A COMPARATIVE STUDY OF THE TOPICAL APPLICATION OF HYDROGEN PEROXIDE AND INSULIN ON DECUBITUS ULCERS

by

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STATEMENT BY AUTHOR

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ABSTRACT

The aim of this study was to demonstrate an effective method of treatment of decubitus ulcers. It was designed as a three group pretest-postest experimental model, to determine the effect of hydrogen peroxide versus topical insulin on the healing rate of decubitus ulcers, compared to a control group which received distilled water.

Based on this study, no harmful effects were demonstrated with any of the treatments applied. None of the subjects who received insulin therapy developed hypoglycemia or demonstrated an allergic reaction to the insulin.

Due to the small sample size and the variability in the size of the ulcers, there were no significant differences in the mean rate of healing between the three groups. Therefore, the study did not support the hypotheses. However, the trend towards support of the hypotheses was developing on the eighth day of the study.

The analysis of the data indicated that the factors which were suspected of influencing the rate of healing and the factors influenced by routine supportive nursing care were randomly distributed among the three groups. None of the factors exerted a significant influence on the mean rate of healing.

CHAPTER 1

INTRODUCTION

Decubitus ulcers have been documented for centuries, and are universal in that they affect people of all ages and disease processes who have undue amounts of pressure applied to areas of their bodies for varying lengths of time. The search for a solution continues, yet, as it remains elusive, the emphasis in the literature is on prevention. However, the point can be made that should a treatment be found that is proven to be effective, it would be most useful to many people.

Decubitus ulcer, pressure sore, bed sore and skin ulcer all refer to a break in the skin's integrity. It has been generally accepted that the cause of the lesion is vascular obstruction, usually the result of pressure, which disrupts cellular metabolism and leads to tissue necrosis (Berecek 1975; Verhonick, Lewis, and Goller 1972).

Statement of the Problem

This study provides a partial replication of the Van Ort and Gerber Study (1976), and will identify the effectiveness of the application of hydrogen peroxide to

decubitus ulcers as opposed to the application of topical insulin to decubitus ulcers.

Significance of the Problem

Kosiak (1961, p. 19) stated that:

> Ulceration of the skin has undoubtedly plagued the debilitated and disabled patient since the beginning of man. Before the advent of antibiotic therapy, secondary infections of the ulcerations led to early death. Today, the patients usually survive for prolonged periods of time in spite of the ulcerations.

During the months of June through August of 1969, there were 815,000 people in nursing and personal care homes. This figure represents an increase of 47 percent over the number of residents in 1964. Of the 815,000 in homes in 1969, 722,000 were over 65 years (United States Department of Health, Education, and Welfare 1973, p. 3). These figures appear to represent an extended life expectancy of incapacitated people.

Kosiak (1961, p. 19) continued to state that:

> Decubitus ulcerations not only prolong the morbidity and interfere with the rehabilitation and maintenance of the severely disabled or debilitated patient, but they also may frequently be implicated as a major contributing factor leading to the patient's death. Improved medical, nutritional and environmental factors have increased the life span of man with the result that there are more people than ever before living to a relatively old age.

Therefore, if people, including the disabled and debilitated, are living longer it is important that an effective treatment for decubitus ulcers be found.

Currently, the discussion in the literature focuses on the newest hypothesized treatment: application of topical insulin.

Purpose of the Study

In reviewing the literature, it is evident that most authors agree that pressure is the precipitating factor in decubitus ulcer formation. Nevertheless, once ulceration has begun there is no agreed upon method for treatment, as even the best attempts to assess the value of different techniques have yielded negative or limited results. A need for an effective treatment of decubitus ulcers is apparent.

Theoretical Framework

The factors which lead to decubitus ulcers have been summarized by Berecek (1975) and are as follows. The physical factors include pressure (compression), shearing force, fever (infection), moisture, friction, and hygiene. The nutritional factors are general undernutrition and specific nutritional deficiencies of protein and ascorbic acid. Anemia and mobility are the last two factors. The goal of traditional nursing care of decubitus ulcers as outlined by Beland and Passos (1975), has been to apply as many of the above factors as possible in the prevention and treatment of decubitus ulcers.

It has been stated that primary decubitus ulcers, those that are the result of an injury to the epidermis, will undergo the normal wound healing process identified by Ross (1969), providing the above factors have been taken into consideration (Adams and Bluefarb 1968). The process of wound repair has been divided into three stages by Ross (1969), each characterized by particular cell populations. Hydrogen peroxide cleans the wound through a debriding action and is most effective during the first stage. Insulin has been shown to increase the tensile strength of collagen fibers in chronic wounds, and is most effective in the third stage.

The aim of this study was to demonstrate an effective method of treatment of decubitus ulcers. It is recognized that it is not always possible to give optimum nursing care to ulcers, as the amount of pressure to the decubitus may be decreased but not completely eliminated. An additional method of treatment is needed to promote healing in such situations. However, without the benefit of at least some, if not all of the factors deemed necessary for healing incorporated by nurses into their treatment of decubitus ulcers, ulcers would fail to heal regardless of what was applied topically.

Hypotheses

There will be a significantly faster rate of healing of decubitus ulcers for subjects receiving hydrogen peroxide as opposed to those receiving topical insulin. The control Group, which will receive distilled water, will evidence the slowest rate of healing.

Null Hypothesis

As both hydrogen peroxide and topical insulin act as debriding agents, the effects of their application on newly formed decubitus ulcers will be similar.

Assumptions

1. Decubitus ulcers will heal although the ischemic area is not completely free of pressure at all times.
2. Non-ambulatory patients with or without varying degrees of sensory deficit are more likely to develop decubitus ulcers than ambulatory patients with or without sensory deficit.

Limitations

1. All of the subjects were in a nursing home, required various amounts of nursing care, and were either bed or chair-fast.
2. All of the subjects were 65 years or older, and Caucasian.

3. All of the ulcers were between 1.0 cm. and 7.0 cm. in diameter.
4. All of the ulcers were newly formed, that is, within two weeks prior to treatment.
5. All of the ulcers were superficial, that is, the cellular necrosis began in the dermis and epidermis, not in the muscle.

Definitions

1. Decubitus ulcer was a break in the skin's integrity as a result of pressure.
2. Newly formed decubitus ulcers were those where the skin had been broken for not more than two weeks prior to treatment.
3. Bedfast or chair-fast were nonambulatory subjects, who showed none or very little ability to reposition themselves.
4. The rate of healing was determined by the decrease in the millimeter squared size of the ulcer within a fifteen day period.
5. Supportive care was nursing care which the staff of the institution gave to patients with decubitus ulcers. This care included, but was not limited to position changes, increased fluid intake, a high protein diet or local massage.

CHAPTER 2

REVIEW OF THE LITERATURE

Berecek (1975) has clearly outlined the factors which lead to skin breakdown. These factors are of interest to nurses in the prevention and treatment of decubitus ulcers and are discussed in detail in this chapter.

Ross (1969) has divided the process of wound healing into three stages. The process is similar for all tissues and is generally independent of the form of injury. The third stage, which involves the deposition and formation of collagen, was of interest to this study as some authors postulate that insulin acts in the collagen phase of healing (Grewal et al. 1972).

