hg with the highest mean increase in mean pressure of 10.4 mm/Hg in five patients.

Head of bed elevation: In six patients, there was a mean decrease of 6.7 mm/Hg, with a wide range of 4 to 9 mm/Hg.

Airway Stimulation

Variations in intracranial pressure with airway stimulation included suctioning, oral stimulation, cough, and manual ventilation.

Suctioning: This agent showed a mean increase in pressure of 5.2 mm/Hg with a narrow range of 5 to 6 mm/Hg for five patients.

Oral stimulation: There was an increase of 5.7 mm/Hg with a narrow range of 5 to 6 mm/Hg for a three patient sample.

Cough: In the seven subject sample there was a range of 4 to 10 mm/Hg with a mean increase of 5.7 mm/Hg.

Manual ventilation: This agent produced a mean increase for five patients of 9.0 mm/Hg with a range of 4 to 11 mm/Hg.

There was no evidence of decreases in pressure with any airway stimulation.

Numerous categories of agents affecting intracranial pressure have been identified and described. Mean changes in intracranial pressure, either increases or decreases, have been described. Representations of individual pressure changes according to the agents identified are listed in

appendix D, figures 1 to 17. As a result of the analysis of the data conclusions and recommendations for further study are identified in chapter V.

CHAPTER V

CONCLUSIONS AND RECOMMENDATIONS

In this chapter an overview of the study is presented along with a discussion of the findings. Implications are offered and recommendations for further study are made.

Increased intracranial pressure can be a life threatening problem. Close and constant monitoring are of vital importance. The purpose of this study was to identify agents present in the environment of adult patients with Ladd epidural monitors and concurrently record changes in their intracranial pressure. A conceptual framework of stress, adaptation and the physiology of increased intracranial pressure was used. The review of the literature revealed very little in the way of descriptive studies. According to Dickhoff and James (1960), when a field is so new, such as this, it is important to begin using first level or naming theory. Much of what has been researched has dealt with specific agents and their effects on intracranial pressure, rather than describing other agents present. This study, then, used a descriptive design to collect and analyze data. The setting was a 12 bed neurosurgical and trauma intensive care unit in a large midwestern university medical center. The sample included thirteen patients, nine were males and four females, ranging in age from 45 to 76 years.

There were numerous medical diagnoses including space occupying lesions and trauma. Levels of consciousness ranged from stuporous to deeply comatose with Glasgow Coma Scale ratings from 3 to 8. Each patient had a Ladd epidural monitor in place in the cranium, for the purpose of monitoring fluctuations in intracranial pressure prior to the observation. The principle investigator used non-participant observation of each patient for a period of one hour. That hour was one of heightened activity for the patient. During that hour the investigator observed agents present in the environment of adult patients which affected intracranial pressure and concurrently recorded pressure readings. The analysis of data was done following the descriptive design, using descriptive statistics. Seventeen categories of agents affecting intracranial pressure were identified and described according to mean changes on intracranial pressure. The range of these changes were also reported. A discussion of the findings follows.

Conclusions

Analysis of the data suggests that there are many agents which affect intracranial pressure. Seventeen of these agents were identified and described in this data analysis. Many of these agents have not been previously described in the literature as affecting intracranial pressure.

Little has previously been written regarding touch

and intracranial pressure. Lundberg (1960) noted transient and sustained increases in intracranial pressure with nursing manipulation of the patient. In this study, nursing manipulations which altered intracranial pressure readings were further identified. These agents include touch, invasive procedures, auditory stimuli, movement and airway stimulation.

Alterations in intracranial pressure subsequent to functional and therapeutic touch were not previously described in the literature. In this study, a slight decrease in intracranial pressure was noted when therapeutic touch was performed by family members and friends. Conversely, therapeutic, as defined in this study, when performed by nurses resulted in slight increases in intracranial pressure. An increase in intracranial pressure was noted with functional touch.

The category of invasive procedures showed a relatively large mean increase in intracranial pressure. The range in that category was small suggesting that invasive procedures do contribute to increases in intracranial pressure.

Little has been previously written about auditory stimuli and intracranial pressure readings. Professional verbal stimuli showed a mean increase of 4.0 mm/Hg but the range was wide. This may indicate that professional verbal stimuli affects patients differently and the mean pressure changes may be due to other factors such as the variations

in voice quality or tone of male and female voices. Environmental noise showed a wide range also, with a mean of 5.0 mm/Hg increase in pressure. Intracranial pressure readings were observed to decrease with personal verbal stimuli. Here again the range was wide suggesting that not all familiar voices have similar effects on intracranial pressure.

Variations in intracranial pressure with movement has been documented in the literature. Findings of this study are consistent with those of other studies such as Shallit and Umansky. In addition, some new agents have been identified. Passive range of motion showed a mean increase of 4.7 mm/Hg. This is consistent with the results of Mitchell and Ozuma (1981). Turning also showed a mean increase of 5.4mm/Hg. This again was consistent with the results of Mitchell and Ozuma (1981) and Shalit and Umansky (1977). Spontaneous movement was noted in this study to produce a mean increase of 6.5 mm/Hg with a range of 5 to 10 mm/Hg. Neck hyperextension showed a large mean increase in intracranial pressure. This is consistent with much of the literature such as Becht (1920), Watson (1974), Bell (1975) and Hulme and Cooper (1976). Elevation of the head of the bed was noted in this study to decrease intracranial pressure. A mean decrease of 6.7 mm/Hg was observed.

Air way stimulation has also been cited in the literature as effecting intracranial pressure. In this study, there was a mean increase of 5.2 mm/Hg noted with

suctioning. This was consistent with the findings of Shalit and Umansky (1977). This is thought to be due to high $p\text{CO}_2$ levels produced during suctioning. Oral stimulation showed an increase of 5.7 mm/Hg. This has not been previously recorded. The effect of cough was also consistent with the findings of Shalit and Umansky (1977) in that it produced a mean increase in pressure. Finally, manual ventilation produced the most marked changes with a reported mean increase of 9.0 mm/Hg. The result of using manual ventilation is a decreased $p\text{CO}_2$ and, in turn, a decreased intracranial pressure. In this study, however, intracranial pressure readings increased with manual ventilation. The possible mechanism behind this is the lack of standardization of the administration of the oxygen. When done by hand, the oxygen is delivered with varying amounts of pressure and over various amounts of time.

In addition to these findings, further observations may be considered. Shalit and Umansky (1977) suggested some agents which under normal physiological conditions would have little effect on intracranial pressure will strongly affect these patients with already compromised intracranial pressure. Findings in the present study seem to validate this position. The subjects were divided into three groups: those with normal pressure, 0-10 mm/Hg, those on the upper limits of normal, 12-23 mm/Hg and those with high pressure, above 25 mm/Hg. The greatest increases in pressure were

seen in those who were considered on the upper limits of normal, or the ones with potentially dangerous intracranial pressures.

In conclusion, several of the agents identified in this study as affecting intracranial pressure were not noted elsewhere in the literature. This study also revealed findings that were consistent with much of the current literature. The conclusions and limitations of the study have been identified and are presented next.

Limitations

One of the limitations of this study is the use of only one observer. Reliability and validity of observations may be improved with inter-rater testing of multiple observers. Also, in observing the environment it is very difficult for one observer to identify everything. Other factors in this study were the lack of control of the use of medication used to decrease intracranial pressure and the small sample size. The lack of standardization of some procedures such as turning might also be considered a limitation, but the research setting considered to be as close to a normal situation as possible. A final limitation is the lack of observation of possible cumulative effects of agents affecting intracranial pressure. With this information, recommendations for further study are offered.

Recommendations

The first of the recommendations is to repeat another descriptive study. There is still very little done in this area. Considering some of the surprising results of this study, there may be many other factors yet to be identified which influence intracranial pressure. A larger sample size and involvement of more than one observer are also recommended. Another type of design should be considered. The use of a time series design to observe cumulative changes might be advantageous. The use of an experimental design may be used to test such things as the use of an Ambu bag versus the use of a ventilator for administering oxygen. Control of extraneous variables, such as medication, is recommended. Standardizing some of the procedures that have an effect on intracranial pressure might also be considered. The concurrent observation of such physiologic measures as blood pressure and heart rate might be very revealing. Observations limited to subjects with one or two selected medical diagnoses might also provide more information in those areas where intracranial pressure seems to be the most sensitive to fluctuations, such as patients with aneurysmal bleeding. Another area which might be controlled for with benefit would be to observe persons of all different levels of consciousness from "alert and responsive" to "deeply comatose." These findings could be analyzed for the way different agents affect persons with higher levels of consciousness.

