COMPARISON OF CHANGES IN BREAST TISSUE PRESSURE OF PARTURIENTS WITH COMPRESSIONAL VERSUS SUPPORTIVE BINDERS

A THESIS

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We hereby recommend that the thesis prepared under our supervision by Darlene Jane Branscome entitled Comparison of Changes In Breast Tissue Pressure of Parturients With Compressional Versus Supportive Binders

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CHAPTER I

INTRODUCTION

Just as there are two sides to every coin, there are two sides to infant feeding practices. A mother-to-be must decide if she will breast or bottle feed her baby. If the new mother elects to bottle feed, she has made a choice that a large number of mothers in the United States are making today. According to a nationwide survey by Meyer in 1966, only 18 per cent of the babies leaving the hospital nursery were wholly breast fed and this choice was more frequently made among higher intellectual and socioeconomic levels of society.[1] This has some implications for believing that we may see a trend "back to nature" led by the young educated women of society. But in the meantime, what can be done to make the majority of mothers who choose to bottle feed more comfortable in their role?

When a mother chooses to bottle feed her infant, she is subject to the natural phenomena of lactation. On the third or fourth day after delivery her breasts become engorged-- very full, tender, and leak fluid. If the mother breast fed regularly, the suckling would remove the fullness

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[1]Herman F. Meyer, "Breast Feeding in the United States." Clinical Pediatrics, VII (December, 1968), 708, 712.

and in some instances prevent it. Since there is no stimulation from suckling with the bottle fed baby, there is an exaggeration of the normal venous and lymphatic structure of the breast. In about twenty-four to forty-eight hours after the development of engorgement, the symptoms subside. The engorgement process is uncomfortable for many women. This can be a factor in delaying a positive relationship with the infant.

In utero there is a close symbiotic relationship between the mother and the unborn child. At the time of birth in hospitals today the symbiotic relationship is often interrupted. As soon as the cord is cut the baby is placed into a heated bed until the baby has adjusted satisfactorily to the environment. Then, the baby is shown to the mother, perhaps held for only a few minutes, and taken to a central nursery. There is little opportunity for the continuation of a symbiotic relationship through close body contact.

In order to promote a climate of satisfaction for the mother and security for the infant, close body contact should be instituted as soon as possible.[2] Many hospitals only provide for close contact with the infant at feeding time. If the mother's breasts are engorged and uncomfortable, she will be tense and tend to hold the infant away from her

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[2]Ashley Montagu, Touching: The Human Significance of the Skin (New York: Harper and Row, 1971), pp. 75-76.

body while bottle feeding. If the type of support for her breasts will reduce the pressure build-up in the breasts, she will be more comfortable and perhaps more willing to hold the baby close to her.

Personnel caring for new mothers may indirectly promote a more comfortable mother-infant relationship if they will instruct the mothers to maintain proper breast support. However, the problem medical personnel face is, "Which method is the best choice?" Should one apply a tight compressional binder or support the breasts by means of a supportive binder or brassiere?

Statement of Problem

The problem in this study was to determine if there was a significant difference in breast tissue pressure of parturients who wore a compressional versus a supportive binder.

Purpose of Study

The purposes of this study were:

1. To compare the effectiveness of a compressional versus a supportive binder in reducing breast tissue pressure of parturients.

2. To make available research data that will enable personnel caring for new mothers to make judgments regarding which method of breast support provides the least amount of

engorgement and the most comfort-- a compressional binder or a supportive binder.

Background and Significance

The process of lactation is complex and not completely understood by medical science. There is a lack of reliable chemical methods for determining the levels of the various hormones in the body and medical science does not know precisely how hormones function in the lactation process. Therefore, medical science has been unable to find any hormone preparation to be one-hundred per cent effective in preventing breast symptoms. In current obstetrical textbooks and medical journals both mechanical suppression and hormone preparations are recommended.

It is very difficult for medical personnel to decide what course of action to follow when suppression of lactation is desired. Benson lists four appropriate methods to suppress initial lactation: oral estrogen (diethylstilbesterol or ethinyl estradiol), an injection of androgen-estrogen (Deladumone), oral androgen (methyltestosterone), and mechanical suppression via a tight compression binder with elevation of the breasts. After the early puerperium hormonal suppression is not effective; therefore, mechanical

measures of a tight compression binder, no expression or pumping, analgesics, and ice packs are recommended.[3]

Vorherr compares the effectiveness of current sex steroids used in suppressing postpartum lactation. He concludes that even though about twenty per cent of patients do not respond to drug therapy, Deladumone OB is at present the most efficient and least hazardous procedure for suppression of lactation via drugs. He believes it is unlikely that estrogen-induced thromboembolism or other serious complications will occur with this regimen.[4]

A pharmaceutical approach to suppression of lactation must be prescribed with care. Vorheer lists seven contraindications for drug therapy with estrogens in puerperas: (1) a family or personal history of suspected or established breast or genital cancer, (2) present or prior thromboembolic disorders or cerebral apoplexy, (3) impaired liver function, (4) vaginal bleeding of unknown cause, (5) Hodgkin's disease or malignant melanoma, (6) plans for immediate elective surgery, or (7) hypertension.[5]

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[3]Ralph C. Benson, Handbook of Obstetrics & Gynecology (Fourth Edition, Los Altos: Lange Medical Publications, 1971), p. 213.

[4]Helmuth Vorherr, "Suppression of Postpartum Lactation," Postgraduate Medicine, LII (July, 1972), 151-52.

[5]Ibid. 149-50.

If one cannot take drugs to suppress lactation, the only course of action is to use mechanical measures. Gunther expressed the belief that pressure reduces secretion, the effectiveness depending on the individual. Thus, he suggested a tight binder as a method to reduce secretion in women.[6]

The current edition of William's Obstetrics recommends a simple treatment of engorgement to be one of supporting and compressing the breasts with a binder or brassiere, applying ice bags, and administering mild analgesics. In about a day following the evidence of engorgement, signs and symptoms will disappear if the breasts are not stimulated by pumping.[7]

In contrast to William's Obstetrics, Reid, Ryan, and Benirschke recommends that, if engorgement occurs, the breasts should be held upward and to the midline. The breasts should not be bound tightly to the chest wall because passive congestion and additional discomfort results.[8]

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[6]Mavis Gunther, "Lactation in Women," Canadian Medical Association Journal, XLVII (November, 1942), 412.

[7]Louis M. Hellman and Jack A. Pritchard, William's Obstetrics (14th ed.; New York: Appleton-Century-Crofts, Meredith Corporation, 1971), p. 993.

[8]Duncan E. Reid, Kenneth J. Ryan, and Kurt Benirschke, Principles and Management of Human Production (Philadelphia: W.B. Saunders Company), p. 548.

There has been only one study directly concerned with the effectiveness of a support versus a compression binder in the reduction of engorgement. This was a small study by Bristol in which nineteen women with compression binders were compared to nineteen women with supportive binders or brassieres. Symptoms of engorgement were recorded in four areas-- engorgement, tenderness, leakage, and means used to obtain relief. A point system of one to four was recorded subjectively by the investigator and the subject in the hospital. After discharge, information was obtained by means of a telephone report by the subject. Final results revealed the only significant difference in the two groups to be in the area of tenderness. The supportive binder or brassiere was more effective in reducing tenderness.[9]

When nursing practice attempts to implement medical recommendations regarding mechanical suppression of lactation, there is confusion which method of breast support should be applied. Recommendations should be made on the basis of objective data rather than subjective data and opinion. Objective research is needed to provide rationale for nursing practice.

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[9]Wanda M. Bristol, "Comparative Effectiveness of Compressional and Supporting Breast Binders in Suppressing Lactation," Nursing Research, XV (Summer, 1966), 203-6.

Hypothesis

The projected hypothesis of the researcher was that there would be no significant difference in breast tissue pressure of parturients wearing compressional versus supportive binders.

Definition of Terms

For the purpose of this study, the following definitions were used:

Engorgement - an exaggeration of the normal venous and lymphatic system of the breasts causing an increase in tissue pressure in preparation for lactation.

Lactation - the secretion of true milk which results from continued release of tissue pressure by pumping or suckling.

Suppression - prevention of the usual exaggeration of venous and lymphatic breast symptoms experienced in engorgement.

Parturient - a woman, 38-42 weeks gestation, who has delivered a baby within the past five days and has been wearing either a supportive or compressional binder within sixteen hours after delivery.

Tissue pressure gauge - an instrument designed to measure changes in tissue tension as engorgement progresses.

Compression binder - a cloth with wide straps applied as tightly as possible for the purpose of preventing the engorgement process.

Supportive binder - a cloth with wide straps which provides support and uplift but no constriction, similar to a brassiere.

Delimitations

1. The population for this study was limited to fifty non-nursing parturients who: (a), were clinic patients at one large metropolitan city-county hospital where drugs were not given to suppress lactation; and (b). lived in close approximation to the above hospital in order to facilitate testing when discharge occurred prior to five days after delivery.

