ROLE OF ULTRASOUND EXAMINATION IN MINIMIZING INTRA-UTERINE DEVICE COMPLICATIONS

THESIS

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By

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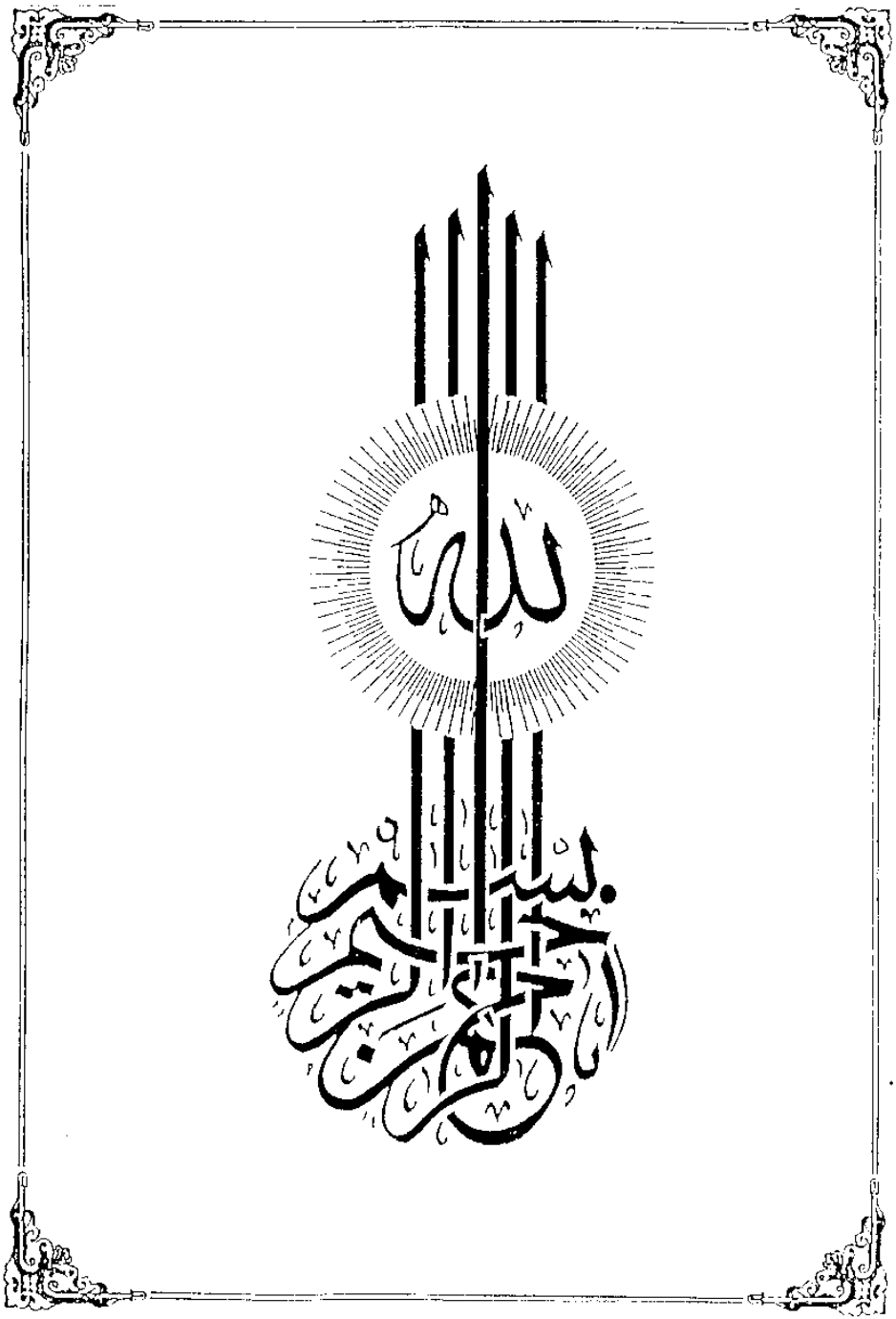

C O N T E N T S

In Comparison to other reversible methods of contraception, the rates of failure and of mortality resulting from use of I.U.D. or indirectly from failure of I.U.D. are low (KEITH et al 1983).

Inspite of this fact, the fears and rumers associated with these complications, reduces the wide use of I.U.D. in national family programs. Methods which satisfy physicians and users at the time of insertion for proper location of I.U.D. inside the proper endometrial cavity with normal geometric orientation, will accentuate the use of I.U.D.

Ultrasound gynecologic examination, can play an important role in identification of patients at risk of perforation due to uterine factors or detection of abnormal uterine configuration or pathology which contraindicate the use of I.U.D. in acceptors and it is the safest method of diagnosis of associated pregnancy with I.U.D. and the relation of I.U.D. to the gestation sac.