Much is still to be studied in the area of agents affecting intracranial pressure. It is hoped that this study will lead the way to further investigation which, in turn, can further increase the base of knowledge from which patient care is derived.

Bibliography

- Aidinis, S., M.B. and Lafferty, J., M.D. "Intracranial Responses to PEEP" Anesthesiology. V.45: No.4, Oct. 1975.
- Bell, Mercedes and Lorig, Ronald. "Nursing Involvement with Monitoring or ICP" Journal of Neurosurgical Nursing 1:28-31, 1975.
- Beyers, Marjorie and Dudas, Susan. The Clinical Practice of Medical-Surgical Nursing. Boston: Little Brown and Co., 1977.
- Davis, Joan and Kason, C. Neurologic Critical Care. New York: Van Norstrand Reinhold Co., 1979.
- Dubos, Rene. Man Adapting. London: Yale University Press,
- Eliasson, Sven and Presnky, A. Neurological Pathophysiology. New York: Oxford University Press, 1978.
- Guyton, A. Textbook of Medical Physiology. Philadelphia: W. B. Saunders Co., 1979.
- Hulme, A. and Cooper, R. "The Effects of Head Position and Jugular Vein Compression on Intracranial Pressure" Intracranial Pressure III, ed. by J.W.Beks and others. New York, Springer-Verlay, 1976, pp. 259-263.
- King, Imogen. Toward A Theory for Nursing. New York: Wiley Sons, Inc., 1971.
- Luckmann, J. and Sorensen, K. Medical-Surgical Nursing. W.B. Saunders Co.: Philadelphia, 1974.

- Levin, A. "The Use of a Fiberoptic Intracranial Pressure Monitor in Clinical Practice" Neurosurgery. 1977, 1:266-271.
- Levine, Myra. Introduction to Clinical Nursing. Philadelphia: F.A. Davis Co., 1973.
- Lipe, H. and Mitchell, P. "Positioning The Patient with Intracranial Hypertension: How Turning and Head Rotation Affect the Internal Jugular Vein" Heart and Lung. V.9, No.6, Nov-Dec 1980.
- Lundberg, N. "Continuous Recording and Control of Ventricular Fluid Pressure in Neurosurgical Practice" Acts Psychiatrica Neurologica Scandinavia 36: 1-193, 1960.
- Magnas, B. "Body Position and Cerebrospinal Fluid Pressure" Journal of Neurosurgery 44:687-697, June 1976.
- Mauss, Nancy and Mitchell, Pamela. "Relationship of Patient-Nurse Activity to Intracranial Pressure Variations: A Pilot Study" Nursing Research 27:4-10, Jan-Feb 1978.
- Miller, J.D.,M.D. and Leech, P.,M.B. "Effects of Mannitol and Steroid Therapy on Intracranial Volume-Pressure Relationships in Patients" Journal of Neurosurgery, 42 March 1975.
- Mitchell, P., Ozuna, J. and Lipe, H. "Moving The Patient In Bed: Effects on Intracranial Pressure" Nursing Research, Vol.30, No.4, July-Aug.1981.

- Nikas, D. and Konkily, R. "Nursing Responsibilities in Arterial and Intracranial Pressure Monitoring" Journal of Neurosurgical Nursing. 7:115-122, December, 1975.
- Nornes, H. "Observations in Intracranial Pressure Plateau Waves" Intracranial Pressure II., ed. by N. Lundberg, New York: Springer-Verlag, 1975.
- Polit, D. and Hungler, B. Nursing Research: Principles and Methods. Philadelphia: J.B. Lippincott Co., 1978.
- Plum, F. and Posner, J. Diagnosis of Stupor and Coma. Ed. 3 Philadelphia: F. A. Davis Co., 1970.
- Rogers, Martha. The Theoretical Basis of Nursing. Philadelphia: F.A. Davis Co., 1979.
- Roy, Stater Callista. Introduction to Nursing: An Adaptation Model. Englewood Cliffs, N.J.: Prentice Hall, Inc., 1976.
- Selye, Hans. The Stress of Life. New York: McGraw Hill Book Co., 1978.
- Shapiro, H. M.D. "Intracranial Pressure: Therapeutic and Anesthetic Considerations" Anesthesiology, V.43: No.4, Oct.1975.
- Slater, Marianne. "Nursing Intervention for the Patient with Central Nervous System Dysfunction" Advanced Concepts in Clinical Nursing, Ed. Kintzel, Toronto: Lippincott Co., 1971.
- Shalit, M. and Umansky, F. "Effect of Routine Bedside Procedures on Intracranial Pressure" Israel Journal Medical Science, 9:881-886m Sept., 1977.

Taylor, Joyce and Ballenger. Neurological Dysfunctions and Nursing Intervention. New York: McGraw Hill Book Co., 1980.

Watson, G. H. "Effects of Head Rotation on Jugular Vein Blood Flow" Arch.Dis.Child 49:237-239, March 1974.

APPENDIX A



Center for Health Sciences
University of Wisconsin-Madison

University Hospital and Clinics

49

600 Highland Avenue
Madison, Wisconsin 53792

April 16, 1981

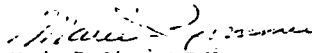
Mary Kachoyanos
Assistant Professor
School of Nursing
Loyola University of Chicago
6525 North Sheridan Road
Chicago, Illinois 60626

Dear Mary,

You or Amy Perrin can contact Karen Jankowski, Clinical Nurse Specialist in Neurosurgical Nursing and Dr. Allen Levin to coordinate data collection for Amy's thesis topic. The project will need prior approval by the University of Wisconsin Committee on Human Subjects. Either Karen, Dr. Levin or Dr. Dorothy J. Douglas can provide information about what forms need to be submitted. If you have questions you would like to ask me about pursuit of this study, please feel free to get in touch with me.

It is nice to hear from you, Mary, and to know the kind of research projects your graduate students are undertaking. When you are in Madison, do drop in and see your many friends here.

Sincerely,


Marie J. Zimmer, R.N.
Director of Nursing Service

MJZ:pmm

cc: K Jankowski
A Levin
D Douglas



LOYOLA UNIVERSITY MEDICAL CENTER

2160 South East Avenue, Maywood, Illinois 60153

312 531-3000

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June 25, 1981

Ms. A. Perrin, B.S.N.
School of Nursing
Loyola University Medical Center

RE: "An Observational Study of Selected Agents and Intracranial Pressure Readings in Adult Patients with Ladd Epidural Monitoring."

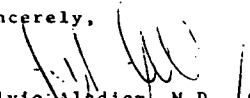
Dear Ms. Perrin:

At the June meeting of the Institutional Review Board, the above-captioned proposal was considered. The Board considered this study non-reviewable and does not require an Informed Consent form.

Recommendation was made that a copy of the IRB approval from the University of Wisconsin be kept in our files since the study will be done there.

I want to thank you for submitting your proposal to the Board because whenever there is a "gray area" it is best to seek the Board's opinion.

Sincerely,


Silvio Aladjem, M.D., Chairman
Institutional Review Board for the
Protection of Human Subjects - Medical Center

SA/s

cc: M. Kachoyneas, R.N., B.S.N.
M. Ryan, Director Nursing
IRBPHS Members
IRBPHS file

* Note: After June 17th IRB meeting, Ms. Perrin stated that the IRB at the University of Wisconsin would bypass the study also as it was non-reviewable. Ms. Perrin was advised to obtain a letter from the University of Wisconsin stating their IRB's opinion for our file and that she would not be able to begin her study until she received that letter.



University of Wisconsin Hospital & Clinics

Division of Neurological Surgery

600 Highland Avenue
Madison, Wisconsin 53792

Telephone: (608) 263-1410

51

Thomas A. Duff, M.D.

M. J. Javid, M.D., Chairman

Allan B. Levin, M.D.