2. The time of day tissue pressure measurements were recorded was not considered.

Assumptions

The following assumptions were basic to this study:

1. Parturients who have not been given drugs to suppress lactation will experience some degree of engorgement within five days if they are going to experience engorgement.

2. Changes in tissue pressure as engorgement progresses can be measured with reasonable accuracy.

3. Support for the breasts is necessary to prevent breast tissue breakdown as engorgement progresses.

Summary

Chapter I includes an introduction, statement of problem, and purposes. The background and significance presented the need for more objective research regarding the best type of support for the breasts when suppression of lactation is desired-- compressional versus a supportive binder. A null hypothesis was projected. The chapter concluded with a list of terms, delimitations, and assumptions used in this study.

The following information will be presented in the succeeding chapters: Chapter II includes a review of literature relating to the subject; Chapter III deals with the methodology used in the study; Chapter IV presents the analysis and interpretation of data; and Chapter V provides a brief summary, recommendations, conclusions, and implications of this study.

CHAPTER II

REVIEW OF LITERATURE

Introduction

In order to understand the principles involved in the engorgement process, this chapter will present a review of literature relating to three areas: (1) anatomy and physiology of lactation, (2) suppression of engorgement, and (3) objective measurement of engorgement.

Anatomy and Physiology of Lactation

The anatomy of the breast that is important in secretory function consists of fifteen to twenty-four lobes of alveolar glandular tissue which are separated by fatty tissue. Each lobe has several lobules, which are comprised of many tiny sacs called acini or alveoli. The acini or secretory portion of the breast have a single layer of epithelium with a rich bed of capillaries.[1]

Milk, which is secreted by the acini, travels through tiny ducts that join others to form a single larger canal for each lobe. Behind the areola (pigmented area), each large duct widens into a lactiferous sinus that serves as a small reservoir for milk. These sinuses connect separately with minute openings at the nipple surface. The ability to pro-

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[1]Hellman and Pritchard, Obstetrics, pp. 468-69.

duce milk is not related to the size of the breast since fatty tissue comprises much of the structure of large breasts.[2]

The knowledge of the process of lactation has been studied and postulated for years by researchers. Most of the factual knowledge has come from researchers who have studied lactation in animals. The dairy industry has produced some of the most intense studies of lactation because they are looking for ways to increase milk production. This research has shown the least amount of understanding in the neuro-endocrine regulation of the mammary gland function. At the present time, little is known about the central nervous pathways and mechanisms involved in prolactin secrection.[3] Postulation is the best information science can offer. Therefore, one must remember to consider the difference in species before transferring information obtained from animal studies as fact to the human body.

For a working hypothesis of lactation, Sulman suggests the following:

Stages of Lactation	Active Hormones
Preparation of milk gland Mammogenesis	Pituitary and later placental FSH and LH
	Estradiol and progesterone

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[2]Erna Ziegel and Carolyn C. Van Blarcom, Obstetric Nursing (6th ed.; New York: The Macmillan Company, 1972, pp. 616-17.

[3]A.T. Cowie and J.S. Tindal, The Physiology of Lactation (Baltimore: The Williams and Wilkins Company, 1971), p. 278.

Initiation of lactation Colostrogenesis	Prolactin-inhibiting factor depressed
	Prolactin-releasing factor stimulated
	Removal of placental hormones
Secretion of milk	Pituitary LTH (prolactin)
Lactogenesis	Pituitary ACTH and corticosteroids
Maintenance of lactation Galactopoiesis	Pituitary STH: intrinsic lactogenic effect and augmentation of prolactin
	Pituitary TSH, tri-iodothyronine and thyroxine
Promotion of excretion Ejection: "Let-Down"	Oxytocin: concentration of mammary myoepithelium and slight stimulation of prolactin
	Neurohormones inhibit "let-down"[4]

Martin believes that the most important mammotropic hormone is the follicle-stimulating hormone (FSH) which stimulates the secretion of estrogen by the ovarian follicles. Estrogen alone is secreted until ovulation, when both estrogen and progesterone are secreted by the corpus luteum. The corpus luteum is controlled and stimulated by the luteinizing hormone (LH) and the luteotropic hormone (LTH). The breast also needs growth hormone, prolactin, and perhaps mammogen, cortisol, and thyroxin for growth and differentiation.

4F.G. Sulman, Hypothalmic Control of Lactation (New York: Springer-Verlag, 1970), p. 1.

In mid-pregnancy, maximum growth and differentiation occurs.[5]

During pregnancy, it is believed that the high levels of estrogen or progesterone inhibit prolactin release and perhaps prolactin action on the breast itself. At delivery, inhibitory effects would tend to be removed by the sudden decrease in steroids. This is supported by the observation that high doses of estrogen in the first postpartum week will usually prevent breast engorgement. However, it is not known if this is due to prolactin inhibition.[6]

Once milk secretion is started and maintained by prolactin, estrogen and progesterone are not necessary for continued lactation. There are two parts to lactation: secretion of the milk into the alveoli and discharge of the milk via the milk-ejecting action of oxytocin. Oxytocin, secreted by the adenohypophysis, affects the myoepithelial layer surrounding the alveolar sac to cause the "let-down" reflex. Secretion will continue as long as the milk is removed from the alveoli and small ducts.[7]

By the third or fourth day of the postpartum period, the breasts become distended, firm, and nodular. This condition is known as engorgement or "caked breasts" and

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[5]Daniel J. Martin, "Puerperal Lactation: Physiology and Suppression," GP, XXX October, 1964), 79-80.

[6]Reid, Ryan, and Benirschke, Human Production, p. 132.

[7]Ibid., p. 131.

represents an exaggeration of the normal venous and lymphatic structure of the breasts. It is not the result of milk accumulation in the lacteal system. In the absence of breast stimulation, involutional changes begin to take place in twenty-four to forty-eight hours.[8]

Suppression of Engorgement

Prior to the nineteen thirties, there was little scientific rationale for the methods of suppression of engorgement or lactation. Treatment of engorgement related to the preference of the doctor in charge. Local applications of ice, saline purgatives, camphorated oil compresses, tight constricting binders, analgesic drugs, and pumping of the breasts were used. These methods only provided for temporary relief.

In 1936, Klein studied the observation of Rosenblatt who had reported that women who were on camphor therapy for cardiac problems had a reduction or cessation of lactation after several days of treatment.[9] Klein used thirty control

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[8]Hellman and Pritchard, Obstetrics, p. 993.

[9]"Action of Camphor on Lactating Breast," Zentralblatt fur Gynakologie, XLVI (September 23, 1922), n.1, quoted in Lena F. Edwards and Marie S. Metroyer, "Review of Methods of Suppression of Lactation in the Puerperium and Report of 108 Cases Treated with Androgen-Estrogen Combination," Journal of the National Medical Association, XLVII (July, 1955), 239.

patients and thirty who were injected with one and one-half grains of camphor in oil within twenty-four hours after delivery. No other treatment was given. His results showed that eighty per cent who received treatment during the first twenty-four hours developed no engorgement. If treatment was started after twenty-four hours but before engorgement was advanced, six hours after treatment was instituted, symptoms started to subside. It took two to three days for symptoms to subside if treatment was delayed until engorgement was advanced.[10]

Until the discovery of prolactin in 1933.[11] hormone therapy was not employed in the suppression of lactation. In 1938, Kurzrok and O'Connell used an androgen preparation-testosterone propionate in twenty-one cases to relieve engorgement. Two injections of twenty-five milligrams were given daily for one to three days beginning on the third day. Within a few hours after the injection, relief was noted. Complete relief was noted in forty-eight hours after the second injection. No side effects, recurrence of

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[10]"A Clinical Study of the Effects of Camphor in Oil on Lactation," American Journal of Obstetrics and Gynecology, XXXI (May, 1936), n.2, quoted in ibid.

[11]O. Riddle, R.W. Bates, and S.W. Dykshorn, "Preparation, Identification and Assay of Prolactin - hormone of the anterior pituitary," American Journal of Physiology, CV (July, 1933), 191-216.

congestion and pain, or altered course of the puerperium was reported.[12]

Foss and Phillips in 1938 first suggested the use of estrogen to inhibit breast engorgement.[13] Since that time, numerous articles have appeared in medical journals to advocate the efficacy of estrogen to inhibit engorgement.

King in 1959 evaluated existing literature of hormone therapy. He came to the conclusion that many of the reports were uncontrolled experiments based on mere impressions. In order to evaluate a drug, one must analyze: (1) the physiologic effect of withholding the baby from the breast; (2) the pharmacologic action of the drug; and (3) the psychological elements of suppression.[14]

Very few studies take into consideration the psychological make-up of the woman experiencing pain from engorgement. If she feels deprived of medication or has guilt feelings about shirking her mother role, she is likely to amplify pain at the slightest breast tension. Thus, a study

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[12]P. Kurzrok and C.P. O'Connell, "Inhibition of lactation During the Puerperium by Testosterone Propionate," Endocrinology, XXIII, (October, 1938), 476.