Objectives:

Evaluation of the utilization of ultrasound examination at the time of I.U.D. insertion on the immediate and delayed I.U.D. complications.

History:

The first I.U.Ds. , may have been pebbles inserted into uteri of Cammels by Arabs and Turks who wanted to protect their saddle animals from pregnancy during long desert treks (Finch and Green 1963).

Hippocrates is credited with using a hollow lead tube to insert medication or pessaries into human uteri but translation differ as to whether the process was intended for contraception or other purposes (Davis, 1971, Southam 1965).

In human, the use of contraceptive pessaries was reported in the 11th century by the Islamic scientist Avicenna (Population report, 1979) .

During the late 19th century stem pessaries made from materials as common as pewter and as exotic as diamond-studed platinum were in use (Southam, 1965). Many of these stem pessaries were used not only as contraceptives but also as abortiviciants and to correct uterine position. Since they were applied cervico-uterine in a period when antibiotics were not available, hence medical complications up to death were possible. (Siddall 1974).

The first I.U.D. designed solely for human contraception was developed in 1909 by a German physician Richard Richter. It was ring shaped and made of silk-worm gut (Richter 1909).

coil and the lippes loop were the first widly used plastic I.U.D. Jack Lippes of the U.S. added a transcervical thread to his loop and a small amount of barium sulfate to render it radiopaque. (Lippes 1962).

By the mid 1970s, following a decade of continuing research on I.U.D. design and world-wide experience with I.U.Ds in national family planning programs, two major reviews of I.U.D. development took place, a workshop sponsored by the Battelle Memorial Institute in Seatlle in October 1973. (Wheeler, Duncon and Speidle, 1974), and a third international conference sponsored by the population council in Cairo in April 1974. (Hefnawi and Segal 1975).

It both sessions, the locus of attention on I.U.Ds. was shifting to a so called second generation of devices these were the bioactive or medicated devices, in which the plastic I.U.D. became a carrier for other substances such as metals, hormones, and antibleeding agents.

In the first medicated devices, developed by Jaime Zipper and Howard Tatum, Copper wire was wrapped around the T or 7 devices, which had a relatively small surface area, to improve their contraceptive efficacy. (Stewart, Gibor, Deysach and Nillson 1973). (Tatum & Zipper 1968) (Tatum Pastene, Medel and Rivera 1969). Shortly, thereafter, hormones were incorporated in various devices in order to deliver

some of the same steroids which had proved effective in oral contraceptive directly to the uterus in much smaller doses. (Dayle and clew 1968). Somewhat later, other compounds designed to reduce the heavy menstrual bleeding associated with the I.U.Ds. were incorporated in different I.U.Ds. Meanwhile research continued on different shapes of I.U.Ds. that would be more suitable for multipara , provide better protection against pregnancy, resist expulsion, and minimize other complications in case of perforation or accidental pregnancy (Population report 1979).

Chemical Composition of I.U.D.

Inert I.U.D. :

Until recently, in the course of development of I.U.Ds. the major emphasis has been a variation in the shape and size of the I.U.D. to increase effectiveness. The chemical composition of the material from which the various I.U.Ds. are fabricated has been a subject given much less consideration. The inert I.U.Ds. reported in the literature and in reviews by Davis (1970) and Shubeck et al (1971) were made of diverse materials such as silver, gold, nickel, stainless-steel, silk worm gut, rubber, silk,celluloid thread, etc.. With the introduction of synthetic polymers available commercially since the World War II, most of todays I.U.Ds are made of polyethylene, with about 20% of barium sulfate incorporated into the resin to render it radiopaque. There are many types of polyethylene, i.e. low density polyethylene, high density polyethelene, ultra high molecular weight polyethylene, and cross-linked polyethylene, offering a wide range of physical properties for I.U.D. fabrication . (Mayer, Shaw and Fu 1980).

The purity of the poly-ethylene resin is of concern. Residual chemicals, e.g. catalysts or additives, may elicit tissue reaction. Polyethylene with diacetyl phosphate in the formulation produced more tissue reaction than polyethylene Without it (Lee Veen, 1949.) . Polyethylene with high

catalyst residue and phenolic antioxidant revealed more reaction upon subcutaneous implantation than purer poly-ethylene. (Little & Parkhouse, 1961).

Bioactive Devices:

The commercially available bioactive I.U.Ds. Consist of the Multiload Cu 250, the T Cu 200 , the 7 Cu 200, and the progesterone releazing device, the Copper devices rely on the dissolution of the copper wire by the uterine fluid to release the"bioactive " copper ions. The progesterone releazing I.U.D utilizes a different method, by which the bioactive substance is disperced in a viscous fluid containing progesterone can migrate into the uterine cavity. Scommegna has also reported the release of progesterone from drug filled silastic tubing that substitutes for the vertical limb of a T-shaped device.