August 6, 1981

Dr. Aladjem
Chairman
Institutional Review Board for
Protection of Human Subjects
Loyola Medical Center
2160 First Avenue
Maywood, IL 60532

Dear Dr. Aladjem:

I reviewed the research proposal entitled "Observational Study of Selective Agents in Intracranial Pressure Readings in Adult Patients with Ladd Epidural Monitoring" by Ms. Amy Perrin. I have also discussed this proposal with the program coordinator for the Center for Health Sciences Human Subjects Committee at the University of Wisconsin. It is our feeling that the research was purely observational. Since there is no patient contact or changes in patient care there is no risk to the patient. No consent form is going to be used because of the above mentioned lack of patient contact and risk, and further this data is presently being collected in other forms on a routine basis and the patient anonymity is being preserved. In view of this, there is no need to send this proposal through the Human Subjects Committee. The fact that it has passed the Loyola University Human Subjects Committee would more than suffice to satisfy any rules and regulations at this institution. We, therefore, feel it would be appropriate for us to allow Ms. Perrin to proceed with her research study. If you have any further questions regarding this, please feel free to contact me.

Sincerely,

Allan B. Levin, M. D.
Associate Professor of Neurosurgery

CC: Amy Perrin
5415 North Sheridan Rd., Apt. 5008
Chicago, IL 60640



LOYOLA UNIVERSITY MEDICAL CENTER

2160 South First Avenue, Maywood, Illinois 60153

312 531-3000

52

August 12, 1981

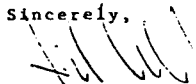
Allan B. Levin, M.D.
Associate Professor of Neurosurgery
University of Wisconsin Hospital & Clinics
600 Highland Avenue
Madison, Wisconsin 53792

Re: Perrin, "An Observational Study of Selected Agents
and Intracranial Pressure Readings in Adult Patients
with Ladd Epidural Monitoring."

Dear Dr. Levin:

Your letter of August 6, 1981, regarding Ms. Perrin's observational study has been reviewed. In order to rectify what appears to be a misunderstanding, the Institutional Review Board for the Protection of Human Subjects here at Loyola University Medical Center felt that this was a non-reviewable grant and what we recommended was that it be reviewed at your institution for the study to be carried out. If your review board also felt that it was non-reviewable, that is entirely your prerogative, it should not however, be based on the fact that the project has been accepted by our institution.

Sincerely,


Silvio Aladjem, M.D., Chairman
Institutional Review Board for the
Protection of Human Subjects - Medical Center

SA/s

cc: Amy Perrin ✓
5415 N. Sheridan Rd., Apt. 5008
Chicago, Il. 60640

APPENDIX B

LOYOLA UNIVERSITY MEDICAL CENTER
Maywood, Illinois

Consent to Participate in Research Study

Patient Information:

1. Procedure - Aims of Study

The purpose of this study is to determine what, if any, procedures such as turning, suctioning, drawing blood, etc. have on the pressure within the head. Such procedures are usual functions of patient care. For this study, the procedure will be to observe and record what happens to you and the reading on the monitor. Patients who are asked to participate in this study already have a Ladd Epidural Monitor in place which measures the third pressure in the head.

2. Risks or Discomforts

Taking the reading simply involves recording the number that appears on the monitor. There are no known or anticipated risks involved in reading the monitor. No pain or discomfort is associated with reading the monitor. There will be no names used in the recordings so no one will know the patients' identity.

3. Description of Benefits

It is not expected that the patient will directly benefit from participation in the study; however, we hope that eventually nursing can gain more knowledge about what functions affect patient conditions and use that knowledge to improve patient care.

4. Cost to Patient

There will be no cost to the patient participating in this study.

5. Confidentiality

I agree to allow my name and medical records to be available to other authorized nurses and researchers for the purpose of evaluating the results of this study. I consent to the publication of any data which may result from these investigations for the purpose of advancing medical and nursing knowledge, providing my name or any other identifying information (initials, social security number, etc.) is not used in conjunction with such publication. All precautions to maintain confidentiality of medical records will be taken.

6. Statement and Signature of Investigator

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability.

Signature of Investigator

7. I offer to answer any inquiries concerning the procedure, its potential or possible effects or risks.

8. Withdrawal

The subject is free to withdraw his/her consent and to discontinue participation in the project at any time with-

out prejudice to the subject.

9. Signature of participant indicating he has been informed and understands the role of Loyola regarding responsibility for care in event of injury.

I have been fully informed of the above-described procedure with its possible benefits and risks. I gave permission for my family members' participation in the study. I know that Amy Perrin or her associates will be available to answer any questions I may have. If, at any time, I feel my questions have not been adequately answered, I may request to speak with a member of the Medical Center Institutional Review Board. I understand that I am free to withdraw this consent and discontinue participation in this project at any time without prejudice to my family members' medical care. I have received a copy of this informed consent document.

I understand that biomedical or behavioral research such as that in which I have agreed to participate, by its nature, involves risk of injury. In the event of physical injury resulting from these research procedures, emergency medical treatment will be provided at not cost, in accordance with the policy of Loyola University Medical Center. No additional free medical treatment or compensation will be provided except as required by Illinois law. In the event you believe that you have suffered any physical injury as the result of participation in the research program please contact

Dr. Aladjem, Chairman, Institutional Review Board for Protection of Human Subjects at the Medical Center (312)531-3380.

Signature: patient

Signature: family member

Signature:witness to signatures

APPENDIX C

Data Collection Form

Age _____

Sex _____

Diagnosis _____

Surgery _____ (prior surgical procedures)

Other complications _____ (any other disease states that
the patient may have such as
renal failure pulmonary edema,
etc.)

Number of days on monitor _____

Level of consciousness _____ (according to Glasgow Coma
Scale)

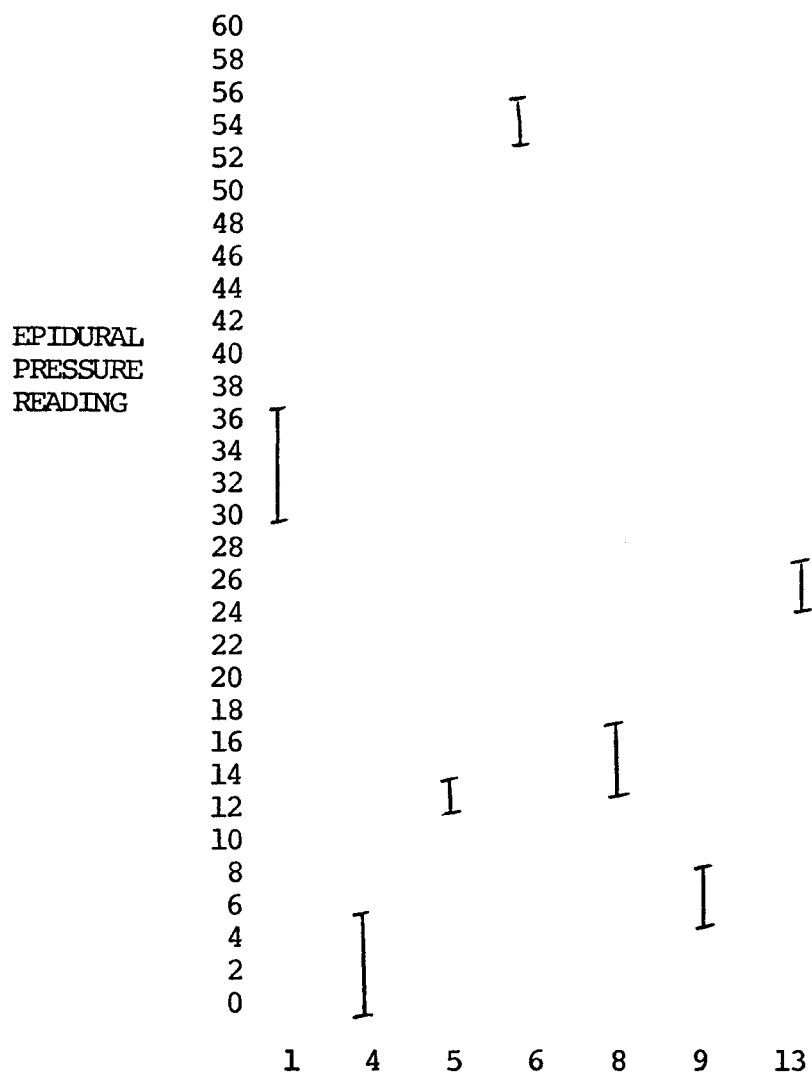
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TIME	INTRACRANIAL PRESSURE	BLOOD PRESSURE	PULSE	RESPIRATIONS	TEMPERATURE	HEAD OF THE BED	TYPE AND TIME GIVEN