[13]G. L. Foss and P. Phillips, "Suppression of Lactation by Oral Oestrogen Therapy," British Medical Journal, II (October, 1938), 887.

[14]Arthur G. King, "Prevention of Puerperal Breast Engorgement with Large Doses of Long-Action Estrogen," American Journal of Obstetrics and Gynecology, LXXVIII, (July, 1959), 80.

should provide a placebo exactly like the test drug. The placebo may psychologically make the mother feel better. Any guilt she has for not breast feeding can be blamed on the doctor for giving her a drug to prevent lactation. In studies where no placebo has been given about forty-two per cent will complain of engorgement pain; when a placebo is given, only thirty per cent will complain. Thus, when women do not suckle their infants at all fifty-eight per cent will have little discomfort from engorgement whether they receive estrogens or not. With a placebo, this is raised to about seventy-five per cent. This leaves twenty-five per cent of post-partum mothers who would benefit from drug suppression.[15]

King expresses the need for experiments to be double blind, that is, neither the patient nor the doctor or the nurse must know which is the drug and which is the placebo until all the results are in. At the same time, one must compare the results within the same experiment, with the same criteria, and by the same observers. This will give the best measurement of pain since engorgement that is not painful is of no great significance.[16]

Within a few years of the advent of estrogen and androgen therapy, mechanical suppression of engorgement was abandoned by many practitioners. However, these hormone

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[15] Ibid., 82, 84.

[16] Ibid.

preparations had disadvantages. Duckman and Hubbard summarize the problems as:

1. Androgens were too expensive and some investigators feared a permanent androgenic effect.

2. There was a rebound engorgement in many cases after the patient was discharged from the hospital.

3. Some had a delay in menstruation for as long as two months past the expected time.

4. Some reported that a long-continued use of either androgen or estrogen had deleterious effects upon the regeneration of uterine mucosa.

5. Occasionally there was profuse bleeding the fourth or fifth week post partum, necessitating transfusion and curretage. Endometrial hyperplasia was usually demonstrated.

6. Some suggested endocrine therapy might complicate puerperal recovery of normal cyclic ovarian function.[17]

Complications with hormone therapy led Duckman and Hubbard to study the effects of diuresis versus restricted fluids. They forced fluids on 139 non-nursing mothers, restricted fluids on 89, and permitted a control group of 50 to drink what they desired. The difference in the percentages of women who complained of pain were: 43, 42, and 42 per cent

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[17]Simon Duckman and John F. Hubbard, "The Role of Fluids in Relieving Breast Engorgement Without the Use of Hormones," American Journal of Obstetrics and Gynecology, LX (July, 1950), 200.

respectively. It was concluded that the amount of fluid taken in had nothing to do with the degree of complaints of discomfort from engorgement.[18]

In the nineteen fifties, a combination of androgen-estrogen drugs were introduced with enthusiasm. Roland, Veprovsky, and Linhart compared Vallestril (ethyl dimethyl allenolic acid), diethylstilbesterol, TACE (chlorotrianisene), injectable Depo-testosterone (cyclopentylpropionate) and a placebo capsule. The breasts returned to normal after initiation of therapy within four to five days in 82, 67, 70, 88, and 42 per cent respectively. The recommendation was to give Vallestril rather than Depo-testosterone because it is less expensive, an oral drug, and debatable if large doses of androgen (Depo-testosterone) are advisable during the reproductive years.[19]

Of the methods currently used today, a single intramuscular injection of long-acting androgen-estrogen in the form of Deladumone-- 90 milligrams of testosterone enanthate and 4 milligrams of estradiol valerate per milliliter, is the drug of choice. The drug is administered just before or

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[18] Ibid., 202-3.

[19] Maxwell Roland, Edward Veprovsky, and Warren Linhart, "The Use of Various Endocrine Preparations in the Suppression of Lactation: A Comparative Study in 800 Cases," American Journal of Obstetrics and Gynecology, LXX (November, 1955), 1005, 1011.

shortly after delivery in order to insure maximum efficiency in the prevention of breast symptoms.[20]

Numerous articles have been published to support the advantages of Deladumone as a suppressant of engorgement. Lo Presto and Caypinar reported a study of 197 women, who were given Deladumone, 3 cubic centimeters, after the first stage of labor, to be 92 per cent asymptomatic of breast symptoms.[21]

Gold studied short-acting preparations versus long-acting preparations in 225 subjects. Deladumone was the drug of choice. It was 95 per cent effective in providing excellent to moderate relief of pain, engorgement, and leakage. His conclusions were-- "Although it is not the ideal lactation suppressant, it is by far superior to any available up to the initiation of this study."[22]

Womack and Associates studied 1,090 women who were given Deladumone 2X (180 milligrams of testosterone enanthate and 8 milligrams of estradiol velerate per milliliter). Control

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[20]W.E. Foley, Jr., "Influence of Hormone Dosage and Time of Administration on Suppression of Lactation," American Journal of Obstetrics and Gynecology, XXCII (October, 1961), 857.

[21]Benjamin Lo Presto and Erol Y. Caypinar, "Prevention of Postpartum Lactation by Administration of Deladumone During Labor," Journal of the American Medical Association, CLXIX (January 17, 1959), 250.

[22]Jay J. Gold, and others, "Hormone Therapy to Control Postpartum Breast Manifestations," American Journal of Obstetrics and Gynecology, (July, 1959), 94.

of lactation was recorded as excellent in 78.9 per cent, satisfactory in 16.1 per cent and poor in 5 per cent.[23] In a small study by Jones and Tanner a similar effectiveness of Deladumone 2X was confirmed.[24]

A recent study was conducted by Morris, Creasy, and Hohe in order to clarify if routine administration of drugs to the non-nursing mothers is warranted in terms of effectiveness and incidence of adverse side effects. Four hundred eighty-four puerperal patients were treated with one of three preparations: (1) oral chlorotrianesene (TACE), in three different dosage strengths-- 300, 288, and 432 milligrams; (2) a two milliliter intramuscular injection of Deladumone OB, 360 milligrams of testosterone enanthate and 16 milligrams of estradiol valerate; and (3) identical placebos. This was a well-controlled study. The results clearly demonstrated that both drugs were significantly more effective than placebo therapy for inhibition of lactation, relief of breast engorgement, and discomfort. Response was evaluated in three categories-- engorgement, lactation, and discomfort. At least one-third of all patients given placebo therapy had these

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[23]William S. Womack, and others, "A Comparison of Hormone Therapies for Suppression of Lactation," Southern Medical Journal, LV (August, 1962), 818.

[24]Harry E. Jones and Jack E. Tanner, "Suppression of Lactation: Use of a Single Androgen-Estrogen Injection," Obstetrics and Gynecology, IXX (January, 1962), 55.

complaints. Of the patients receiving TACE, 41 per cent experienced no adverse symptoms, only 11 per cent of those who received a placebo did likewise. Deladumone OB had a 65 per cent lack of adverse symptoms while only 10 per cent of the placebo group did likewise. The groups were indistinguishable at the six-week examination in regard to lochia, breast and uterine involution, and resumption of menses. Even though Delademone OB is sixty per cent more costly than TACE, the authors recommend the former to be given to all puerperants who do not wish to breast feed.[25]

The above presented studies of Deladumone therapy for the suppression of engorgement and lactation did not report any significance of delayed engorgement, pain, or increased lochia in their patients. Markin and Wolst compared the efficacy of five commonly used endocrine preparations by conducting a double-blind placebo-controlled study of 486 subjects via statistical analysis. The drugs used were: diethylstilbesterol, dienestrol and methlytestosterone (Estan), conjugated estrogens, equine, plus methlytestosterone (Premarin with methlytestosterone), and testosterone enanthate plus estradiol valerate (Deladumone). All of the endocrine agents except Deladumone failed to prevent the significant occurrence of delayed engorgement, lactation, and pain. Only Deladumone was

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[25]John A. Morris, Robert K. Creasy, and Paul T. Hohe, "Inhibition of Puerperal Lactation," Obstetrics and Gynecology, XXXVI (July, 1970), 107, 114.

more effective than the placebo materials. The lochia, and withdrawal bleeding was not significant. The onset of regular postpartum menses was delayed slightly in the endocrine treated patients. No subinvolution of the uterus, edema, or virilization was encountered. Only Deladumone was rated better than placebo therapy by the patients. However, only placebo therapy had one-hundred per cent slight or no delayed symptoms when the patient went home from the hospital.[26]

In recent years the use of estrogen to suppress lactation has been linked with thromboembolism. This was suggested in 1967 by Daniel, Campbell, and Turnbull.[27] Follow-up reports by Tindall[28] and Turnbull[29] presented further information in this regard. Millar suggests that more study needs to be done: but, it would be advisable in

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[26]K.D. Markin and M.D. Wolst, Jr., "A Comparative Controlled Study of Hormones Used in the Prevention of Postpartum Breast Engorgement and Lactation," American Journal of Obstetrics and Gynecology, XXC (July, 1960), 128-37.