While attempting to identify a new treatment which increased the rate of healing in decubitus ulcers, the theory of wound healing was taken into consideration. It was postulated that insulin would be of value, as it had been shown that in some manner insulin stimulated protein biosythesis (Grewal et al. 1972). Hydrogen peroxide was chosen as a second therapy to compare with insulin, as it is commonly used by nurses in their treatment of decubitus ulcers, although this therapy had not been identified in the literature.

Several authors have given their definitions of decubitus ulcers. Adams and Bluefarb (1968, p. 269) defined them as a lesion caused by "tissue ischemia secondary to pressure." Husain (1953, p. 355) defined decubitus ulcers as "foci of skin and subcutaneous tissue necrosis most often found in the dependent portions of the body when the soft parts are subjected to long continued pressure between the bed and some more or less superficial bone." Kahn (1960, p. 1657) stated "an ulcer is present when there is loss of continuity of an internal or external body surface." Kosiak (1961, p. 19) stated that "decubitus ulcers are localized areas of cellular necrosis." In summary, a decubitus ulcer is an area of the body, most likely over a bony prominence, where the integrity of the skin has been broken due to vascular obstruction, usually the result of pressure, followed by cellular necrosis.

Causal Factors

Physical Factors

Pressure. The most widely agreed upon causal factor of decubitus ulcers was vascular obstruction due to pressure (Berecek 1975; Verhonick et al. 1972), although there was disagreement in the literature as to the amount, duration and area where compression was likely to occur.

The physiology behind vascular obstruction is as follows. Verhonick et al. (1972, p. 233) stated that:

> Capillary pressure is approximately 32 mm. Hg., and if microcirculation underlying these vulnerable skin areas is impaired because of excessive pressure, ischemia results. Prolonged excessive pressure exceeding 32 mm. Hg. ultimately leads to the development of pressure sores.

Landis (1930, p. 214) found the normal capillary hydrostatic pressure to be 32 mm. Hg. at the arteriole end and 12 mm. Hg. at the venule end. In any event, pressure in excess of these, lead to capillary obstruction with resultant ischemia. Cellular metabolism is dependent on adequate blood flow for the delivery of oxygen and nutrients to the tissues and the removal of carbon dioxide and the wastes of cellular metabolism. Therefore, prolonged ischemia leads to necrosis.

Several investigators have noted that if arterial compression is released prior to necrosis, reactive hyperemia, as a natural protective response, occurs (Kosiak 1961). Husain (1953, p. 357) stated, "release of persistent compression is followed by reactive hyperemia, edema and often capillary and venous hemmorrhage in the affected area." Reactive hyperemia is "due to active vasodilatation in response to partial or complete obstruction to blood flow" (Husain 1953, p. 354). The degree of hyperemia is proportional to the needs of the tissues (Husain 1953), duration of the occlusion and to the temperature of the limbs (Kosiak

1961). Landis (1928) noted capillary pressures of up to 60 mm. Hg. during hyperemia. From his studies, he felt that anoxemia was the primary reason for reactive hyperemia. However, should the obstruction remain for longer than the critical time period of one to two hours, "the mechanism of reactive hyperemia is insufficient, irreversible pathology changes occur in the tissues, and their death ensues, resulting in the formation of a decubitus ulcer" (Berecek 1975, p. 162).

Air pressure has been calculated at 15 pounds per square inch of body surface (Husain 1953). Husain (1953) found that following application of 100 mm. Hg. of pressure, the critical time period at which pathologic changes occurred in both normal and denervated tissues was one hour. Kosiak (1959) found the amount of pressure needed to cause pathologic changes to be 60 mm. Hg., applied for two hours. It must be noted, that the time period varies inversely with the amount of pressure, and can be as short as one-half four in some people.

Husain (1953, p. 357) concluded that:

> Pressure evenly distributed over a wide area of the body is much less damaging to the tissues than localized or point pressure. . . . Low pressure for long periods of time produces more tissue damage than high pressure for short periods. The time factor is thus more important than pressure intensity.

Exton-Smith and Sherwin's (1961) conclusions following their study on the effects of pressure were the same. Kosiak

(1959) also found that tissue damage occurred almost exclusively over bony prominences which were subjected to numerous point pressures for varying lengths of time.

In summary, it has been shown that compression of short duration is followed by reactive hyperemia. The critical amount of time for ischemia to occur appears to be one to two hours, although this can vary. As to the amount of pressure, the skin appears able to tolerate high pressures of 75 mm. Hg. for short periods of time, without pathologic changes, as long as there are frequent pressure free intervals (Lindan, Greenway, and Piazza 1965). "Decubitus ulcers are usually produced by moderate pressure applied continuously for long periods of time" (Berecek 1975, p. 160).

Lindan et al. (1965) researched the pressure distribution on the surface of the body in both lying and sitting positions. They found that in normal subjects with ideal body weight, the points of highest pressure in the supine position were the sacrum, buttocks, and heels. These areas were found to support pressures in the range of 40-60 mm. Hg. In the sitting position, the points of greatest pressure were found to be over the ischial tuberosities and ranged up to 75 mm. Hg. On a hard, flat surface the pressure on the ischial tuberosities was greater than 300 mm. Hg. (Kosiak et al. 1958). All of these pressures are in excess of normal capillary hydrostatic pressure.

Lindan et al. (1965) found that in underweight subjects the peak pressures were higher in both lying and sitting positions, when compared to normal weight and obese subjects. They hypothesized that this was because the latter subjects had a greater surface area over which to spread the pressure. Merlino (1969), in support of the Lindan et al. study (1965), found that 75 percent of all decubitus ulcers were over the sacrum, greater trochanters and ischial tuberosities.

Shearing Force. Both Binks (1968) and Reichel (1958) studied the effects of shearing force as a contributing factor to the formation of decubitus ulcers. Reichel (1958, p. 762) stated:

> When the head of the bed is raised, the torso tends to slide down, transmitting this action to the sacrum and its firmly attached deep fascia. Due to friction, the skin will tend not to slide as much as the underlying tissues, which will result in stretching and angulation of blood vessels which in turn will result in multiple thrombosis of small vessels.

Subsequent ischemic necrosis then follows the process of shearing force.

Fever and Infection. Fever, when it is an indicator of an infection in the body, may be a contributing factor to decubitus ulcer formation. With fever, there is an increase in cellular metabolism in an effort to fight the infection. As a consequence of the increased basal

metabolism rate, there is an increased demand placed on the body for oxygen and nutrients. The supply of nutrients may already be compromised by compression (Schell and Wolcott 1966). Williams (1971) found significant correlations between the presence of infection other than genitourinary, and body temperature with skin breakdown of 6.066 and 4.455 respectively.

Moisture. "An increase in moisture, as a result of perspiration and incontinence of urine or feces, reduces the resistance of the skin to other physical factors contributing greatly to the risk of development of necrosis and ulceration" (Schell and Wolcott 1966, p. 110). Binks (1968) found that the most useful single indication of the risk of developing pressure sores was incontinence of urine or feces; those patients who were incontinent of both being the most liable.

Friction. An injury due to friction usually results in the loss of the epidermis. "Any break in the integrity of the skin's surface predisposes to infection, edema, and increased moisture. Friction alone has no direct effect on the dermis or deeper structures" (Berecek 1975, p. 165).

Hygiene. "Hygiene is important in decreasing the bacterial population of the skin" (Schell and Wolcott 1966, p. 110). If the skin becomes infected, a decubitus ulcer may result.