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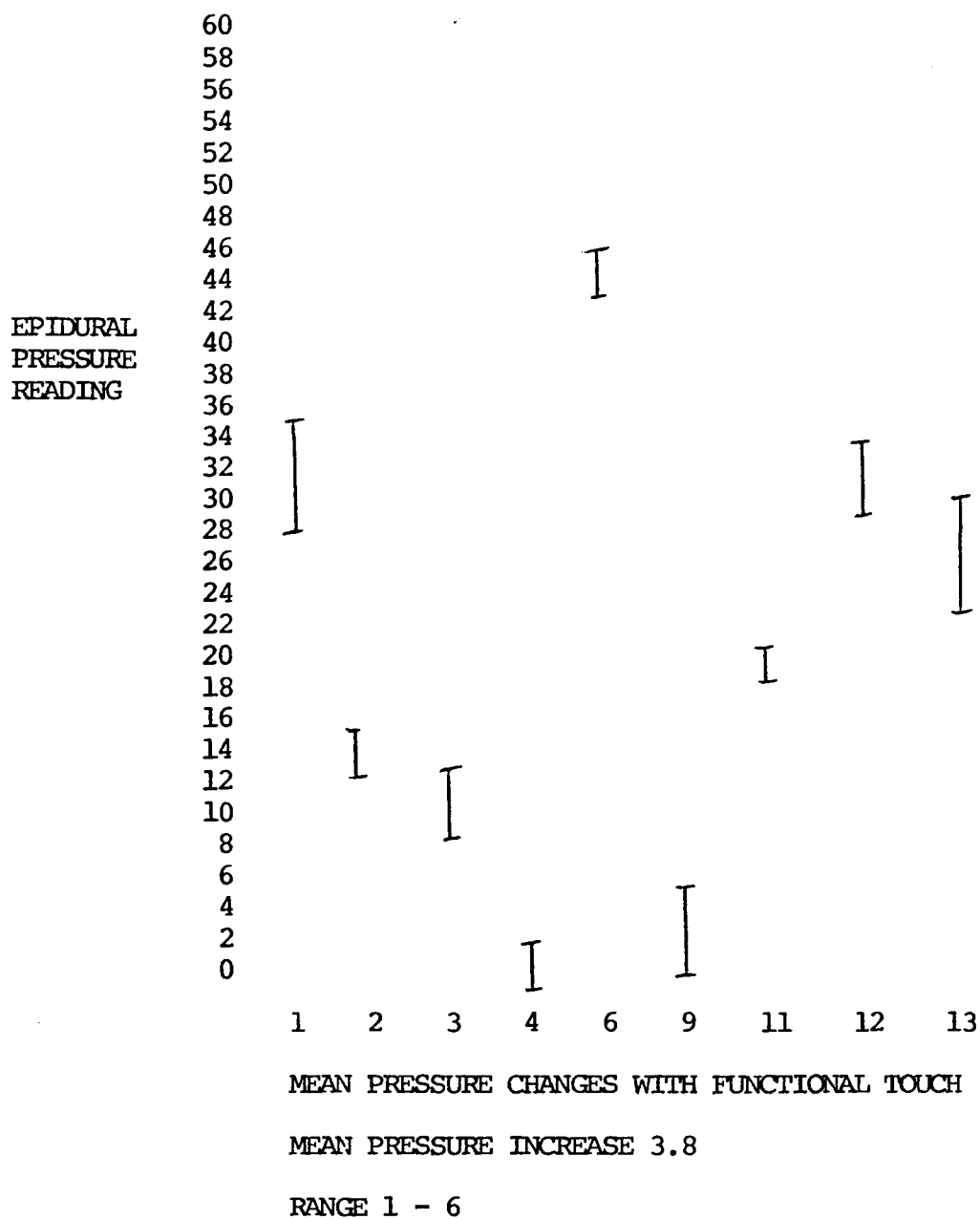
APPENDIX D