[27]D.G. Daniel, H. Campbell, and A.C. Turnbull, "Puerperal Thromboembolism and Suppression of Lactation," The Lancet, II (August 5, 1967), 287.

[28]V.R. Tindall, "Factors Influencing Puerperal Thrombo-Embolism," Journal of Obstetrics and Gynaecology of the British Commonwealth, LXXV (December, 1968), 1324.

[29]Alexander C. Turnbull, "Puerperal Thrombo-Embolism and Suppression of lactation," Journal of Obstetrics and Gynaecology of the British Commonwealth, LXXV (December, 1968), 1326-27.

women over twenty-five years and any complicated delivery in women under twenty-five years to be treated without the use of estrogens to suppress lactation. He further relates that this complication does provide a good reason to persuade older women or those with complicated deliveries to try to breast feed.[30] Stewart and others support this recommendation.[31]

The current medical text of Obstetrics by Clayton and others recommend support of the breasts and analgesics for engorgement in mothers in the high risk group-- over thirty-five, overweight, operative delivery, history of previous thrombophlebitis, anemia, or those with other medical diseases.[32]

Herbst, Ulfelder, and Poskanzer were the first to recognize a high correlation of vaginal adenocarcinoma in young women as being accociated with stilbestrol therapy of the mother during pregnancy. It is proposed that fetal

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[30]David G. Millar, "The Lactating Breast," The Practitioner, CCIII (August, 1969), 165.

[31]K.S. Stewart, D.F. Kerridge, and K.J. Dennis, "Suppression of Lactation," British Medical Journal, II (April 26, 1969), 249.

[32]Stanley G. Clayton, Donald Fraser, and T.L.T. Lewis, eds., Obstetrics (12th ed.; London: Edward Arnold (Publishers) Ltd., 1972), p. 157.

tissue underwent transformation due to stilbestrol and at puberty, began to produce abnormal cells.[33]

This link has been the basis for Vorheer's recommendation that any drug containing estrogen should not be given to any person with a family or personal history of suspected or established breast or genital cancer.[34]

Martin recommends the use of long-acting androgen-estrogen in some patients. He believes that routine prophylactic treatment of all non-nursing mothers constituted gross overtreatment in seventy to eighty per cent of cases. The most important factor in suppression is avoidance of suckling. Adequate breast support is necessary to prevent breast discomfort from increased weight of the breasts. In anxious mothers, a mild tranquilizer should be prescribed to elevate the pain threshold and decrease the amount of endogenous epinephrine produced. About twenty to thirty per cent of non-nursing mothers who complain of breast pain will require more specific treatment such as analgesics and ice caps. If pain occurs in the first three days, oral estrogen may be tried. Later discomfort (third to the fifth day)

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[33]Arthur L. Herbst, Howard Ulfelder, and David C. Poskanzer, "Adenocarcinoma of the Vagina: Association of Maternal Stilbestrol Therapy with Tumor Appearance in Young Women," New England Journal of Medicine, CCXXCIV (April 22, 1971), 878.

[34]Vorherr, "Suppression of Lactation," 149.

may be relieved by nasal synthetic oxytocin which promotes "let-down."[35]

The current Synopsis of Obstetrics recommends a conservative treatment for drying up the breasts. If engorgement becomes painful, ice bags and codeine may be used. The secretion will almost disappear within a week. The use of estrogens or other hormones to dry up the breast is not advised.[36]

There has been limited research coming from nurses regarding the suppression of engorgement. The effectiveness of a tight compression binder versus a supportive binder was studied by Bristol. (See pages 6 and 7). The rationale for the compression binder is the belief that pressure applied to the breast will prevent engorgement and lactation and thus reduce tenderness by not allowing the ducts to fill with milk. A brassiere or supportive binder is generally thought to stimulate the nipples by rubbing against them, thus promoting the release of prolactin or oxytocin and therefore, not aiding suppression. However, this is not the same stimulation, physically or psychologically, as suckling. Bristol recommended that supportive binders or brassieres be used since they did not cause as much discomfort as the

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[35]Martin, "Puerperal Lactation," 86.

[36]Charles E. McLennan, Synopsis of Obstetrics. (8th ed.; Saint Louis: The C.V. Mosby Company, 1970), p. 422.

compression method. It was further recommended that a larger scale study be carried out to verify these findings.[37]

Objective Measurement of Engorgement

The studies to date in this chapter did not utilize objective means to measure engorgement. The most common type of analysis was based on a point system where symptoms were assigned points. Observation by the investigator assigned these points. In some cases, the nurses on the unit completed the evaluation. Watrous and others employed a point system such as-- grade 0 to 4, to evaluate the effectiveness of Deladumone in suppressing lactation. Conclusions were made that subjective factors play a considerable role in such an approach. The recorder is influenced by what he thinks is normal, by what he expects or desires to think, and by his own attitude to pain. The variations of each patient's "threshold of pain" are too intangible to measure.[38]

One of the first attempts to use objective means to measure breast function was by Hytten. He developed a system of water displacement to test the capacity of the breast to

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[37]Bristol, "Breast Binders," 204, 206.

[38]Joseph B. Watrous, Jr., Robert E. Ahearn, and Milton A. Carvalho, "Lactation Inhibition by Deladumone Injected During Labor or Just After Delivery," Journal of the American Medical Association, XLXIX (January 17, 1959), 246, 248.

secrete milk. A container was shaped to fit closely to the average chest wall. A rubber ring was inflated by mouth to form a cushion and seal. With the subject in a sitting position, the apparatus was held firmly against the chest and filled with water through an opening at the highest point. The water was drained off and measured by one observer. Results were reproducible within five per cent. The size of the lactating breast was measured after emptying in 86 primiparae and 23 multiparae. There was a significant correlation between breast size and the output of milk on the seventh day of lactation. Small breasts indicated an upper limit to storage capacity.[39]

In 1969, Menczer and Eskin published a report of the use of thermography to evaluate the postpartum breast. This technique uses polaroid photographic film to record an image of light gray to black where engorged veins lie. These veins demonstrate increased blood flow and heat emission. The amount of infrared emission from the skin is proportional to its temperature. A total of 90 patients were tested on four consecutive days-- 49 with Deladumone-OB and 41 with placebo therapy. The group of patients complaining of postpartum discomfort had statistically significant higher temperature than the group without complaints; although, the actual

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[39]F.E. Hytten, "Clinical and Chemical Studies in Human Lactation: The Functional Capacity of the Breast," British Medical Journal, I (April 17, 1954), 913, 915.

temperature differences involved were modest-- 0.5 degrees centigrade. The densitometric scan showed that a drug which alleviates postpartum breast discomfort also reduces venous engorgement.[40]

Realizing the need for objective measurement in recording breast engorgement of breast feeding mothers on self-demand versus routine feeding, Geissler developed an instrument to measure breast engorgement. This instrument was based on a principle similar to that of the Schiotz tonometer used to measure ocular pressure. Three different disk sizes at three different depths were tested on day one and day three after delivery in order to determine which disk and depth would register the most difference in breast pressure. The final recommendation was to mark the site measured and to use a disk size of 2.4 centimeters at a 10 millimeter depth. This disk and depth demonstrated optimum changes without producing discomfort to the patients. The instrument was able to reproduce results when the same site was retested within 0.3 points. Thus, the conclusion was made that this instrument used to measure breast pressure was found to be a valuable tool in assessing breast engorgement.[41]

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[40]Joseph Menczer and Bernard A. Eskin, "Evaluation of Postpartum Breast Engorgement by Thermography," Obstetrics and Gynecology, XXXIII (February, 1969), 260-63.

[41]Natalie Jean Geissler, "An Instrument Used to Measure Breast Engorgement," Nursing Research, XVI (Spring, 1967), 130-36.

Chapter II presented a review of literature in three areas concerned with lactation and engorgement: the anatomy and physiology of lactation, suppression of engorgement, and objective measurement of engorgement.

CHAPTER III

METHODOLOGY

Introduction

The methodology used in this research study will be presented in the following pages in six areas: type of study, population, description of tool for data collection, pretest, collection of data, and analysis of data.

Type of Study

An experimental design of an explanatory nature was used in this study. A comparison was made of the application of alternative values-- compression versus support, of the independent variable-- breast binders. The dependent variable-- change in breast tissue pressure, was studied in order to find out which alternative produced the least amount of tissue pressure change.

Population

Subjects for this study were selected from non-nursing postpartal patients at a large metropolitan city-county hospital where there are no drugs given to suppress lactation. See Appendix A, page 63.