Nutritional Factors

General Undernutrition. Schell and Wolcott (1966, p. 110) concluded that:

> Poor nutrition is frequently associated with chronic illness. The marked loss of weight which so often occurs, in addition to the muscle atrophy often present, results in a substantial reduction in the subcutaneous fat and muscle bulk which reduces the mechanical padding between the skin and underlying bone.

Williams (1971, p. 31) found a significant correlation between body weight and skin breakdown of 13.590; that is, "thin people seemed more likely to form decubitus ulcers."

Specific Nutritional Deficiences. Hypoproteinemia has been shown to interfere with normal tissue integrity. The daily dietary requirement for protein is one gram per kilogram per day (Taylor and Pye 1966). A sufficient intake of protein increases resistance to infection by its effect on complement and antibody production (Taylor and Pye 1966). Berecek (1975, p. 165) stated that:

> When the body lacks protein due to inadequate intake or unusual loss, a negative nitrogen balance ensues predisposing to edema of the dependent parts of the body. The presence of edema decreases the elasticity, resiliency, and vitality of the skin, making it more susceptible to injury. Edema also slows the rate of diffusion of oxygen and metabolites from the capillaries to the cells, since the rate of diffusion decreases in proportion to the distance from the capillary to the cell.

Healing will not occur when a person is in a negative nitrogen balance (Guyton 1976). McElhinney (1968, p. 284)

stated, "it is well known that the protein lost from oozing sores is profound." Protein contains nitrogen which is vital for producing new tissues. Mulholland et al. (1943, p. 1021) hypothesized that, "in patients with protein malnutrition, tissues are so changed in character that it apparently takes a smaller amount of pressure for a shorter period of time to cause tissue necrosis." They found that the administration of an amino acid and dextrose solution in saline seemed to lead to weight gain, reversal of the negative nitrogen balance, and wound healing.

Ascorbic acid is a water soluble vitamin which is necessary for tissue integrity. The daily requirement for an adult male is 60 mg. per day (Bergersen and Krug 1969). Ascorbic acid is concerned with the "formation of collagen in all fibrous tissue, including bone, and with the development of teeth, blood vessels and blood cells. It is believed to stimulate the fibroblasts of connective tissue and thus promote tissue repair and healing of wounds" (Bergersen and Krug 1969, p. 450). Burr and Rajan (1972) found that the healing of wounds was dependent on the availability of ascorbic acid for collagen synthesis. They found that vitamin C did have an effect on collagen formation, but could not equate this effect with the acceleration of wound healing. They also demonstrated that a deficiency of ascorbic acid must be severe before healing is inadequate, but

noted that stressors of various kinds increased the requirement for vitamin C.

Anemia

"Anemia or anoxemia, with the resulting reduction in the delivery of oxygen will further embarrass cellular metabolism and tissue necrosis will become more imminent" (Schell and Wolcott 1966, p. 111). Vasile and Chaitin (1972, p. 129) found that "the level of mobility of the patient, his hemoglobin reading and fasting blood sugar and whether he has single or multiple ulcers are important prognostic factors." In order to maintain a positive nitrogen balance, a hemoglobin of 12 Gm. or more is essential (Merlino 1969).

Mobility

Berecek (1975, p. 166) noted that:

> In health, tissues are not subjected to high pressures for long because the discomfort that arises from compression of the skin and subcutaneous tissues readily initiates a change in position. In the normally active person the limit of tolerance to pressure is rarely exceeded, but in illness it appears that the protective mechanisms may be ineffective or even absent.

"Extreme weakness associated with poor physical condition, apathy, clouding of consciousness, paralysis, or sensory disturbances may all lead to a lack of response to stimuli arising from the area of skin that is compressed" (Exton-Smith and Sherwin 1961, p. 1125). Their study found that

healthy people shift their positions 20-40 times a night. They went on further to show that the incidence of pressure sores is directly proportional to the number of spontaneous body movements made during sleep. Those people who moved less than twenty times a night inevitably developed ulcerations.

In summary of the causal factors of decubitus ulcer formation, almost all authors agreed that vascular obstruction, due to pressure, was the primary predisposing factor which led to ulceration. The other factors were not accepted by all authors.

Williams (1971, p. 41) formed a description of the people most likely to develop decubitus ulcers: "This person is a thin man, not yet in old age, who has some infectious process and a temperature. . . . He may be receiving treatment with corticosteriods. He may have some impairment of sensation, some inability to move himself, or a depressed level of consciousness."

Treatments

There were many treatments suggested in the literature for decubitus ulcers. There was no agreed upon method for treatment; as even the best attempts to assess the value of different techniques had given negative or only limited results. The current hypothesized treatment is the application of topical insulin.

Insulin

Insulin is a hormone normally manufactured by the beta cells in the pancreas. It functions in the regulation of glucose, lipid and protein metabolism (Rieser 1967). Regular U-100 Insulin (U.S.P.) is an aqueous protein solution taken from pork or beef pancreas.

Topical Insulin with Chronic Wounds. Several investigators found that insulin had an effect on the healing of chronic skin ulcerations of diabetics (Paul and Calcutta 1966; Lopez and Mena 1968; Hughey 1974).

By definition, a chronic wound is one that will not heal or whose healing is retarded by systemic or local factors (Boxer et al. 1969). In all of the above studies, the subjects were diabetics with skin ulcerations of long standing. Topical insulin was used as a treatment for the ulcer, after antibiotic therapy, amputation, applications of furacin or diet control were ineffective. In all of the studies, the samples were five patients or less. However, in all cases evidence of healing was noted.

Lopez and Mena's study (1968) was interesting because one of the treatments they used prior to topical insulin was an ulcer irrigation of 0.1 percent potassium permanganate, an oxidizing agent, similar to hydrogen peroxide. Their study indicated that the ulcer did not respond to this type of

treatment, and so they went on to use topical insulin with success.

Parenteral Insulin in Acute Wounds. Moolten (1972) found correlation between the formation of decubitus ulcers and low levels of serum albumin which reflected malnutrition and excessive loss of serum protein in the ulcer exudates. His treatment consisted of giving the subject five units of insulin parenterally fifteen minutes before meals, dietary supplements, anabolic steroids and parenteral vitamins. He felt that this combination of therapy proved effective in promoting healing of decubitus ulcers.

Rosenthal (1968), Udupa and Chansouria (1971), and Grewal et al. (1972), found that the sutured incisional wounds of rats receiving parenteral insulin showed a significantly higher tensile strength than the control groups. The experimental rats had significant weight increases proportional to the increase in tensile strength. Rosenthal (1968) used alloxan-induced diabetic rats for subjects. He hypothesized that the increased tensile strength was due to increased protein synthesis, which resulted in increased amounts of collagen deposition. Udupa and Chansouria (1971) used non diabetic rats for subjects. They felt that the increased tensile strength was due to the beneficial effect of an altered state of metabolism caused by the insulin, rather than the primary action of insulin.