Synthetic Progestin Devices:

Intrauterine synthetic progestins have been shown to produce quantitative differences in the endometrial tissues in comparison to the same amount of crystalline progesterone (Lifchez & Scommegna , 1970). , Stryker et al, 1972).

Asynthetic Progestin such as norgestral produces maximal endometrial glandular suppression and a decidual (pseudodecidual) stromal reaction when significantly fewer progestin molecules are used when compared to progesterone. On the promise that

the intrauterine adminstration of a potent synthetic progestin would decrease uterine sensitivity and muscle tonus without inducing some of the side effects seen with the progesterone I.U.D., (investigators have studied an effective progestin, D-norgestrel in an intrauterine carrier that allowed the constant diffusion of the compound into the uterine cavity) the use of a poly-lactate film containing 4.5 mg D- norgestrel was attached to a plain T-shaped I.U.D. and inserted into the uterine cavity in each of five patients (Nilsson et al, 1975). The norgestrel was gradually releazed into the systemic circulation during the menstrual cycle. No pregnancies resulted in this preliminary study. The endometrial changes included small non tortous glands and a pseudodecidual stromal reaction similar to that of patients who had the continuous diffusion of synthetic intra-uterine progesterone (approximately 60 µgm./day) .

Insertion Procedures

Mishell 1974 emphasized at Cairo conference "Since insertion technique and correct intra-uterine positioning of an I.U.D. are probably more important for effectiveness than design of the device per se, more attention should be directed toward development of optimal I.U.D. insertions than changes in I.U.D. design, the I.U.D. which will yield the best performance under field conditions will be the one that is easiest to insert into the correct intra-uterine position by personnel who have not had extensive experience with this contraceptive technique".

Descriptions of optimal I.U.D. insertion equipment and technique have been prepared by the population Council, the Pathfinder Fund, the IPPF, and various training centers. Most of these differ only slightly. The instructions given below represents a composite of basic procedures plus recent refinements (Kleinman, 1972).(Rudel 1973) (Sobrero 1971) (Sobrero 1973).

- Sterilize devive and instruments, unless provided in a presterile package, the device and inserter should be soaked for 24 hours in 1:750 aqueous benzalkonuim chloride solution or for 10 to 15 minutes in 1: 2500 iodine solution (Anonymous) (U S Food Drug Adminstration Advisory Committee on Obs. And Gynecology 1968).

- Perform a careful biomanual pelvic examination to establish position, size and regularity of the uterus .

- Visualize the cervix with a speculum.

- Grasp the anterior lip or the cervix with a tenaculum and swab the cervix and vaginal walls with antiseptic solution.

- Straighten the cervical canal and uterine cavity by applying gentle traction on the forceps.

- Use a uterine sound to determine depth and direction of the uterus.

- Load the device into or onto the applicator and gently insert into the uterus.

Release the I.U.D. in the transverse plane of the uterine cavity in a high fundal position.

- Remove the inserter.

- Check and trim the marker tails (if present) to within two to three cm of the external os.

- Remove the forceps and speculum.

Placement in the uterus: -

The mechanism by which the I.U.D. is releazed from the inserter varies according to the model used. Some I.U.Ds are carried into the uterus on an inserter with a hooked end such as the Dalkon shield and some ring shaped models.

The inserter is then removed. Another device, the Antigon, is inserted by extruding the folded device through the cervical canal with the inserting apparatus remaining at the external cervical os (Kleinman, 1972). For most I.U.D. models, however the inserter consists of a plunger within a thin tube, the I.U.D. is either pulled or folded manually and pushed into the tube immediatelly prior to insertion.

There are two basic methods of insertion, a " push-out" and a " withdrawal technique. In the push-out technique used for the lippes loop and Saf -T-Coil, the tube bearing the I.U.D. is inserted just beyond the internal os and the plunger is moved forward until the I.U.D. is pushed out of the inserter, then the plunger and the tube are withdrawn together. In the withdrawal technique, used for the Cu - 7, Copper T and Soonawalas Y (Soonawala 1974), the tube bearing the I.U.D. is inserted right up to the fundus of the uterus and then the outer tube is withdrawn while the plunger maintains the I.U.D in the proper position, the plunger is then withdrawn

Another device, the Spring Coil, employs a unique insertion technique following its insertion through a tube by a combined " Push-out and withdrawal method (Thomas 1975), this device is further adjusted to its proper uterine placement by manipulating an auxiliary set of cervical

threads attached towards the middle of the device. This situates the curved center part of the device over the internal os thus reducing the chances for expulsion (Ragab 1971) This manipulation is described by those who have used the device as being perhaps " Too complicated for general use" (Kessel 1974, Lampe , Randic, Thomas and Kessel 1974).