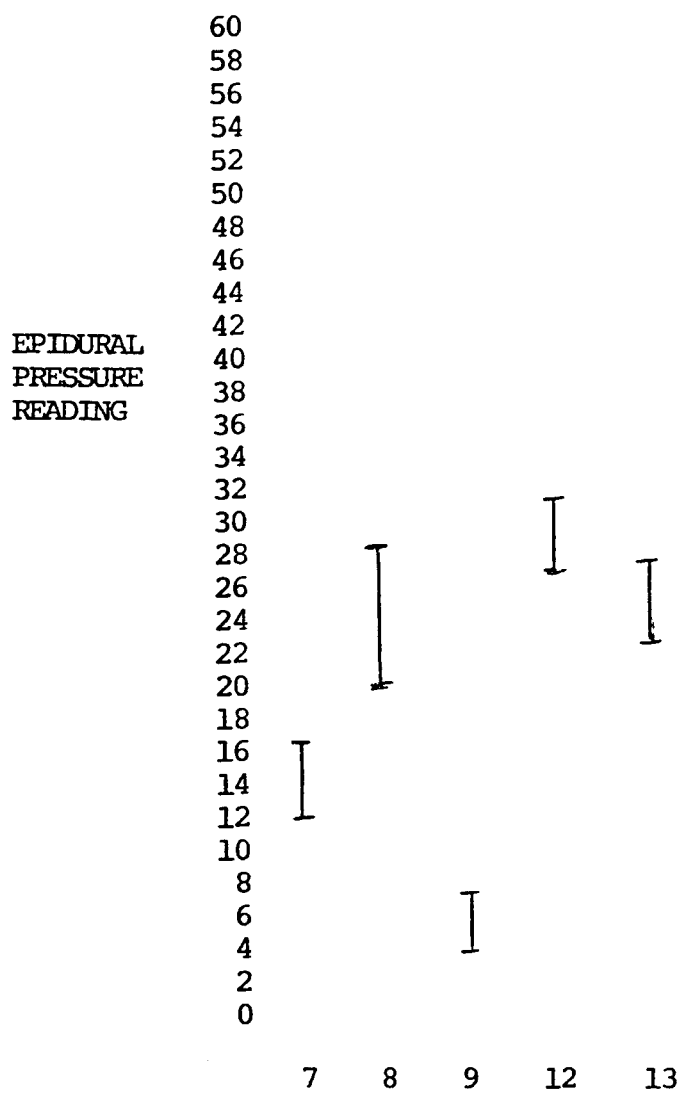


MEAN PRESSURE CHANGE WITH PROFESSIONAL VERBAL STIMULI

MEAN PRESSURE INCREASE 4.0

RANGE 1 - 7

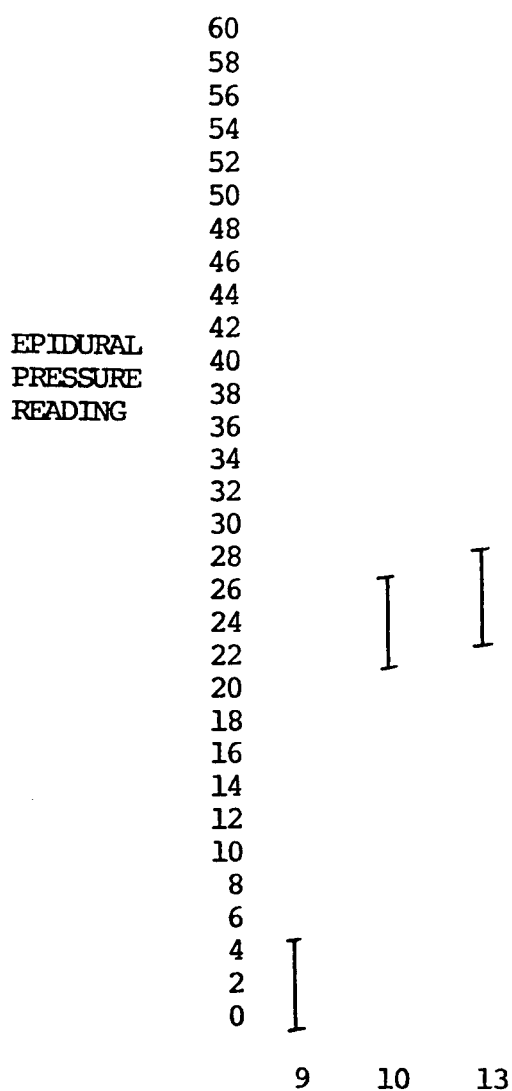




MEAN PRESSURE CHANGES WITH PAINFUL TOUCH

MEAN PRESSURE INCREASE 4.4

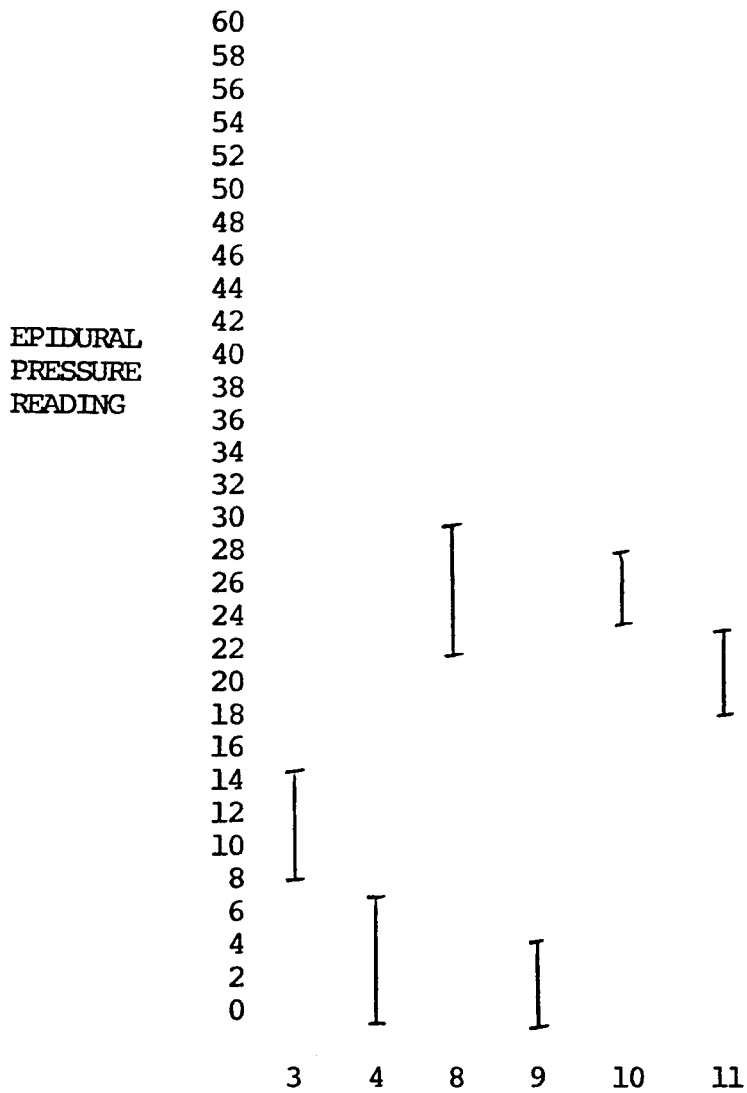
RANGE 2 - 7



MEAN PRESSURE CHANGE WITH PASSIVE RANGE OF MOTION

MEAN PRESSURE INCREASE 4.7

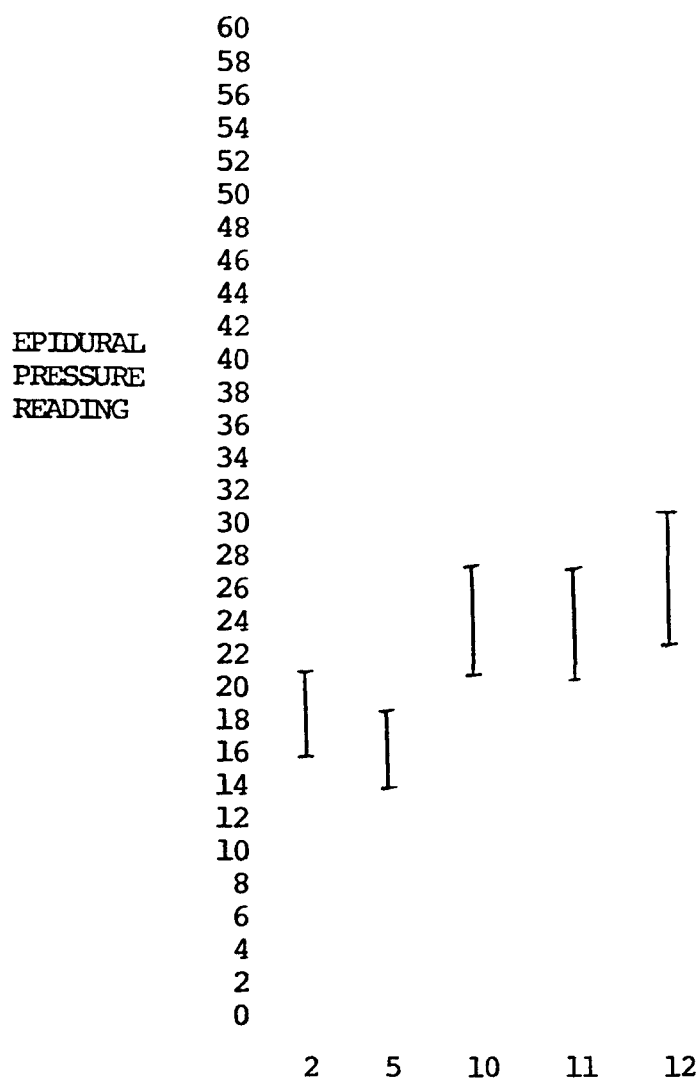
RANGE 4 - 5



MEAN PRESSURE CHANGE WITH ENVIRONMENTAL NOISE

MEAN PRESSURE INCREASE 5

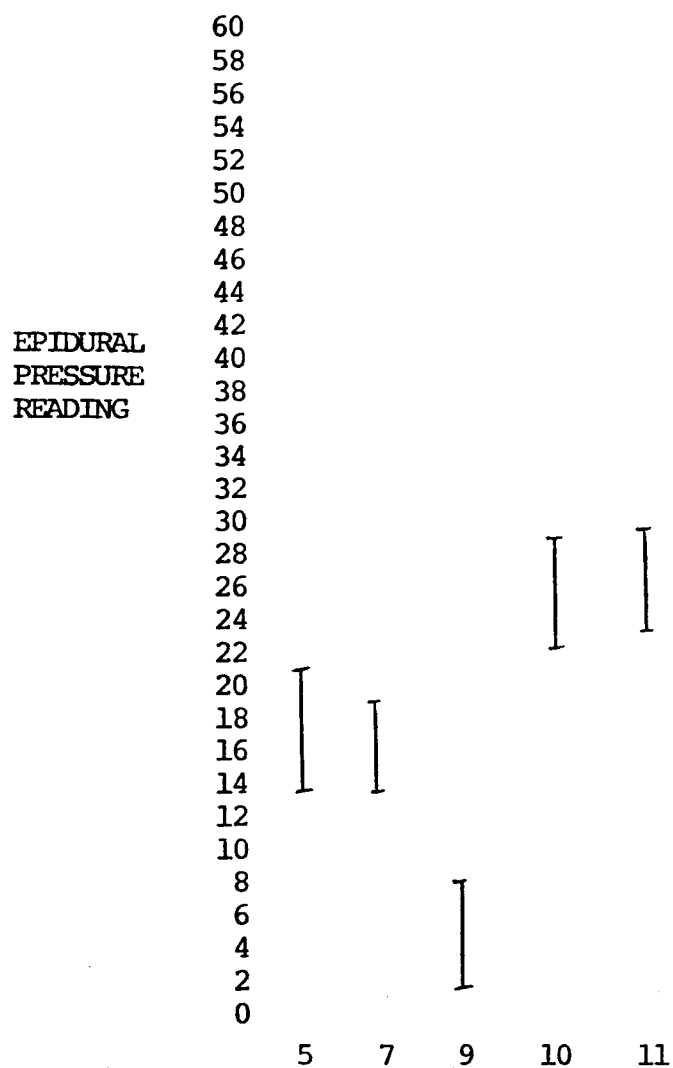
RANGE 3 - 7



MEAN PRESSURE CHANGES WITH SUCTIONING

MEAN PRESSURE INCREASE 5.7

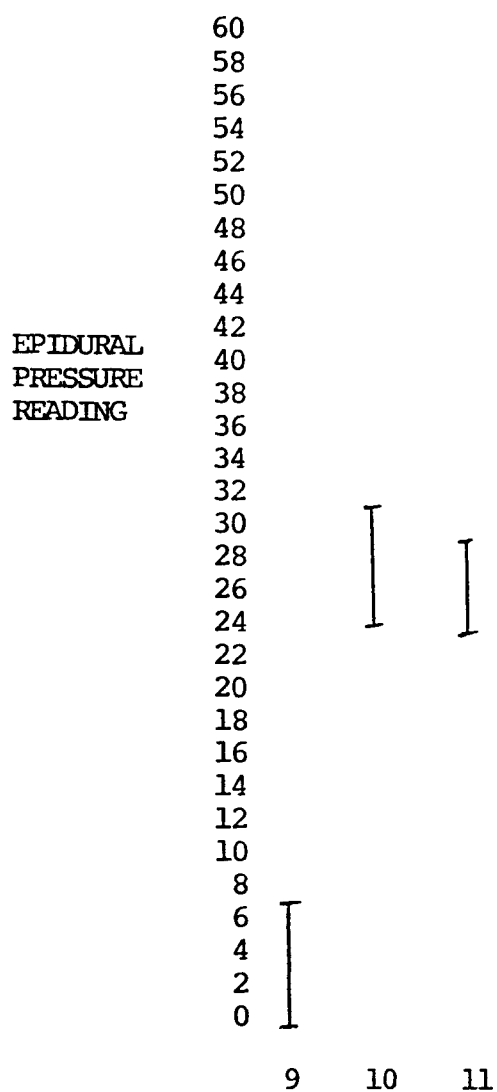