Harley states, "From the second to the fifth postpartum day the acini and small milk ducts are filled with milk."[1] Therefore, subjects were tested for five days in order to determine the amount of tissue pressure changes which occurred as engorgement progressed. Since most parturients only remain in the hospital for three days, subjects were selected from areas in close approximation to the hospital in order to facilitate home visitation by the researcher.

A convenient random sample was selected from clinic parturients admitted to the postpartal units. Subjects met the following criteria: had delivered within the past sixteen hours, had worn no breast support since delivery, were classified as a term pregnancy (thirty-eight to forty-two weeks), ranged in age from fourteen to forty-two years, and had delivered by cesarean section, by forceps, or spontaneously.

As a result of the pretest, one addition was made to the criteria for selection of subjects. Any parturient with breasts smaller than the depth of the plunger, eleven sixteenths of an inch, was excluded from the population sample. This criteria was necessary to prevent measurement of the chest wall tension instead of breast tissue pressure.

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[1]J.M.G. Harley, "The Endocrine Control of the Breasts," The Practitioner, CCIII (August, 1969), 156.

Subjects were assigned alternately to the compression or supportive group if they met the above criteria, agreed to wear the binder for five days, and would permit home visitation. Subjects were eliminated if they had removed the binder or were unable to continue in the study for five days. A total of fifty parturients were included in the study, twenty-five in each group.

Description of Tool for Data Collection

A tissue pressure gauge was designed to measure the tissue of the subject.[2] See Figure 1.

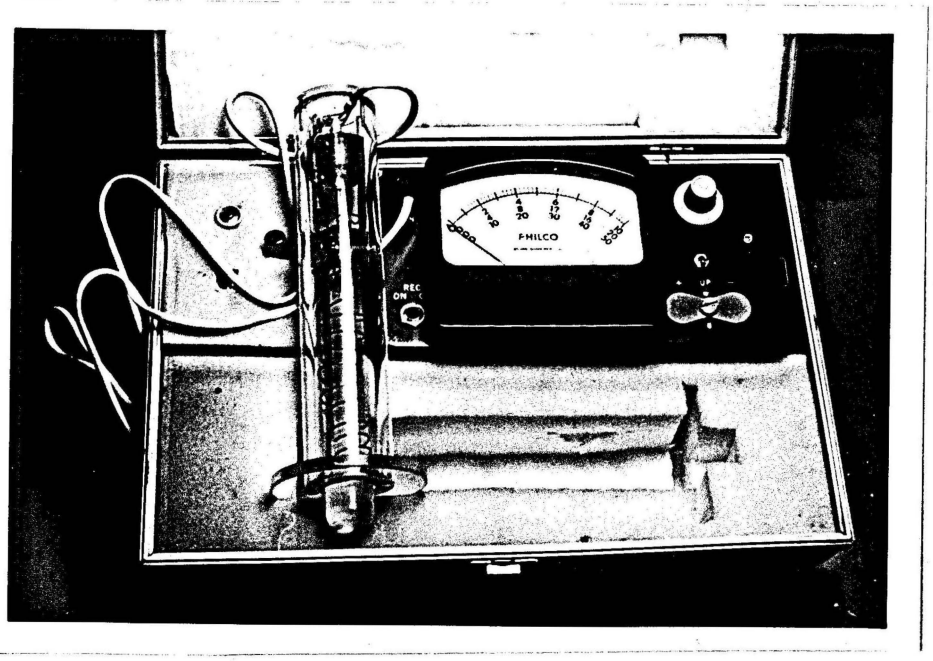

Fig. 1.-- Tissue Pressure Gauge

[2]Design by K. M. Branscome, E.E., Professional Engineer. The cost of raw materials was approximately twenty dollars.

The following is a description of the principle behind the tissue pressure gauge:

A long spring is used to pre-load a plunger. The size of the plunger and its length of travel was selected on the basis of results of a study by Geissler.[3] See Appendix B, page 65. The spring tension was set to give the best differential reading from soft to hard of the tissue. No attempt was made to correlate the scale readings with absolute pressure values, since relative readings would record change in tissue tension.

A relatively long spring in relation to maximum displacement of the plunger was used in an attempt to make the force-displacement ratio have a relatively constant value, thereby making the displacement of the plunger up, directly proportional to the pressure of the tissue in contact with the plunger.

To change the displacement of the plunger into meter readings, a linear coaxial capicator was attached to the stem of the plunger and the body of the probe.

A simple capacity meter was attached to the coaxial capacitor which converted changes in capacity of the coaxial capacitor to meter readings, zero through ten.

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[3]Geissler, "Instrument," 131, 134.

Subjective information of the degree of discomfort and the amount of lactation was recorded by a point system similar to Miyamoto and others.[4]

Discomfort:
0 no discomfort
1 discomfort with touch
2 aware of discomfort without touch
3 discomfort constant, medication taken

Lactation:
0 absent
1 slight
2 moderate
3 marked leakage requiring pad changes

A data sheet was developed to record pertinent information of the subjects and their daily tissue pressure readings. See Appendix C, page 67.

Pretest

A pretest was conducted prior to data collection in order to test the ability of the tissue pressure gauge to consistently record breast tissue pressure changes as engorgement progresses, to clarify the procedures for using the tissue pressure gauge, and to develop final technique procedures.

A total of ten subjects were used who met the established criteria for the study. The tissue pressure

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[4]Junhaku Miyameto, Louis Gomez, and Jay J. Gold, "Effect of MRL-41 on Postpartum Breast Manifestations," American Journal of Obstetrics and Gynecology, XXCV (April, 1963), 871.

gauge was able to measure changes from subject to subject. It demonstrated 0.25 points repeatibility in the same site. On the recommendation of Geissler, a mark was placed at the site of measurement to ensure measurement of the same duct structure.[5] The researcher found gentian violet in combination with a small piece of micropore tape to be the best method for marking the test site. Recording was made in terms of 0 to 10 with tenths between numbers. Subjects were placed in a horizontal position in order to prevent shifting of breast tissue. Saran wrap was placed over the breast tissue to prevent contamination of the probe.

One subject was not available after discharge for testing; thus, was discontinued from the pretest. One patient had very small breasts which could not be measured by the tissue pressure gauge because of close approximation to the chest wall. Therefore, any patient with very small breasts, a depth less than eleven sixteenths of an inch, was excluded from the study.

Collection of Data

Collection of data continued from March to August of 1973 in order to obtain twenty-five subjects in each group who met the established criteria.

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[5]Geissler, "Instrument," 134.

Breast tissue pressure and subjective symptoms were recorded as soon as a subject met the established criteria and was assigned to wear either the compression or support binder. Compression binders were applied with uplift and as tightly as possible in order to prevent the engorgement process. Support binders were applied for support and uplift, but did not constrict the breast tissue. A tag was placed on each subject to identify the type of binder. The patient was instructed to keep the straps tight and to keep the binder on at all times. If the patient had to have a medical procedure requiring removal of the binder, the nursing staff was requested to reapply the binder according to the tag the patient was wearing. Binders were checked the following morning by the researcher for correct application before continuing the patient as a subject in the study.

As soon as the binder was removed on each subject, breast tissue pressure and subjective symptoms were recorded daily for five days. After morning care was completed, the binder was reapplied by the researcher.

When a subject began to leak fluid, pads were placed next to the nipple in order to keep the nipple area dry. The patients were instructed to change these pads if there was profuse leaking. This is relatively easy to do by readjusting the straps.

The patients were informed to request medication and ice bags if there was breast discomfort. Codeine, grains one, is routinely ordered for all postpartum patients. Cesarean section patients were given Demerol 50 to 100 milligrams for discomfort during the first two days before they resumed routine postpartum orders.

Subjects who were discharged before the completion of the five days of study were instructed to wear the binder home. On the following day, the researcher visited the subject in the early afternoon, tested the subject, assisted the subject with good body hygiene, and reapplied the binder. When the subject had completed the five-day series of study, she was instructed to wear a good supportive brassiere constantly until the breast tissue returned to the pre-pregnant state.

Analysis of Data

The one-tailed t-test was used to test the significance of the difference between the two samples-- compression versus support binders. Subject measurements were compared according to the difference between the lowest and the highest tissue pressure reading for each breast during the five day period. The total number of points per subjective symptom of discomfort and lactation were also analyzed by the t-test. Breast tissue pressure changes in primigravidas

versus multigravidas, activity of the right versus the left breast in right handed subjects, and cesarean sections versus vaginal deliveries were also analyzed in the same manner.

In the t-test, significance is assessed by determining whether the difference exceeds the amount that could be attributed to random sampling. The t-test represents the following ratio:[6]

$$\frac{\text{difference in sample means minus difference in population means}}{\text{standard error of the difference in sample means}}$$

Significance occurred when the t-test was at the 0.05 level or higher for a one-tailed test.