Topical Insulin with Granulating Wounds. Fee (1973) studied rats to determine if the topical application of insulin significantly increased the healing rate of granulating wounds. Her definition of a granulating wound was, "a gaping wound which heals by the outgrowth of new capillaries and formation of fibrous scar tissue" (Fee 1973, p. 5). Fee surgically induced the wound, and found that topical insulin had no effect on the healing process of a granulating wound. When Fee interpreted her findings, she hypothesized that the physiologic difference between chronic and granulating wounds was the reason for the difference in healing of decubitus ulcers. She stated that topical insulin, when applied to chronic wounds, acted as a debriding agent, removing nonviable debris and necrotic material. After this was accomplished the wound underwent the normal healing process identified by Ross (1969) for clean incisional or granulating wounds.

Her findings correlated with those of Rosenthal and Enquist (1968), who used three groups of rats. The control group evidenced the fastest rate of healing, the group with topical application of insulin next, and those receiving parenteral insulin last. All of the rats had surgically induced wounds that were not sutured. The difference in the healing rate between the control and topical insulin groups was not statistically significant. The group receiving

parenteral insulin showed marked delay in wound healing, and 12 of the 24 animals died before complete healing. Rosenthal and Enquist (1968, p. 1098) hypothesized that:

> Apparently parenteral insulin given to normal animals, although stimulating protein synthesis and increasing tensile strength of sutured wounds, in some way impedes the contraction and epithelial ingrowth necessary for the healing of granulating wounds.

Hydrogen Peroxide

Hydrogen peroxide (U.S.P.) is a three percent solution which decomposes to water and oxygen. It is germicidal to anerobic bacteria when actively releasing oxygen. Its actual value lies in its ability to remove organic debris through its effervescent action, rather than its direct antibacterial effect (Bergersen and Krug 1969).

The review of the factors which lead to ulcer formation has been taken into account. The factors of duration and amount of pressure, shearing force, fever and infection, moisture, friction, hygiene, nutrition, anemia and mobility affected equally both the control and experimental groups.

This study was undertaken to determine the effect of hydrogen peroxide versus topical insulin on the healing rate of decubitus ulcers. There were no controlled studies in the literature using both diabetic and non diabetic subjects with acute ulcerations receiving topical insulin as a

treatment. There were also no controlled studies in the literature using hydrogen peroxide as a topical agent. It is known that hydrogen peroxide's main value is as a debriding agent. If Fee's (1973) hypothesis was correct, that topical insulin acts as a debriding agent, there will be no significant difference between the healing rate of the two experimental groups.

CHAPTER 3

METHODOLOGY

This study was a partial replication of the Van Ort and Gerber study (1976). It was designed as a three group pretest-postest experimental model, to determine the effect of hydrogen peroxide versus topical insulin on the healing rate of decubitus ulcers, compared to a control group which received distilled water.

Research Design

Permission to conduct this study was obtained from The University of Arizona Human Subjects Committee. Verbal permission was obtained from all subjects, regardless of whether or not they were able to give legal permission. The explanation of the study given to the subject and his guardian is in Appendix A (see Forms 1, 2, and 3). It was emphasized that their permission was voluntary and that they could withdraw from the study at any time. They were also told that they would not be charged for any of the blood tests or treatments. All subjects were informed of the researcher's graduate student status. Individual anonymity and confidentiality of replies were assured. Written permission from the subject and/or his guardian were then obtained.

Permission to conduct this study was obtained from the appropriate administrator in the health care facility prior to data collection (see Appendix B). The purpose of the study and a brief description of the methodology were given to the nursing staff of the institution in an inservice meeting.

The explanation given to the subject's physician was a brief description of the study. It was emphasized that a blood glucose level and hemoglobin would be drawn without charge to the subject. Controls for the advent of hypoglycemia in those subjects receiving topical insulin was also emphasized. The physician was contacted by phone and a verbal order was received for the treatments and blood tests. This order, in written form, was then mailed to the physician for his signature.

The Tool

The researcher compiled a list of factors considered relevant to the problem of skin breakdown and devised a rating system used in the appraisal of each of these factors for each subject. The factors were chosen as a result of the researcher's personal experiences, the experiences of others, and those cited in the literature. The factors of mobility and activity were taken from Gosnell's research (1973). The factors on level of consciousness, body weight, and sensation were taken from Williams' research (1971).

The general format of the tool is similar to the assessment tool used in the Van Ort and Gerber study (1976).

About one-fourth of the items are dichotomous and were scored on a two point scale. The others had three or more values and were rated accordingly. The rating system was developed in a similar fashion. A copy of the Pre-procedural Assessment Form which includes a list of the factors and the rating system can be seen in Appendix C. This assessment form was also used for data collection.

The Population and Sample

The population which was studied consisted of patients in an extended care facility in a southwestern city. The sample consisted of fifteen subjects; five in experimental group A, five in experimental group B, and five in the control group.

Data Collection Plan

The data were gathered by the researcher during a three month period at an extended care facility in a southwestern urban community. Data collection activities were performed between 7:00 A.M.--9:30 A.M. and 5:00 P.M.--7:00 P.M., seven days a week, to admit subjects to the study and to follow subjects already admitted to the study.

Criteria for Selection

When the researcher was notified by a staff member that a patient had a skin lesion, the researcher assessed the ulcer to determine if it met the criteria for selection. To determine if the ulcer was between 1.0 cm. and 7.0 cm. in diameter, a transparent scale was placed over the decubitus ulcer. This scale consisted of concentric circles in increasing diameters in centimeters. The transparency of the scale allowed for direct visualization of the diameter and ulcer simultaneously. The staff were questioned as to the length of time the ulcer had been in existence and if any treatment had been given to the ulcer.

If the ulcer met the criteria for selection, permission was obtained from the patient, his guardian, and his physician. The staff were notified that the patient had been included in the study in order to prevent them from initiating treatment of the ulcer. This was accomplished by means of a written notice at the nurses' station and by speaking to the staff member who usually gave the patient his physical care.

The factors influenced by routine supportive nursing care were controlled by randomization. Subjects were randomly assigned to one of the three groups by means of a table of random numbers. If two subjects were admitted simultaneously a coin was flipped. If the subject had more

than one ulcer present, the ulcer for the study was chosen by numbering each ulcer, and then asking a staff member, who did not know which of the ulcers had been assigned a number, to choose between the numbers one and ten. Aside from the ulcer chosen for the study, subjects with multiple lesions had the control regimen applied to their remaining lesions.

Data Collection

The data collection plan for subjects in both the experimental and control groups encompassed a fifteen day period. During this period subjects had a blood sample drawn by a local laboratory for determination of the hemoglobin level. The researcher assumed the responsibility for the cost of the test. The results, however, were placed on the subject's chart for use by other medical personnel. During the fifteen day period all subjects had at least one fasting blood glucose determination made to rule out diabetes mellitus.

On the first day of the study the Pre-procedural Assessment Form was completed. Information such as age, diagnosis, and medications were obtained from the chart. Body weight, incontinence, sensation, activity, mobility, pressure on the site of the ulcer, and level of consciousness were observed directly by the researcher and indirectly through interactions with the staff. The fluid and protein

intake was approximated by the researcher by recording the subject's intake for one twenty-four hour period. The fluid was recorded in milliliters per day. The amount and kind of proteins ingested were converted into grams of protein per day. The researcher determined from the staff as to whether or not the twenty-four hour intake was recorded on a typical day for the subject. An oral temperature was taken on all subjects with an electric thermometer between the hours of 5:00 P.M.--7:00 P.M. A temperature greater than 37.8 degrees centigrade was defined as a fever (Erickson and Storlie 1973).