RANGE 5 - 6



MEAN PRESSURE CHANGES WITH TURNING

MEAN PRESSURE INCREASE 5.4

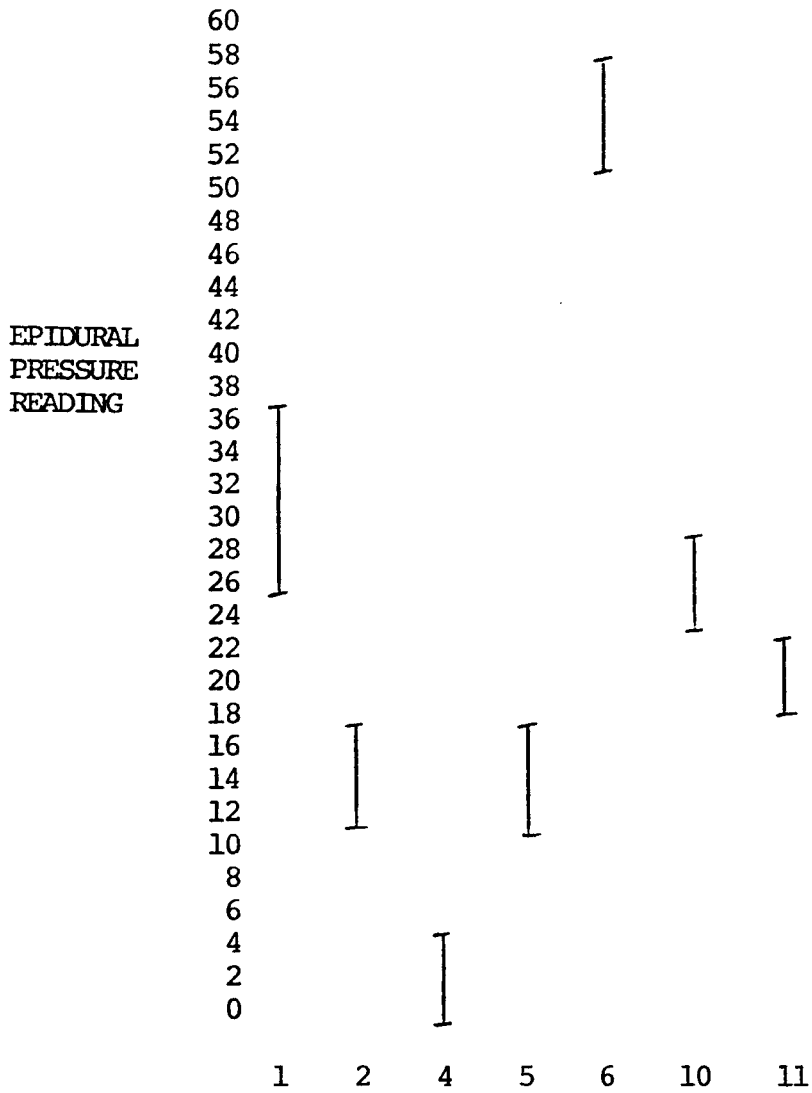
RANGE 4 - 6



MEAN PRESSURE CHANGE WITH ORAL STIMULATION

MEAN PRESSURE INCREASE 5.7

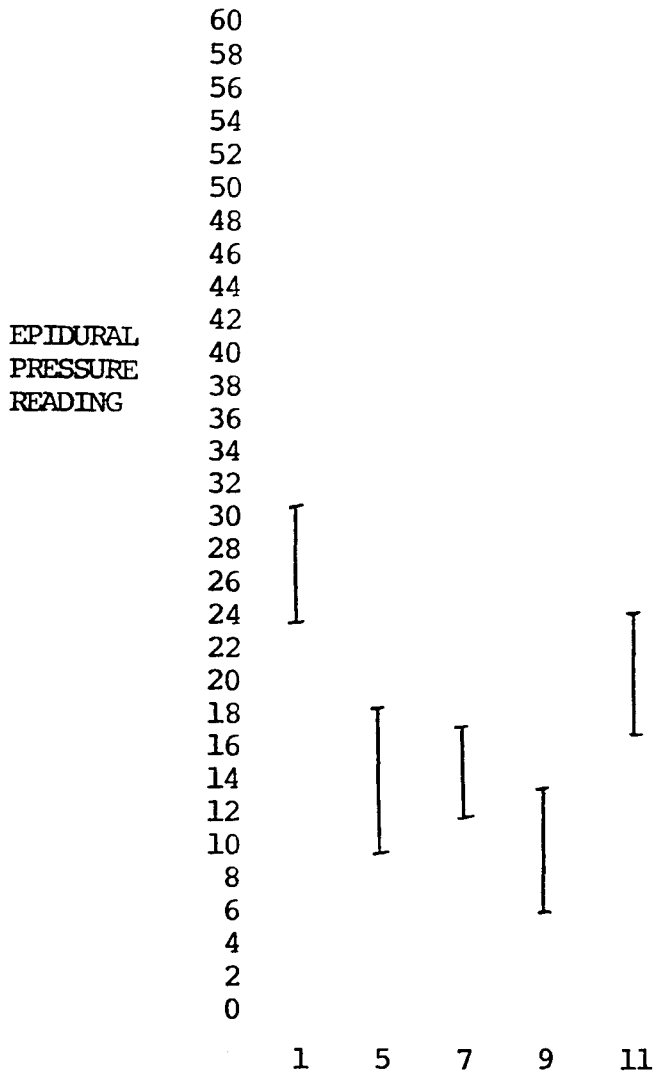
RANGE 5 - 6



MEAN PRESSURE CHANGES WITH COUGH

MEAN PRESSURE INCREASE 5.7

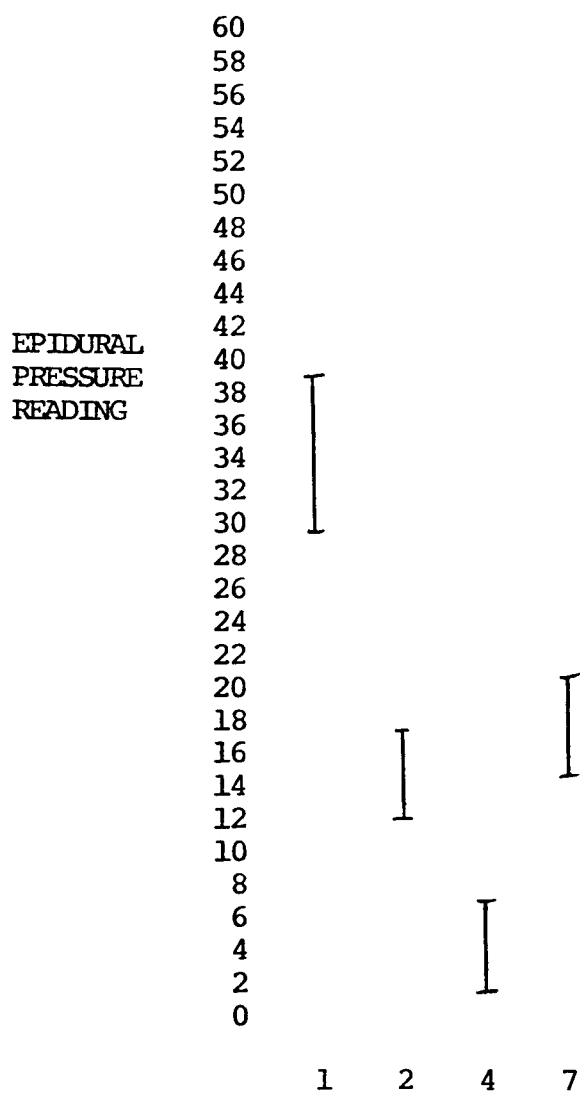
RANGE 4 - 0



MEAN PRESSURE CHANGES WITH HEAD OF BED LOWERING

MEAN PRESSURE INCREASE 6.2

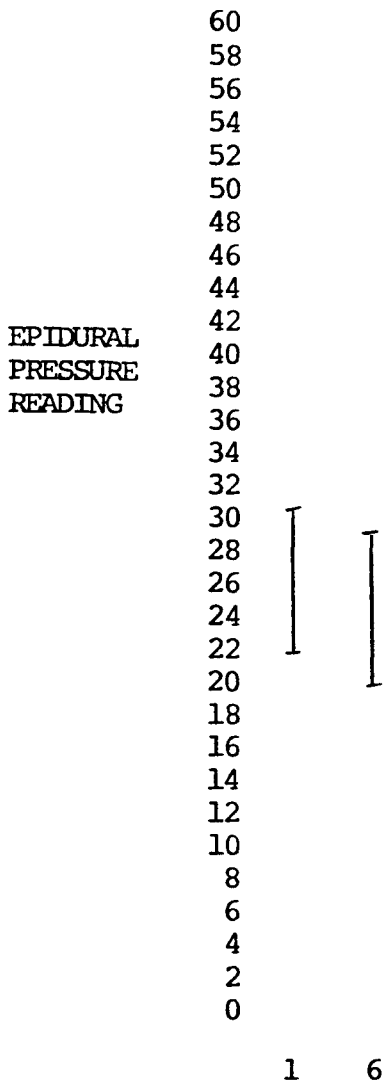
RANGE 5 - 7



MEAN PRESSURE CHANGE WITH SPONTANEOUS MOVEMENT

MEAN PRESSURE INCREASE 6.5

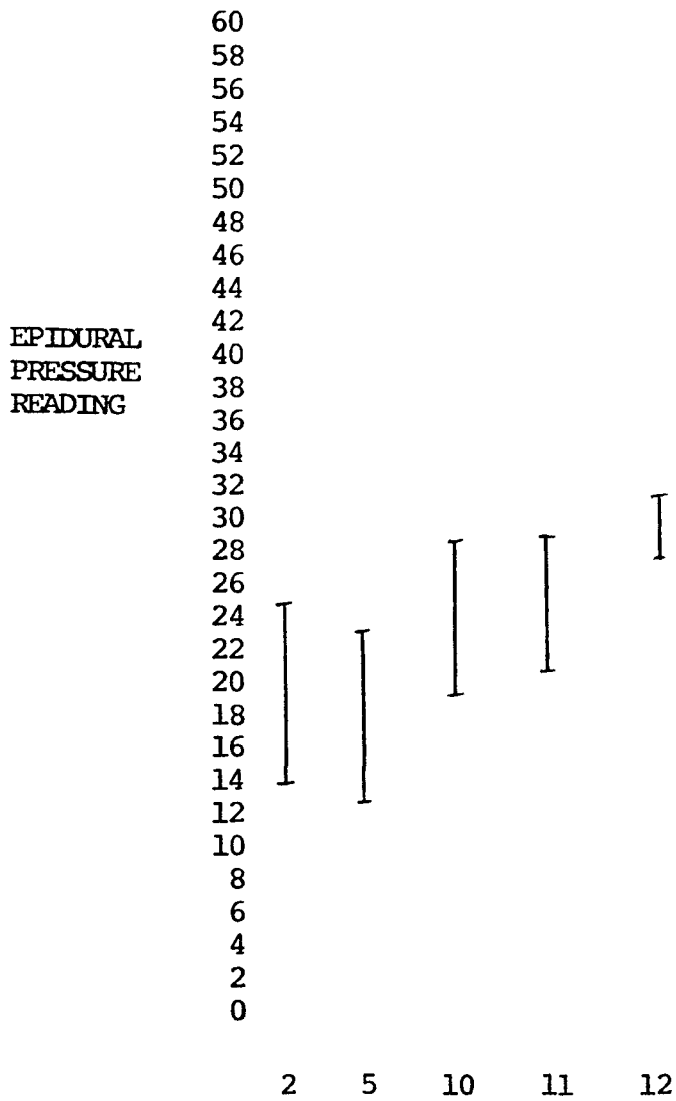
RANGE 5 - 10