Summary

Chapter III presented the methadology used in this research study. Six topics were discussed: type of study, population, description of tool for data collection, pre-test, collection of data, and analysis of data.

The analysis and the interpretation of data will be discussed in the following chapter.

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[6]Faye G. Abdellah and Eugene Levine, Better Patient Care Through Nursing Research (New York: The Macmillan Company, 1965), p. 703.

CHAPTER IV

ANALYSIS AND INTERPRETATION OF DATA

Introduction

The effects of compressional versus supportive binders on the change in tissue pressure, day of maximum tissue pressure, discomfort reported by the subjects, and lactation will be analyzed and interpreted in this chapter. A description of the sample will be followed by the presentation and analysis of the findings.

Description of the Sample

The total population of this study consisted of fifty non-nursing parturients from the census of a large metropolitan city-county hospital. The subjects were alternately assigned. Twenty-five were in the support binder group and twenty-five were in the compression binder group. Subjects met the following criteria: had delivered within the past sixteen hours, were classified as a term pregnancy (thirty-eight to forty-two weeks), ranged in age from fourteen to forty-two years, breasts were larger than eleven sixteenths of an inch in depth, had worn no breast support since delivery, and had delivered by cesarean section, by forceps, or spontaneously.

Breast tissue pressure was measured by the tissue pressure gauge and subjective symptoms of discomfort and lactation were recorded by a point system of 0 to 3 on each subject daily by the researcher for a total of five days. Results were recorded on a data sheet for each subject.

Presentation and Analysis of Findings

The data collected regarding tissue pressure during the five day period was recorded as the difference between the lowest daily reading and the highest daily reading. If the subject demonstrated an increase in tissue pressure, a positive measurement was recorded. If the subject did not demonstrate an increase, the difference was recorded as a negative.

The total number of points for the five day study was recorded regarding subjective symptoms of discomfort and lactation.

In order to test the hypothesis that there would be no significant difference in breast tissue of parturients wearing compressional versus supportive binders, the independent variable, the t-test was applied to the change which occurred in the tissue pressure reading, the dependent variable. Also, the t-test was applied to the day of maximum tissue pressure reading and subjective symptoms of discomfort and lactation.

Table I, page 44, presents the results of the t-test regarding tissue pressure change, day of maximum tissue pressure, discomfort, and lactation of twenty-five subjects wearing compressional binders and twenty-five wearing supportive binders. There was no significant difference in any of these areas tested. However, in the area of discomfort, those subjects wearing compressional binders had a mean point level of 4.2400 $\pm$ 2.1219 while those wearing a support binder had a mean point level of 3.4800 $\pm$ 2.5159. Analysis in this area using the t-test was 1.1313. In order to be significant at the 0.05 level, 1.6829 is required. Thus, in the area of discomfort, those wearing supportive binders are approaching a significant level of less discomfort than those wearing compressional binders. Discomfort is very subjective and difficult to measure because of individual tolerance to pain, anxiety level of the subject, and the attitude of the researcher at the time of testing. Since the number of subjects in this study was not very large, a larger population sample would provide more conclusive results. However, within the limits of the population studied and the established criteria for the study, the null hypothesis, that there would be no significant difference in breast tissue pressure of parturients wearing compressional versus supportive binders, must be accepted.

TABLE I

ANALYSIS OF TISSUE PRESSURE CHANGE, DAY OF MAXIMUM TISSUE PRESSURE DISCOMFORT, AND LACTATION OF ALL SUBJECTS WEARING COMPRESSIONAL VERSUS SUPPORTIVE BINDERS

	COMPRESSION N=25				SUPPORT N=25						
SOURCE	POINTS	MEAN	S.D.	N	POINTS	MEAN	S.D.	N	df	t	p
Tissue Pressure Change of Right and Left Breast	102.2	2.0440	1.0486	50	109.6	2.1920	1.1634	50	98	.6614	N.S.
Day of Maximum Tissue Pressure	201	4.0200	.8364	50	196	3.9200	1.1285	50	98	.4983	N.S.
Discomfort	106	4.2400	2.1219	25	87	3.4800	2.5159	25	48	1.1313	N.S.
Lactation	106	4.2400	2.2677	25	98	3.9200	2.3310	25	48	.4821	N.S.

Table t, one-tailed test
df 40 p 0.05, 1.6839
df 120 p 0.05, 1.6577

Since gravidity was not one of the criteria for selection of subjects into the compressional or supportive study groups, this aspect was analyzed by the t-test for each group in order to examine if there was a significant difference in the primigravida versus the multigravida response to engorgement. Table II, page 46, presents the subjects wearing supportive binders and Table III, page 47, presents subjects wearing compressional binders. In no area was any significance found by using the t-test. However, in both the compressional and supportive groups, multigravidas experienced more discomfort than primigravidas. This is approaching a significant level according to the t-test results of 1.4666 for compressional binders and 1.1355 for supportive binders, (p 0.05, 1.7139). Since multigravidas have experienced engorgement in the past, they may be anticipating pain; thus, they report more discomfort than primigravidas. Also, anticipation of added responsibility and problems at home may increase the multigravida's report of discomfort. A larger sample of subjects would provide more conclusive evidence.

Multigravidas wearing compressional binders experienced peak tissue pressure on day 3.8500 $\pm$ 1.0137 while primigravidas did not experience this until day 4.1333 $\pm$ .6700. This approached a significant level of the t-test,

TABLE II

ANALYSIS OF TISSUE PRESSURE CHANGE, DAY OF MAXIMUM TISSUE PRESSURE, DISCOMFORT, AND LACTATION OF PRIMIGRAVIDAS AND MULTIGRAVIDAS WEARING SUPPORTIVE BINDERS

	PRIMIGRAVIDAS N=13				MULTIGRAVIDAS N=12						
SOURCE	POINTS	MEAN	S.D.	N	POINTS	MEAN	S.D.	N	df	t	p
Tissue Pressure Change of Right and Left Breast	55.4	2.1308	1.1121	26	54.2	2.2583	1.2131	24	48	.3801	N.S.
Day of Maximum Tissue Pressure	103	3.9615	1.2552	26	93	3.8750	.9709	24	48	.2656	N.S.
Discomfort	38	2.9231	1.8171	13	49	4.0833	2.9849	12	23	1.1355	N.S.
Lactation	45	3.4615	1.7372	13	53	4.4167	2.7525	12	23	1.0030	N.S.

Table t, one-tailed test
df 23 p 0.05, 1.7139
df 40 p 0.05, 1.6839

TABLE III

ANALYSIS OF TISSUE PRESSURE CHANGE, DAY OF MAXIMUM TISSUE PRESSURE, DISCOMFORT, AND LACTATION OF PRIMIGRAVIDAS AND MULTIGRAVIDAS WEARING COMPRESSIONAL BINDERS

	PRIMIGRAVIDAS N=15				MULTIGRAVIDAS N=10						
SOURCE	POINTS	MEAN	S.D.	N	POINTS	MEAN	S.D.	N	df	t	p
Tissue Pressure Change of Right and Left Breast	63.6	2.1200	1.0245	30	38.6	1.9300	1.0738	20	48	.6174	N.S.
Day of Maximum Tissue Pressure	124	4.1333	.6700	30	77	3.8500	1.0137	20	48	1.1659	N.S.
Discomfort	56	3.7333	1.9821	15	50	5.000	2.0976	10	23	1.4666	N.S.
Lactation	67	4.4667	2.1250	15	39	3.900	2.4269	10	23	.5916	N.S.

Table t, one-tailed test
df 23 p 0.05, 1.7139
df 40 p 0.05, 1.6839

1.1659, (p 0.05, 1.6839). In the supportive binder analysis, there was minute difference between primigravidas-- 3.9615 ± 1.2552 and multigravidas-- 3.8750 ± .9707. A larger sample may show that multigravidas do reach maximum tissue pressure earlier than primigravidas. However, in the final analysis of tissue pressure change, gravidity was not an influencing factor in tissue pressure change.

Since the analysis of tissue pressure change included points from both the right and left breast, an analysis of the right versus the left breast was completed in order to determine if there was any significant difference in filling between the two breasts. Since there were only five subjects who were left handed, they were excluded from the data since it was believed that the most prominent side may be more developed and lactate more. Table IV, page 49, presents the analysis of tissue pressure change and the day of maximum tissue pressure for right handed subjects. There were no significant findings. However, right handed subjects experienced more filling in the right breast (mean 2.2400 ± 1.3075) than the left breast (mean 1.9244 ± .9192). In order to be significant, the t-test required 1.6707 at the 0.05 level for a one-tailed test. The result of the t-test, 1.3098 was approaching significance. Perhaps a larger sample size would provide conclusive evidence.