Experimental Group A. For subjects in experimental group A, the following activities occurred sequentially. On the first day the Pre-procedural Assessment Form was completed. The decubitus ulcer was measured by placing wax paper over the ulcer and tracing the outlines of the ulcer with a pencil. Each day a separate sheet of wax paper was used for each subject. The wax paper had a notation made on it to indicate the side of the wax paper directed towards the subject's head. Later, the wax paper was placed over graph paper divided into millimeters squared. The outline of the ulcer was traced on the graph paper by means of carbon paper. All ulcers were drawn so that the anterior surface of the wax paper was at the top of the graph paper. This allowed for visualization of the healing process. The

number of millimeters squared was counted from the tracing on the graph paper and recorded on the Pre-procedural Assessment Form. The rate of healing was determined by a decrease in millimeters squared.

After the ulcer was measured, a fasting blood glucose was determined by using an Ames Eyetone Meter. The subject's finger was pricked, and a drop of blood allowed to fall on an Ames Dextrostix. The Dextrostix was then read in milligrams percent using the Ames Eyetone Meter, and recorded on the Pre-procedural Assessment Form.

The insulin regimen was then initiated. This regimen involved the topical application of ten units of Regular Insulin U-100 twice daily by dropping it from a syringe from which the needle had been removed. The decubitus ulcer was then exposed to the air to dry. No dressing was applied.

Two hours after the topical application of insulin, another blood glucose determination was made. As one of the effects of topical insulin may be a lowered blood glucose level, the subject was observed for signs of hypoglycemia, and encouraged to eat during the two hour period following the topical application of insulin.

On the second through the fifth day, the decubitus ulcer was measured and observed once daily. The insulin regimen was applied twice daily, and the subject continued to be observed for signs of hypoglycemia. Blood glucose

determinations were made twice a day; once before the first insulin treatment, and two hours after that treatment.

From the sixth through the fifteenth day, the decubitus ulcer was measured and observed once daily. If the size of the ulcer increased after a 72 hour period of cessation of treatment, the insulin regimen was re-applied.

Experimental Group B. For subjects in experimental group B, the following activities occurred sequentially. On the first day the Pre-procedural Assessment Form was completed. The decubitus ulcer was then measured. A three percent hydrogen peroxide solution, with a dilution of 1:4, was prepared. One milliliter of the solution was dripped onto the ulcer from a syringe from which the needle had been removed. The decubitus ulcer was then exposed to the air to dry. No dressing was applied. The treatment was repeated in the afternoon.

On the second through the fifth day, the decubitus ulcer was measured once daily. The hydrogen peroxide regimen was applied twice daily.

On the sixth through the fifteenth day, the decubitus ulcer was measured and observed once daily. If the size of the ulcer increased after a 72 hour period of cessation of treatment, the hydrogen peroxide regimen was re-applied.

Control Group. For subjects in the control group, the Pre-procedural Assessment Form was completed on the first

day. The ulcer was measured daily for fifteen days. For the first five days one milliliter of distilled water was applied twice daily. The decubitus ulcer was then exposed to the air to dry. No dressing was applied.

Analysis of Data

All data were analyzed with computer assistance. The characteristics of the sample were analyzed using the measures of central tendency to determine if the factors which were suspected of influencing the rate of healing were randomly distributed.

Analysis of variance was used to compare the mean rate of healing between the control and experimental groups, A and B. The F-test was used for simultaneous consideration of the three groups in order to reject or accept the hypotheses. A level of significance of 0.05 or greater was accepted.

The Chi Square test was used to determine the degree of association between the factors which, according to the literature, influenced the rate of healing, and the mean rate of healing for the entire sample. This test was also used to compare the mean rate of healing between the groups. Again, a significance of 0.05 or greater was accepted.

CHAPTER 4

ANALYSIS OF THE DATA

After data collection had been completed, a single score was obtained for each factor for each subject. Using these scores a rating system was then devised. About one-fourth of the items were dichotomous and were scored on a two point scale. The others had three or more values and were rated accordingly. Every factor for every subject was then rescored according to this rating system. The rating system and the code are included in Appendix C.

Characteristics of the Sample

Measures of central tendency were obtained for the factors which were suspected of influencing the rate of healing. The analysis of the data indicated that the factors were randomly distributed among the three groups (see Appendix D). None of the subjects developed a fever during data collection and this factor was therefore not included in the computation of the statistics.

Of the fifteen subjects, there were eleven females and four males. The subjects ranged in age from 72-96 years (see Table 1).

TABLE 1. Distribution of the Subjects According to Demographic Factors.

Factors	Category	Frequency
Sex	Female	11
	Male	4
	Total	15
Age in Years	Below 60	0
	60-69	0
	70-79	8
	80-89	4
	Total	15

Only one subject was placed in the third category of fasting blood glucose, due to a blood level of 130 mg. percent (see Table 2). Therefore, none of the subjects demonstrated an elevated fasting blood glucose, a symptom of diabetes mellitus, during the study.

Findings of the Study

Analysis of variance was used to compare the mean rate of healing between the control and experimental groups, A and B (see Table 3).

The rate of healing was defined as a decrease in the millimeter squared size of the ulcer. Originally it was decided that to arrive at this figure the millimeter squared size of the ulcer on the first day would be subtracted from the millimeter squared size of the ulcer on the fifteenth

TABLE 2. Distribution of the Subjects According to the Factors Influencing the Treatment Response.

Factors	Category	Frequency
Treatment Group	Control Group	5
	Experimental Group A	5
	Experimental Group B	5
	Total	15
Location of Ulcer Studied	Shoulder	0
	Sacrum	5
	Trochanter	2
	Heel	0
	Other	8
	Total	15
Body Weight	Much Too Thin	1
	Thin	2
	Normal	7
	Plump	1
	Overweight	4
	Total	15
Number of Ulcers Present	One	7
	Two	4
	Three	2
	More than Three	1
	Data Incomplete	1
	Total	15
Diagnosed Diabetic	Yes	5
	No	10
	Total	15
Fasting Blood Glucose in Mg.%	Less than 80	7
	80-120	7
	More than 120	1
	Total	15
Hemoglobin in Gm./100 ml.	Less than 12	7
	12 or More	8
	Total	15

TABLE 2. Continued

Factors	Category	Frequency
Medications	Antibiotics	1
	Insulin or Oral Hypoglycemics	2
	Steroids	1
	Vitamin C Supplement	0
	Other Vitamin Supplements	2
	None of the Above	9
	Total	15
Fluid Intake in cc./day	Less than 1000	3
	1000-2000	9
	2001-3000	2
	More than 3001	0
	Data Incomplete	1
	Total	15
Protein Intake in Gm./day	Less than 30	1
	30-50	5
	51-70	8
	More than 71	0
	Data Incomplete	1
	Total	15
Incontinent	Yes	12
	No	2
	Data Incomplete	1
	Total	15
Sensation	Absent	0
	Gross Impairment	8
	Impairment Present	3
	Normal	4
	Hyperesthetic	0
	Total	15
Activity	Bedfast	13
	Walks only to the Chair	2
	Able to Walk with Assistance	0
	Ambulatory	0
	Total	15

TABLE 2. Continued

Factors	Category	Frequency
Mobility	Immobile	8
	Very Limited	4
	Slightly Limited	3
	Full	0
	Total	15
Pressure on Site of Ulcer	Constant	10
	Intermittent	5
	None	0
	Total	15
Level of Consciousness	Unconscious	0
	Stuporous	6
	Confused	5
	Alert	2
	Alert and Cooperative	2
	Total	15

TABLE 3. Analysis of Variance for the Control Group and Experimental Groups, A and B, on Day Five of the Study.