MEAN PRESSURE CHANGES WITH INVASTIVE PROCEDURE

MEAN PRESSURE INCREASE 8

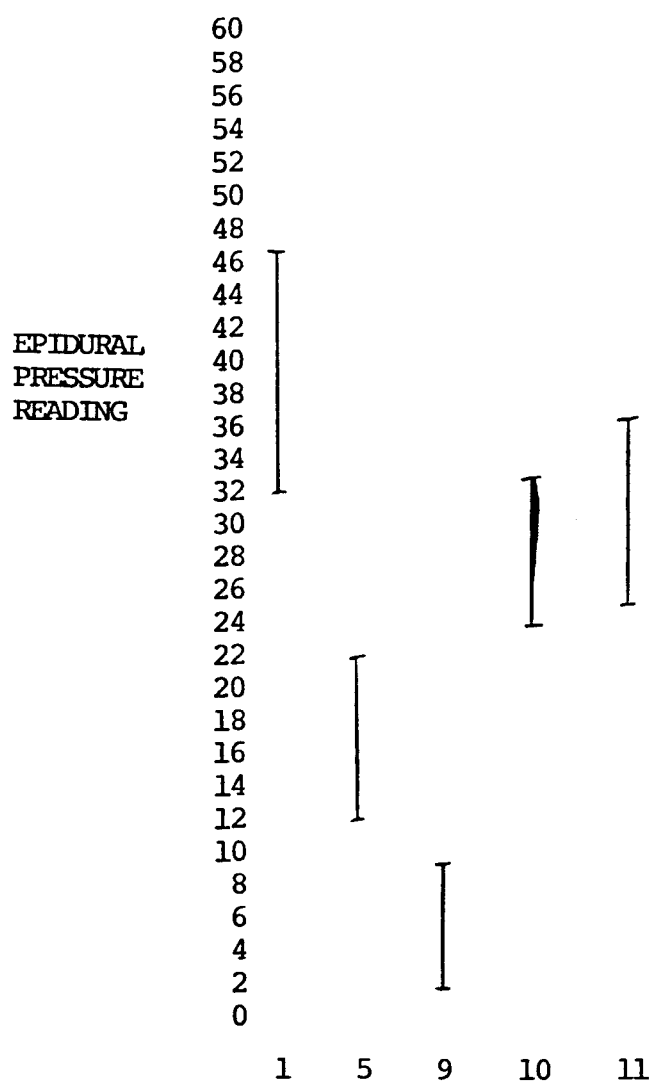
RANGE 8



MEAN PRESSURE CHANGES WITH MANUAL VENTILATION

MEAN PRESSURE INCREASE 9

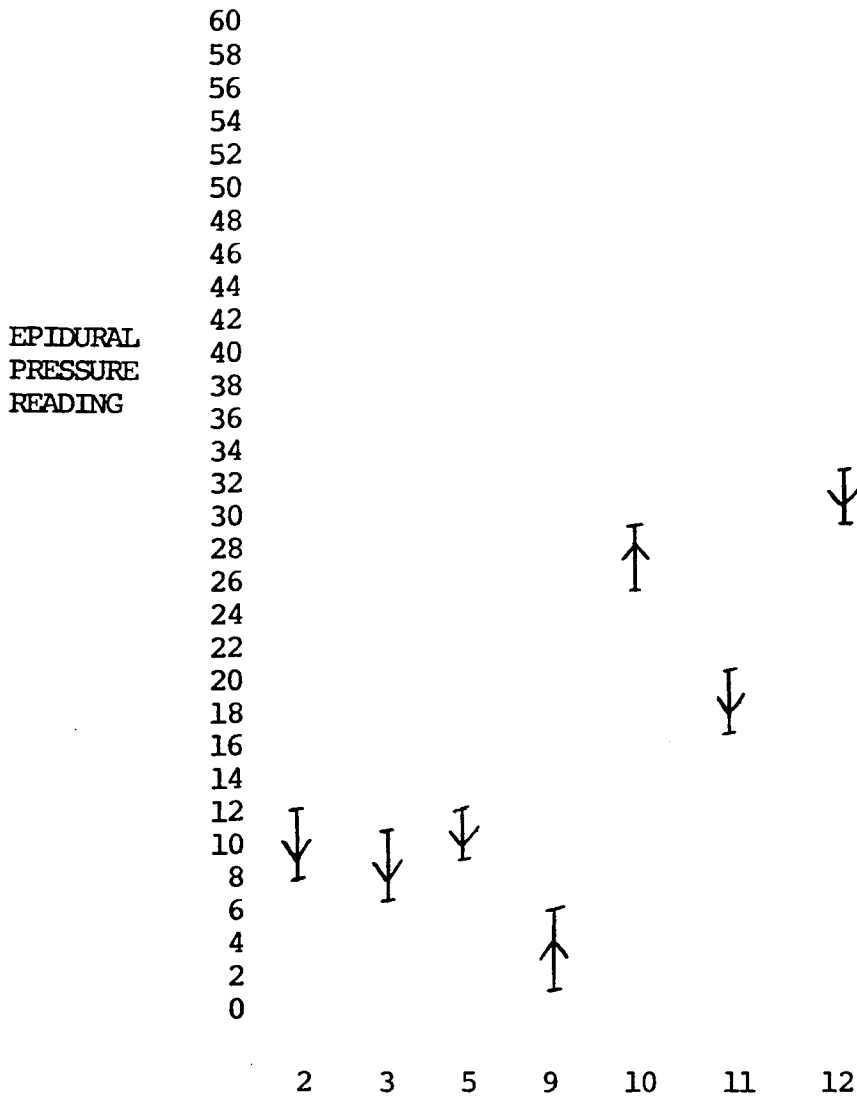
RANGE 4 - 11



MEAN PRESSURE CHANGE WITH NECK HYPEREXTENTION

MEAN PRESSURE INCREASE 10.4

RANGE 7 - 15



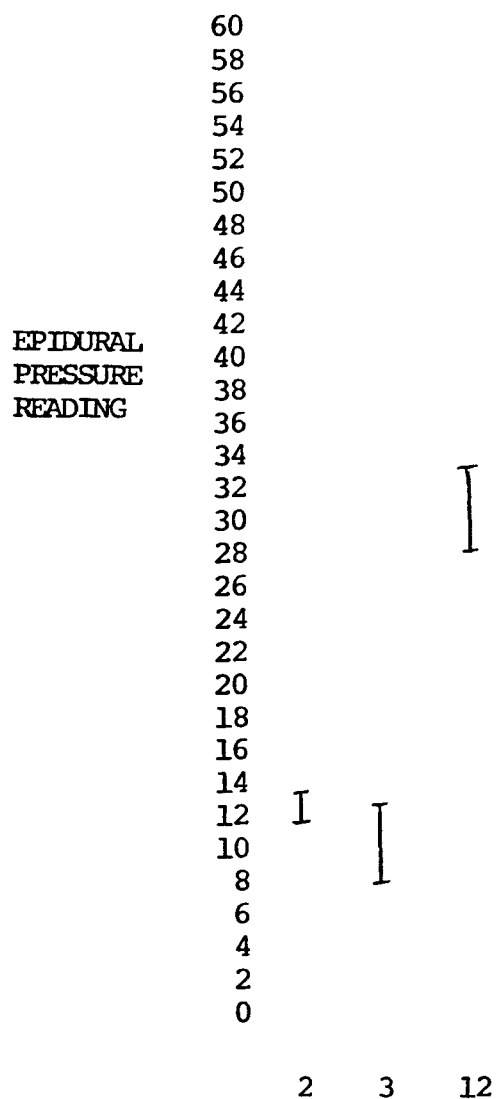
MEAN PRESSURE CHANGES WITH THERAPEUTIC TOUCH

MEAN PRESSURE DECREASE 3

RANGE 2 - 4

MEAN PRESSURE INCREASE 4

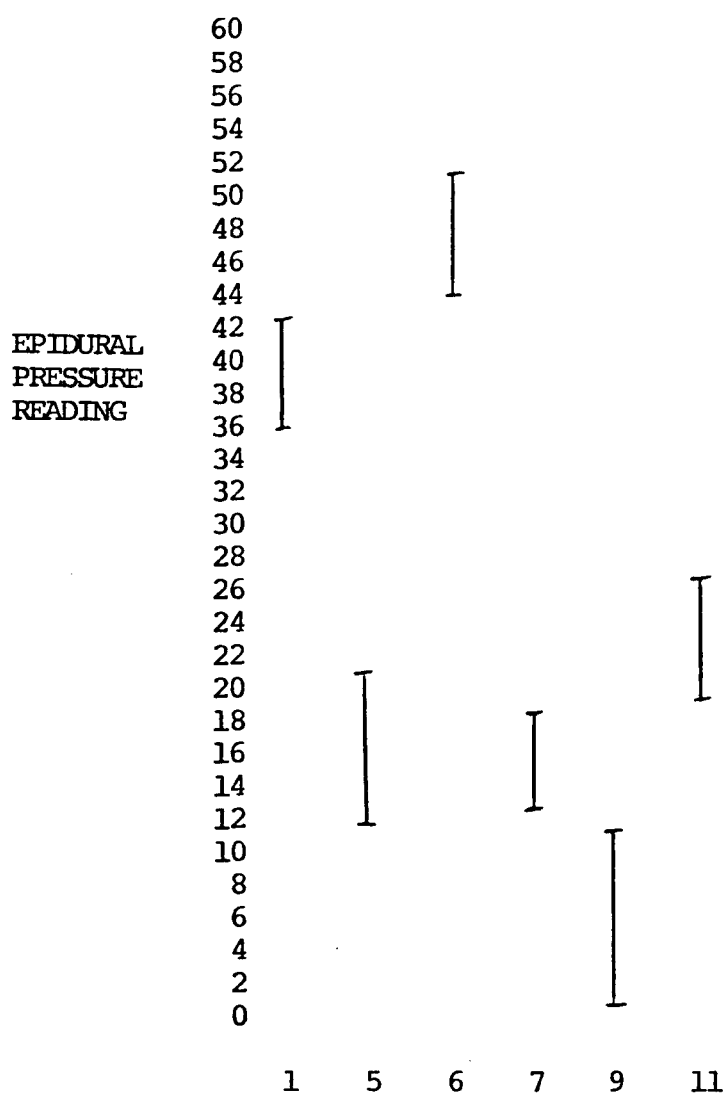
RANGE 4



MEAN PRESSURE CHANGE WITH PERSONAL VERBAL STIMULI

MEAN PRESSURE DECREASE 3

RANGE 1 - 4



MEAN PRESSURE CHANGES WITH HEAD OF BED ELEVATION

MEAN PRESSURE DECREASE 6.7

RANGE 4 - 9

APPROVAL SHEET

The thesis submitted by Amy Perrin, R.N., has been read and approved by the following committee:

Mary Kachoyeanos, R.N., M.S., Director
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The final copies have been examined by the director of the thesis and the signature which appears below verifies the fact that the thesis is now given final approval by the Committee with reference to content and form.

The thesis is therefore accepted in partial fulfillment of the requirements for the degree of Master of Science in Nursing.

December 11, 1981

Mary L. Kachoyeanos R.N.M.S.
Director's Signature