TABLE IV

ANALYSIS OF TISSUE PRESSURE CHANGE AND DAY OF MAXIMUM TISSUE PRESSURE FOR RIGHT HANDED SUBJECTS

	RIGHT BREAST				LEFT BREAST						
SOURCE	POINTS	MEAN	S.D.	N	POINTS	MEAN	S.D.	N	df	t	p
Tissue Pressure Change	100.8	2.2400	1.3075	45	86.6	1.9244	.9192	45	88	1.3098	N.S.
Day of Maximum Tissue Pressure	182	4.044	.9651	45	177	3.9333	1.0832	45	88	.5061	N.S.

Table t, one-tailed test
df 60 p 0.05, 1.6707

Since cesarean section patients were included in the population of this study, cesarean section subjects were analyzed in order to determine if this could affect tissue pressure change. Table V, page 51, presents the analysis of cesarean section subjects and vaginal delivery subjects wearing compressional binders. There were no significant findings in any area tested.

In Table VI, page 52, the analysis of cesarean section subjects versus vaginal delivery subjects wearing supportive binders is presented. Vaginal delivery subjects experienced a greater mean tissue pressure change (2.8038 $\pm$ 1.3197) than cesarean section subjects (1.6231 $\pm$ .5666). This was statistically significant at the 0.005 level for the one-tailed t-test. Vaginal delivery subjects also experienced maximum tissue pressure later than cesarean section subjects. The mean for vaginal delivery subjects was on day 4.2500 $\pm$ .9242 while cesarean section subjects was day 3.6154 $\pm$ 1.2114. This was statistically significant at the 0.025 level, one-tailed t-test.

On the basis of the above information it appears that vaginal delivery subjects wearing supportive binders experienced greater mean tissue pressure change, and experienced maximum tissue pressure earlier than cesarean section subjects wearing supportive binders. However, the researcher is unable

TABLE V

ANALYSIS OF TISSUE PRESSURE CHANGE, DAY OF MAXIMUM TISSUE PRESSURE, DISCOMFORT, AND LACTATION OF CESAREAN SECTIONS VERSUS VAGINAL DELIVERIES WEARING COMPRESSION BINDERS

	CESAREAN SECTION N=14				VAGINAL DELIVERY N=11						
SOURCE	POINTS	MEAN	S.D.	N	POINTS	MEAN	S.D.	N	df	t	p
Tissue Pressure Change of Right and Left Breast	54.2	1.9357	.9755	28	48	2.1818	1.1199	22	48	.8126	N.S.
Day of Maximum Tissue Pressure	111	3.9643	.9813	28	90	4.0909	.5961	22	48	.5221	N.S.
Discomfort	53	3.7857	2.3958	14	53	4.8182	1.5266	11	23	1.1937	N.S.
Lactation	56	4.000	2.5635	14	50	4.5455	1.7768	11	23	.5767	N.S.

Table t, one-tailed test
df 23 p 0.05, 1.7139
df 40 p 0.05, 1.6839

TABLE VI

ANALYSIS OF TISSUE PRESSURE CHANGE, DAY OF MAXIMUM TISSUE PRESSURE, DISCOMFORT, AND LACTATION OF CESAREAN SECTIONS VERSUS VAGINAL DELIVERIES WEARING SUPPORTIVE BINDERS

	CESAREAN SECTION N=13				VAGINAL DELIVERY N=11						
SOURCE	POINTS	MEAN	S.D.	N	POINTS	MEAN	S.D.	N	df	t	p
Tissue Pressure Change of Right and Left Breast	42.2	1.6231	.5666	26	67.4	2.8083	1.3197	24	48	4.0966	0.005
Day of Maximum Tissue Pressure	94	3.6154	1.2114	26	102	4.2500	.9242	24	48	2.0281	0.025
Discomfort	37	2.8462	3.0089	13	50	4.1667	1.5723	12	23	1.3032	N.S.
Lactation	47	3.6154	2.6176	13	51	4.2500	1.9203	12	23	.6584	N.S.

Table t, one-tailed test
df 23 p 0.05, 1.7139
df 40 p 0.05, 1.6839

to find any explanation in current medical literature to explain why compressional binders worn by vaginal delivery subjects versus cesarean section subjects did not produce significant data similar to the statistically significant data of the supportive binder analysis.

The level of discomfort and lactation was not statistically significant between vaginal delivery subjects and cesarean section subjects wearing supportive binders. However, the mean level of discomfort was 4.1667 ± 1.5723 for vaginal delivery subjects and 2.8462 ± 3.0089 for cesarean section subjects. This was approaching a significant level. The t-test result was 1.3032, (p 0.05, 1.7139). Since cesarean section subjects received medication for incisional pain, they were probably less likely to experience breast discomfort.

In order to clarify the response of cesarean section subjects and vaginal delivery subjects, analysis of each category was explored in regard to compressional versus supportive binders.

Table VII, page 54, presents the analysis of cesarean section subjects wearing compressional versus supportive binders. There was no statistically significant data by using the t-test. However, in Table VII, page 55, vaginal delivery subjects wearing compressional binders had a mean

TABLE VII

ANALYSIS OF TISSUE PRESSURE CHANGE, DAY OF MAXIMUM TISSUE PRESSURE, DISCOMFORT, AND LACTATION OF CESAREAN SECTIONS WEARING COMPRESSIONAL VERSUS SUPPORTIVE BINDERS

	COMPRESSION N=14				SUPPORT N=13						
SOURCE	POINTS	MEAN	S.D.	N	POINTS	MEAN	S.D.	N	df	t	p
Tissue Pressure Change of Right and Left Breast	54.2	1.9357	.9755	28	42.2	1.6231	.5666	26	52	1.3991	N.S.
Day of Maximum Tissue Pressure	111	3.9643	.9813	28	94	3.6154	1.2114	26	52	1.1447	N.S.
Discomfort	53	3.7857	2.3958	14	37	2.8462	3.0089	13	25	.8666	N.S.
Lactation	56	4.0000	2.5635	14	47	3.6154	2.6176	13	25	.3710	N.S.

Table t, one-tailed test
df 25 p 0.05, 1.7081
df 60 p 0.05, 1.6707

TABLE VIII

ANALYSIS OF TISSUE PRESSURE CHANGE, DAY OF MAXIMUM TISSUE PRESSURE, DISCOMFORT, AND LACTATION OF VAGINAL DELIVERIES WEARING COMPRESSIONAL VERSUS SUPPORTIVE BINDERS

	COMPRESSION N=12				SUPPORT N=11						
SOURCE	POINTS	MEAN	S.D.	N	POINTS	MEAN	S.D.	N	df	t	p
Tissue pressure Change of Right and Left Breast	48	2.1818	1.1199	22	67.4	2.8083	1.3197	24	44	1.6902	0.05
Day of Maximum Tissue Pressure	90	4.0909	.5961	22	102	4.2500	.9242	24	44	.6719	N.S.
Discomfort	53	4.8182	1.5266	11	50	4.1667	1.5723	12	21	.9617	N.S.
Lactation	50	4.5455	1.7768	11	51	4.2500	1.9203	12	21	.3650	N.S.

Table t, one-tailed test
df 20 p 0.05, 1.7291
df 40 p 0.05, 1.6839

tissue pressure change of 2.1818 ± 1.1199 while those with supportive binders had a mean of 2.8083 ± 1.3197. This was significant on the basis of the one-tailed t-test, 1.6902, at the 0.05 level, (p 0.05, 1.6839). No other significant data was found with vaginal deliveries.

Since the sample size was small of both cesarean and vaginal delivery subjects analyzed, fourteen with compression binders and thirteen with supportive binders in the cesarean section analysis and twelve with compressional binders and eleven with supportive binders in the vaginal delivery analysis, caution must be taken in drawing conclusions and making recommendations. However, on the basis of this limited sample it appears that vaginal delivery subjects who wore compressional binders experienced less tissue pressure change. On the other hand, cesarean section subjects experienced no significant difference in tissue pressure change. This may be explained by the fact that the individual response to surgery of the uterus and the physiological plus the psychological response to surgery may affect the hormone stimulation to the breasts. Until accurate measurement of hormone levels is available and widely used, the hormone level of the individual patient remains unknown.

From the above research, it seems wise to instruct patients who want to suppress lactation to wear a comfortably

tight binder until more extensive objective testing is completed-- either by tissue pressure readings or by an evaluation of hormone levels for the individual when hormone testing becomes available.

Summary

Chapter IV presented the description of the sample and the presentation and analysis of the findings. The sample consisted of fifty non-nursing parturients who were assigned alternately to wear a compressional or supportive binder for five days. Analysis of the established criteria for the study resulted in the acceptance of the null hypothesis. However, further analysis of cesarean section subjects versus vaginal delivery subjects resulted in the recommendation that more extensive objective research should be done on vaginal delivery subjects and binder application. With the limited number of vaginal delivery subjects, analysis revealed the compression binder to cause less tissue pressure change.