Source	Degrees of Freedom	Sum of Squares	F Ratio	F Probability
Between Groups	2	.8885	1.073	.373
Within Groups	12	4.9688		
Total	14	5.8573		

day. All groups received a treatment for the first five days. However, on the ninth day one subject in experimental group B received a second regimen due to an increase in the size of his ulcer. On the tenth and eleventh days of the study two subjects received the second regimen in experimental group A, again due to an increase in the size of their ulcers. However, the second application of the treatment was considered a second treatment modality, and none of the subjects' ulcers, as a group, could be compared after the eighth day. Therefore, the fifth and eighth days of the study were chosen for comparison of the mean rate of healing.

The mean rate of healing on the fifth day was determined by subtracting the millimeter squared size of the ulcer on the first day from the millimeter squared size of the ulcer on the fifth day. A negative score indicated a decrease in healing rate and a positive mean score an increase in the rate of healing. On the fifth day of the study experimental group A demonstrated an increase in the mean rate of healing (see Table 4).

However, due to the variability in the size of the ulcers, the F ratio of 1.073 indicated a probability less than 0.05 (see Table 3). Therefore, on the fifth day, there were no significant differences in the mean rate of healing between the three groups.

TABLE 4. Mean Rate of Healing on Day Five of the Study.

Group	Mean	Standard Deviation
Control Group	-.0354	.7248
Experimental Group A	+.0222	.7425
Experimental Group B	-.5205	.4069

The mean rate of healing on the eighth day of the study was determined by subtracting the millimeter squared size of the ulcer on the first day from the millimeter squared size of the ulcer on the eighth day (see Table 5).

Due to the variability of the size of the ulcers and the small sample size, there were no significant differences in the mean rate of healing between the three groups on the eighth day of the study (see Table 6). The F test indicated a probability of 0.146, a significance less than 0.05.

The Chi Square test determined that the factors which were influenced by routine supportive nursing care were evenly distributed among the three groups through randomization. The Chi Square also determined that there were no significant relationships at the level of 0.05, between the factors which were suspected of influencing the rate of healing and the mean rate of healing (see Table 7).

The number of ulcers present, on the eighth day of the study was a factor which had a significance of 0.0071. This was a probability greater than 0.05. However, the data were questionable. There were only two subjects with three ulcers, and one subject with more than three ulcers. Data were collected on this factor on only fourteen of the subjects (see Table 8). Therefore, the number of ulcers present was a factor which was rejected as having a clinically significant association with the mean rate of healing.

TABLE 5. Mean Rate of Healing on Day Eight of the Study.

Group	Mean	Standard Deviation
Control Group	-.3841	.7067
Experimental Group A	-.2274	.4342
Experimental Group B	-.8623	.1874

TABLE 6. Analysis of Variance for the Control Group and the Experimental Groups, A and B, on Day Eight of the Study.

Source	Degrees of Freedom	Sum of Squares	F Ratio	F Probability
Between Groups	2	1.0938	2.269	.146
Within Groups	12	2.8924		
Total	14	3.9862		

TABLE 7. Mean Rate of Healing for Sample Compared to the Distribution of the Factors on Days Five and Eight of the Study.

Factors	Fifth Day F=	Fifth Day Significance=	Eighth Day F=	Eighth Day Significance=
Location of Ulcers Studied	.4990	.6192	.0933	.9166
Number of Ulcers Present	.3576	.7849	7.2737	.0071
Age in Years	.4083	.6737	1.8146	.2049
Sex	.4486	.5147	1.9180	.2936
Body Weight	.2610	.8963	.5321	.7154
Diagnosed Diabetic	.9916	.3375	1.4675	.2473
Fasting Blood Glucose in Mg.%	1.0020	.3959	.2280	.7995
Hemoglobin in Gm./100 ml.	1.6549	.2207	1.9111	.1901
Medications	4.5699	.1848	5.3359	.1619
Fluid Intake in cc./day	1.7392	.2206	.9047	.4328
Protein Intake In Gm./day	.3424	.7174	.1660	.8491
Incontinent	.4176	.5303	.3938	.5421
Sensation	.1732	.8430	.5216	.6064
Activity	.3800	.5483	.0263	.8736
Mobility	.0660	.9364	1.5527	.2514
Pressure on Site of Ulcer	.0827	.7782	.0332	.8583
Level of Consciousness	.2914	.8308	.5211	.6765

TABLE 8. Analysis of Variance of Number of Ulcers Present on Day Eight of the Study.

Category	N=	Mean Rate of Healing	Sum of Squares*	F=	Sig.=
One	7	- .7086	.1173	7.2737	.0071
Two	4	- .3416	.7503		
Three	2	.4790	.2980		
More than Three	1	-1.0000	0		
Total	14	- .4549	3.7089		

*Between Groups = 2.5434
Within Groups = 1.1656

Conclusions of the Study

Due to the small sample size and the variability in the size of the ulcers, there were no significant differences in the mean rate of healing between the three groups. Therefore, the study did not support the hypotheses. The hypotheses stated that there would be a significantly faster rate of healing of decubitus ulcers for subjects who received hydrogen peroxide as opposed to those who received topical insulin. The second hypothesis stated that the control group, which received distilled water, would evidence the slowest rate of healing.

There was also no support in the data for the null hypothesis, which stated that as both hydrogen peroxide and topical insulin act as debriding agents, the effects of their application on newly formed decubitus ulcers would be similar. There was no support in the data for this hypothesis, as there were no significant differences in the mean rate of healing for the three groups.

The analysis of data indicated that the factors which were suspected of influencing the rate of healing and the factors influenced by routine supportive nursing care were randomly distributed among the three groups. None of the factors exerted a significant influence on the mean rate of healing.

However, the trend towards support of the hypotheses was developing on the eighth day of the study. The analysis of variance indicated the large amount of field noise generated within the groups which obscured any difference there might have been between the groups' mean rate of healing (see Table 6). It is felt that the factors enumerated in the literature do influence the rate of healing of decubitus ulcers. With a larger sample size and with data collected for the full fifteen days, these factors would have been in evidence.

All subjects received a fasting blood glucose determination to rule out diabetes mellitus. The results of the analysis of this factor indicated that none of the subjects demonstrated an elevated fasting blood glucose, a symptom of diabetes mellitus. It should be noted that five of the subjects were diagnosed diabetics. However, it is not possible to infer from the statistics that this is evidence of diabetic control.

An ethical concern of the researcher was the possible side effects of topically applied insulin. None of the subjects who received insulin therapy developed hypoglycemia or demonstrated an allergic reaction to the insulin. It would appear that insulin, applied topically, is not absorbed systemically. However, the data were not conclusive, as the subjects were encouraged to eat during the two hour interim

following the fasting blood glucose, the application of the insulin, and the two hour post prandial blood glucose determination.

CHAPTER 5

SUMMARY AND RECOMMENDATIONS

This study was a partial replication of the Van Ort and Gerber study (1976). It was designed as a three group pretest-postest experimental model, to determine the effect of hydrogen peroxide versus topical insulin on the healing rate of decubitus ulcers, compared to a control group which received distilled water. The sample consisted of fifteen subjects; five in experimental group A, five in experimental group B, and five in the control group.

Due to the small sample size and the variability in the size of the ulcers, there were no significant differences in the mean rate of healing between the three groups. Therefore, the study did not support the hypotheses.

The analysis of the data indicated that the factors which were suspected of influencing the rate of healing and the factors influenced by routine supportive nursing care were randomly distributed among the three groups. None of the factors exerted a significant influence on the mean rate of healing.

None of the subjects who received insulin therapy developed hypoglycemia or demonstrated an allergic reaction to the insulin. It would appear that insulin, applied

topically, is not absorbed systemically. However, the data were not conclusive, as the subjects were encouraged to eat during the two hour interim following the fasting blood glucose, the application of the insulin, and the two hour post prandial blood glucose determination.

Recommendations

It is recommended that replication of this study be conducted utilizing a larger sample, drawn from a more heterogenous population, to clarify the patterns developed in this study.

The following methodological recommendations are made:

1. The Pre-procedural Assessment Form should be revised so that all items are dichotomous. This would aid in the statistical analysis of these factors.
2. The second treatment regimen, applied in this study, negated the analysis of the data for seven days of the study. However, based on this study, no harmful effects were demonstrated with any of the treatments applied. Therefore, it is recommended that all subjects receive a treatment twice daily until the ulcer is healed.
3. The medications considered pertinent to the study should be recorded in a dichotomous manner. This would allow for exclusive statistical analysis of the medications, especially if one subject was on more than one medication.

4. Anticoagulants probably influence the rate of healing of decubitus ulcers, and should be recorded.
5. An accurate method of measuring the depth of an ulcer should be developed and utilized.

This study was expensive in terms of the researcher's time and money. The probable power of this study is great, but it cannot overweigh the expense, unless a larger sample is collected. If, as is recommended, this study were to be replicated with a larger sample, doing so would increase its expense. Therefore, if this study is replicated, it should be done with the aid of grant monies.

APPENDIX A

CONSENT FORMS FOR THE CONTROL AND EXPERIMENTAL GROUPS

A Comparative Study of the Topical Application Of Hydrogen Peroxide and Insulin on Decubitus Ulcers

Subject's Consent
Form 1

The purpose of this study is to identify the effectiveness of topical (surface) application of insulin in the treatment of decubitus ulcers (pressure sores). Topical insulin may lead to hypoglycemia (low blood sugar). To prevent this you will be encouraged to eat after a treatment.

A few drops of insulin will be dropped on the skin of your _____(location) twice a day for five days. Twice a day for five days a few drops of blood will be obtained from your finger to measure the amount of glucose (sugar) in your blood. One morning 10 milliliters (two teaspoons) of blood will be drawn from your arm. The decubitus ulcer will be traced on wax paper every day for fifteen days.

The study will be carried out at no cost to you or to_____(facility). Your physician will be contacted to approve of this treatment.

The knowledge gained will be used to help you and other patients with decubitus ulcers (pressure sores). If at any time you wish to discontinue having the procedure performed, the treatment will be stopped immediately. Your health care and your relationship with your doctor and the nursing staff will remain the same in either case. If you consent to participate in this study all data will be treated in a confidential manner.

Linda Myatt, R.N.
Masters of Science Student
College of Nursing

I have read the above "Subject's Consent." I understand that I may ask questions and that I am free to withdraw from the study at any time without prejudice.

Subject's Signature_____ Date_____

Guardian (if appropriate)_____ Date_____

Investigator's Signature_____ Date_____

A Comparative Study of the Topical Application of Hydrogen Peroxide and Insulin on Decubitus Ulcers

Subject's Consent
Form 2

The purpose of this study is to identify the effectiveness of topical (surface) application of hydrogen peroxide in the treatment of decubitus ulcers (pressure sores).

A few drops of hydrogen peroxide will be dropped on the skin of your _____(location) twice a day for five days. One morning a few drops of blood will be obtained from your finger to measure the amount of glucose (sugar) in your blood. One morning 10 milliliters (two teaspoons) of blood will be drawn from your arm. The decubitus ulcer will be traced on wax paper every day for fifteen days.

The study will be carried out at no cost to you or to _____(facility). Your physician will be contacted to approve of this treatment.

The knowledge gained will be used to help you and other patients with decubitus ulcers (pressure sores). If at any time you wish to discontinue having the procedure performed, the treatment will be stopped immediately. Your health care and your relationship with your doctor and the nursing staff will remain the same in either case. If you consent to participate in this study all data will be treated in a confidential manner.

Linda Myatt, R.N.
Masters of Science Student
College of Nursing

I have read the above "Subject's Consent." I understand that I may ask questions and that I am free to withdraw from the study at any time without prejudice.

Subject's Signature_____Date_____

Guardian (if appropriate)_____Date_____

Investigator's Signature_____Date_____

A Comparative Study of the Topical Application of Hydrogen Peroxide and Insulin on Decubitus Ulcers

Subject's Consent
Form 3

The purpose of this study is to determine the effectiveness of hydrogen peroxide versus topical insulin on the healing rate of decubitus ulcers (pressure sores).

Participants in the study are placed in one of three groups. You have been placed in the "Control" group, which means that your skin will be treated with distilled water.

A few drops of distilled water will be dropped on the skin of your _____(location) twice a day for five days. One morning a drop or two of blood from your finger and about 10 milliliters (two teaspoons) of blood from your arm will be obtained for laboratory tests. The decubitus ulcer on your_____(location) will be traced on wax paper every day for fifteen days.

The study will be carried out at no cost to you or to_____(facility). Your physician will be contacted to approve of this study.

The knowledge gained will be used to help you and other patients with decubitus ulcers (pressure sores). If at any time you wish to discontinue having the procedure performed, the treatment will be stopped immediately. Your health care and your relationship with your doctor and the nursing staff will remain the same in either case. If you consent to participate in this study all data will be treated in a confidential manner.

Linda Myatt, R.N.
Masters of Science Student
College of Nursing

I have read the above "Subject's Consent." I understand that I may ask questions and that I am free to withdraw from the study at any time without prejudice.

Subject's Signature_____ Date_____

Guardian (if appropriate)_____ Date_____

Investigator's Signature_____ Date_____

APPENDIX B

INFORMATION FOR AGENCY, LETTER TO HEALTH CARE FACILITY, AND PERMISSION FORM

Decubitus ulcers have been the subject of comment and speculation for many years. Merlino (1969) stated that estimates indicated an average increase in the cost of a hospital stay of $5,000 for each decubitus ulcer. Exton-Smith and Norton (1960) stated that the average hospital stay for their patients without decubitus ulcers was twenty-five and one-half days, while those with decubitus ulcers stayed for an average of forty days.

Few have done studies which describe the etiology of this problem. Only pressure has been documented as consistently causing decubitus ulcers. The purpose of this study is to identify the effectiveness of the application of hydrogen peroxide to decubitus ulcers as opposed to the application of topical insulin to decubitus ulcers.