CHAPTER V

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Summary

The purposes of this study were to compare the effectiveness of a compressional versus a supportive binder in reducing breast tissue pressure of parturients and to make available research data that will enable personnel caring for new mothers to make judgments regarding which method of breast support provides the least amount of engorgement and the most comfort-- a compressional binder or a supportive binder.

The hypothesis was that there would be no significant difference in breast tissue pressure of parturients wearing compressional versus supportive binders.

The total sample studied consisted of fifty non-nursing clinic parturients from the census of a large metropolitan city-county hospital who were alternately assigned to wear a supportive or a compressional binder. Subjects met the following criteria: had delivered within the past sixteen hours, had worn no breast support since delivery, were classified as a term pregnancy (thirty-eight to forty-two weeks), ranged in age from fourteen to forty-two years, and had delivered by cesarean section, by forceps or spontaneously.

Tissue pressure tested by the tissue pressure gauge, degree of discomfort reported by the subject, and the degree of lactation was recorded daily by the researcher for five consecutive days.

The one-tailed t-test was used to test the significance of the difference between subjects wearing compressional versus supportive binders. Analysis was completed regarding the amount of tissue pressure change, day of maximum tissue pressure, discomfort, and lactation.

Conclusions

Within the criteria established for this study, there was no significant difference in any of the areas tested. Thus, the null hypothesis was not rejected. However, there was a trend towards significance in the area of discomfort. Those wearing compressional binders reported a higher level of discomfort than those with supportive binders.

Further analysis of the data consisted of primigravidas versus multigravidas and revealed no significant findings. Analysis of the amount of tissue pressure change and the day of maximum tissue pressure for the left breast versus the right breast for right handed subjects revealed no conclusive findings.

Since cesarean section patients were included in the population, analysis of cesarean section subjects versus

vaginal delivery subjects was computed. Analysis of compressional binders revealed no significant findings. However, cesarean section subjects wearing supportive binders had statistically significantly less tissue pressure at the 0.005 level for a one-tailed t-test. They also experienced maximum tissue pressure earlier than for vaginal delivery subjects. This was significant at the 0.025 level for a one-tailed t-test.

The analysis of cesarean section subjects wearing compressional versus supportive binders revealed no significant findings.

The analysis of vaginal deliveries wearing supportive versus compressional binders revealed less tissue pressure increase in those subjects wearing compressional binders. This was significant at the 0.05 level for a one-tailed t-test. Since the sample size was small, twelve with compressional binders and eleven with support binders, more extensive research is needed to verify this finding.

Recommendations

Since most non-nursing parturients who do not receive drugs to suppress lactation will experience some degree of engorgement, support to the breasts is important to promote comfort and prevent destruction of breast tissue. In this

regard, the following recommendations are based on the findings of this study:

1. A comfortably tight binder should be applied as soon as possible after delivery to all patients who do not wish to breast feed. This practice should continue until more extensive objective research is available.

2. The tissue pressure gauge is a valuable tool to objectively assess changes in tissue pressure of the breasts and its use should be employed where tissue pressure measurement is needed.

3. A replication of this study should be done excluding all cesarean section patients and increasing the total number of subjects tested.

APPENDIX A

TEXAS WOMAN'S UNIVERSITY
COLLEGE OF NURSING
DENTON, TEXAS

DALLAS CENTER
1810 Inwood Road

HOUSTON CENTER
1130 M. D. Anderson
Boulevard

AGENCY PERMISSION FOR CONDUCTING STUDY*

THE Dallas County Hospital District, Woodlawn and Parkland Hospitals

GRANTS TO Darlene Branscome
a student enrolled in a program of nursing leading to a Master's Degree at Texas Woman's University, the privilege of its facilities in order to study the following problem:

Comparison of Changes in Breast Tissue Pressure of Parturients with Compressional Versus Supportive Binders

The conditions mutually agreed upon are as follows:

1. The agency (may) ~~(may not)~~ be identified in the final report.
2. The names of consultative or administrative personnel in the agency (may) ~~(may not)~~ be identified in the final report. In Nursing only.
3. The agency ~~(wants)~~ (does not want) a conference with the student when the report is completed.
4. The agency is (willing) ~~(unwilling)~~ to allow the completed report to be circulated through interlibrary loan.
5. Other _____

Date December 21, 1976

Elizabeth L. Hays, R.N. S.
Signature of Agency Personnel

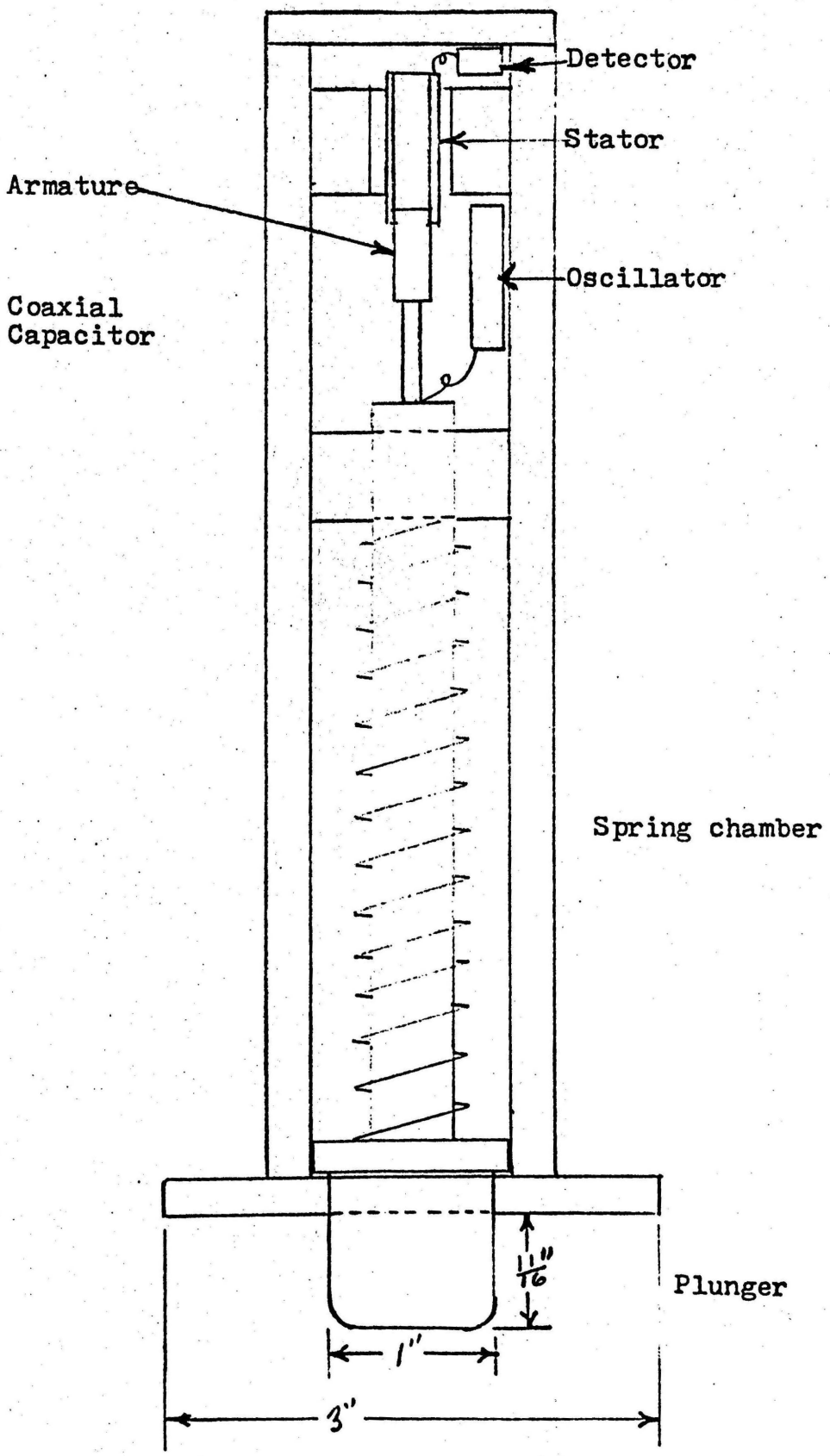
Darlene Branscome
Signature of Student

Margaret Livingstone
Signature of Faculty Advisor

*Fill out and sign three copies to be distributed as follows: Original-Student; first copy - agency; second copy - TWU College of Nursing.

APPENDIX B

Drawing of Tissue Pressure Gauge to Scale



APPENDIX C

DATA SHEET

Name Room No.

Address Hosp. No.

Telephone No.

Age Gravida Para

Delivery Date Time

Type of Delivery

Complications

Date for $\overline{pp}$ Check:

Infant: Sex Birth Weight Apgar

Complications

BREAST MEASUREMENTS

Type of Support Time of Application

Rt. or Lt. Handed

Day	1	2	3	4	5	Measure or of Change	Total No. of points
Right Breast							
Left Breast							
Time of Reading							
Discomfort	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3		
Lactation	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3		

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