The subjects will be appraised according to a list of factors and a rating system designed by the researcher. Once admitted to the study, the subject's skin will be inspected once a day for fifteen days.

Consent will be obtained from the patient, his guardian and his physician, prior to admittance to the study.

The identity of the subject will be protected. The subject will be identified with a number. In addition, data will be combined for all patients in the group, and identification of an individual will not be possible after statistical calculations have been done.

2861 Goret Pl.
Tucson, Arizona 85705
884-9851
February 2, 1976

Dear Sir:

I am a graduate student in nursing at The University of Arizona. At this time I am working on my thesis which is a requirement for graduation. To fulfill this requirement, I will be doing an experimental study to determine the effectiveness of the application of hydrogen peroxide to decubitus ulcers as opposed to the application of topical insulin to decubitus ulcers.

I am enclosing a brief discussion of the proposed study. If you have any questions, please do not hesitate to call me or to write a note. I will be happy to answer any questions.

Please let me know as soon as possible if this proposed plan of study meets with your approval.

Thank you very much for your time.

Sincerely,

Linda Myatt, R. N.

Institutional Authorization for Access to Subjects

Permission is hereby granted to Linda Myatt, a graduate student in nursing at The University of Arizona to use the facilities of _____ to collect data for her study of decubitus ulcer formation. Use of the facility is taken to mean inspection of skin surfaces of patients chosen by Mrs. Myatt and access to medical records and Kardexes.

Signed _____

Position _____

APPENDIX C

PRE-PROCEDURAL ASSESSMENT FORM:

LIST OF FACTORS AND THE RATING SYSTEM

Pre-procedural Assessment Form

Subject Identification:
Group _____ ID# _____
Room # _____ Name: _____

Location of Ulcer being studied:
____1. Shoulder
____2. Sacrum
____3. Trochanter
____4. Heel
____5. Other_____

Number of Ulcers Present:
____1. One
____2. Two
____3. Three
____4. More than Three

Age in Years:
____1. Below 60
____2. 60-69
____3. 70-79
____4. 80-89
____5. Above 89

Sex:
____1. Female
____2. Male

Body Weight:
____1. Much too Thin
____2. Thin
____3. Normal
____4. Plump
____5. Overweight

Diagnosed Diabetic:
____1. Yes
____2. No

Fasting Blood Glucose in Mg.%
____1. Less than 80
____2. 80-120
____3. More than 120

Hemoglobin in Gm./100ml.
____1. Less than 12
____2. 12 or More

Medications: check if "yes"
____1. Antibiotics
____2. Insulin or Oral Hypoglycemics
____3. Steroids
____4. Vitamin C Supplements
____5. Other Vitamin Supplements

Approx. Fluid Intake: (cc./day)
____1. Less than 1000
____2. 1000-2000
____3. 2001-3000
____4. More than 3001

Approx. Protein Intake (Gm./day)
____1. Less than 30
____2. 30-50
____3. 51-70
____4. More than 71

Incontinent:
____1. Yes
____2. No

Sensation:
____1. Absent
____2. Gross Impairment
____3. Impairment Present
____4. Normal
____5. Hyperesthetic

Activity:
____1. Bedfast. Is confined to bed 24 hours a day.
____2. Walks only to the chair; requires assistance to do so, or is confined to a wheelchair.
____3. Able to walk with assistance of another person, braces or crutches. May have limitation on stairs. May have unsteady gait.
____4. Ambulatory. Is able to walk unassisted. Rises from bed unassisted.

Mobility:

____1. Immobile. Does not assist self in any way to change position. Is unable to change position without assistance. Is completely dependent on others for movement.

____2. Very Limited. Requires assistance to change position. Offers minimal assistance in helping to change one's position.

____3. Slightly Limited. Able to control and move all extremities, but some degree of limitation may be present. Requires the assistance of another person to change position.

____4. Full. Able to control and move all extremities at will. May require the use of a device, but can turn, lift, balance and attain sitting position at will.

Pressure on Site of Ulcer:

____1. Constant

____2. Intermittent

____3. None

Level of Consciousness:

____1. Unconscious: does not respond to painful or other stimuli.

____2. Stuporous: responds to painful stimuli appropriately, does not move or respond spontaneously.

Data Collection Form

Date	Size of Decubitus Ulcer in mm^2	Temperature

____3. Confused: rousable, not fully oriented.
____4. Alert: easily rousable to full orientation.
____5. Alert and cooperative: in addition to the above is able to cooperate in his care.

Experimental Group A Only:
Blood Glucose in mg./100ml.

Date	Fasting Insulin Therapy	2 hours After

List of Factors and the Rating System

Factors	Code
Treatment Group	0--Control Group 1--Experimental Group A, Insulin 2--Experimental Group B, Hydrogen Peroxide
Location of Ulcer	1--Shoulder 2--Sacrum 3--Trochanter 4--Heel 5--Other
Number of Ulcers Present	1--One 2--Two 3--Three 4--More than Three
Age in Years	1--Below 60 2--60-69 3--70-79 4--80-89 5--Above 89
Sex	1--Female 2--Male
Body Weight	1--Much too Thin 2--Thin 3--Normal 4--Plump 5--Overweight
Diagnosed Diabetic	1--Yes 2--No
Fasting Blood Glucose in Mg.%	1--Less than 80 2--80-120 3--More than 120
Hemoglobin in Gm./100 ml.	1--Less than 12 2--12 or More

Factors	Code
Medications	1--Antibiotics 2--Insulin or Oral Hypoglycemics 3--Steroids 4--Vitamin C Supplements 5--Other Vitamin Supplements
Fluid Intake in cc./day	1--Less than 1000 2--1000-2000 3--2001-3000 4--More than 3001
Protein Intake in Gm./day	1--Less than 30 2--30-50 3--51-70 4--More than 71
Incontinent	1--Yes 2--No
Sensation	1--Absent 2--Gross Impairment 3--Impairment Present 4--Normal 5--Hyperesthetic
Activity	1--Bedfast 2--Walks only to the Chair 3--Able to Walk with Assistance 4--Ambulatory
Mobility	1--Immobile 2--Very Limited 3--Slightly Limited 4--Full
Pressure on Site of Ulcer	1--Constant 2--Intermittent 3--None
Level of Consciousness	1--Unconscious 2--Stuporous 3--Confused 4--Alert 5--Alert and Cooperative

APPENDIX D

MEASURES OF CENTRAL TENDENCY OF THE GROUP FOR BOTH DEMOGRAPHIC FACTORS AND FOR THE FACTORS THAT INFLUENCED THE TREATMENT RESPONSE

Factors	Mean	Standard Deviation
Sex	1.267	.458
Age in Years	3.667	.816
Treatment Group	1.000	.845
Location of Ulcer Studied	3.733	1.438
Body Weight	3.333	1.234
Number of Ulcers Present	1.786	.975
Diagnosed Diabetic	1.667	.488
Fasting Blood Glucose in Mg.%	1.600	.632
Hemoglobin in Gm./100 ml.	1.533	.516
Medications	3.000	1.673
Fluid Intake in cc./day	1.929	.616
Protein Intake in Gm./day	2.500	.650
Incontinent	1.143	.363
Sensation	2.733	.884
Activity	1.133	.352
Mobility	1.667	.816
Pressure on Site of Ulcer	1.333	.488
Level of Consciousness	3.000	1.069

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