A RANDOMIZED TRIAL OF EXTRA-AMNIOTIC NORMAL SALINE VERSUS INTRACERVICAL PROSTAGLANDIN E2 FOR RIPENING THE CERVIX

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INTRODUCTION

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The degree of cervical ripeness correlates with the ease of induction and the duration of labor ***(Bishop, 1964).*** A score of at least 6 is considered favorable and more likely to result in a successful labor. Cervical ripening does not only occur as a result of uterine contractions but also due to an active ripening process within the cervix.

Methods to ripen the unfavorable cervix include extra-amniotic balloon stretching, laminaria, prostaglandin E2 gel and porcine relaxin ***(Rayburn and Russ, 1986).*** The ripening process is probably controlled by the same hormones that play a role in triggering uterine contractile activity, in particular prostaglandin E2 (PGE2) ***(Garfield, 1987).*** Many double blind investigations have demonstrated the value of PGE2 for cervical ripening and induction of labor ***(Rayburn, 1989).*** Cervical ripening by PGE2 gel is associated with marked changes in the ultrastructure of the cervical fibrous stroma ***(Uldberg et al., 1981).*** In patients with a highly unfavorable cervix (cervical score ≤ 3), the intracervical application is significantly more effective than the intravaginal method while in patients with a more favorable cervical score the 2 routes are equipotent ***(Ekman et al., 1983).***

Extra-amniotic saline infusion via a Foley catheter was found to be more effective than PGE2 vaginal gel in ripening the cervix and inducing labor ***(Rouben and Arias, 1993).*** The mechanism of action of normal saline is still unknown.

AIM OF THE STUDY

The aim of this study is to compare extra-amniotic normal saline infusion through an inflated Foley catheter with intracervical PGE2 gel in ripening the cervix and to evaluate its efficacy and safety as it may prove to be a cheap and readily available method for cervical ripening.

REVIEW OF LITERATURE

CHAPTER I
THE MORPHOLOGY OF THE HUMAN CERVIX

Unlike other structures, the cervix has no fixed morphology. Indeed, the dramatic changes that occur in response to pregnancy and labor appear to be unique in the human body ***(Danforth, 1983)***.

A-The Non Pregnant Cervix :

Gross Characteristics and Attachments

The normal human cervix is about 2.5 to 3 cm in length. Its anteroposterior diameter is about 2 to 2.5 cm, the lateral diameter about 2.5 to 3 cm. Their difference is due to the shape of the cervical canal which in the sagittal plane is straight and in the frontal plane, spindle shaped. The wall of the cervix is about 1 cm thick throughout its length. The cervix is divided into two portions, the portiovaginalis and portiosupravaginalis, according to the segments that lie respectively below and above the vaginal reflection. The vaginal reflection is located at about the junction of the inferior and middle thirds of the cervix. The uterine supports (the pubocervical fascia anteriorly, the utero-sacral ligament posteriorly and of most importance, the transverse cervical or cardinal ligaments laterally) are attached to the cervix immediately superior to the vaginal reflection. In the non pregnant woman, they stabilize the cervix in approximately the center of the pelvis , and during pregnancy they are the "guy ropes" the uterus pulls upon to expel the baby in the second stage of labor ***(Danforth, 1983).***

The Fibrillar Composition of the Cervix

1.Collagen :

The human cervix is composed predominantly of fibrous connective tissue, which is demonstrated by contrast stains to be almost entirely collagen ***(Danforth,1947,1954 and 1983; Hughesdon, 1952).*** The uterine cervix from fertile non pregnant women contains 80% water ***(Liggins, 1978).*** Collagen can account for as much as 50% of the total dry weight, as ***Danforth et al. (1974)*** demonstrated in the human cervix. As a proportion of total cervical protein, collagen represents 82% ***(Danforth and Buckingham, 1973).***

2.Elastic Tissue

In Danforth's specimens (1947), stains for elastic tissue showed the presence of minute and in his opinion, insignificant amounts of these fibers. The fibers were found to be very sparsely scattered in a haphazard manner throughout the substance of the cervix. They were most abundant in and around the walls of the large blood vessels. Elsewhere they constituted a fraction of 1% of the total fibrous tissue of the cervix.

Leppert el al*.*(1982) concluded that although the amount of elastin appeared to be low, its presence might account for rapid dilatability of the cervix in labor and the rapid return to normal shape after delivery.These elastic fibers are very thin compared with elastic fibers of other tissue ***(Leppert PC and Yu SY, 1991).***

3.The Fibromuscular Junction :

The transition from myometrium of the corpus to connective tissue of the cervix is quite variable from one specimen to another. Its characteristics can often be discerned by gross examination of the stained slide held before a light or view box, the contrast in color between myometrium (red) and the collagenous cervix (blue in Masson, green in Milligan trichome) is readily apparent. Microscopic examination is usually needed to determine the exact point of transition from predominantly muscle to predominantly collagen. In most cases, the transition occurs over the course of 2 or 3 mm, in some less so. When a line is drawn across the critical area of transition it is sometimes wavy ***(Danforth,1983).***

4.Muscle :

As noted by ***Hughesdon (1952),*** the outer quarter or third of the wall is muscular like the corpus: the inner and major part consists of moderately cellular connective tissue, rich in collagen and containing some bundles of immature muscle fibers. He referred to the outer muscle layer as the extrinsic muscle of the cervix. Internally, forming the bulk of the cervix, lies a broad mass of fibrous connective tissue. It contains a variable proportion of scattered muscle bundles, to which he referred as the intrinsic muscle of the cervix.

The studies of the contractile ability of the non pregnant cervix have been made by ***Najak et al. (1970)*** in vitro. From a functional and practical viewpoint the cervix consists of an outer narrow contractile layer and an inner broad firm non-contractile mass ***(Hughedson, 1952).***

Actual counts have not been made, but examination of many specimens suggests that, at most, smooth muscle accounts for from 10%-15% of the normal cervical substance ***(Danforth, 1954).***

B-The Cervical Changes During Pregnancy :

The clinical changes undergone by the cervix during normal pregnancy and delivery are quite dramatic. Before the urinary pregnancy test becomes positive, increased cervical softening may be detected. During the course of pregnancy, the cervix may become softer and usually enlarges two to threefold in diameter ***(McInnes et al., 1980).***

Hughesdon (1952) studied the effect of pregnancy on cervical structure. The collagen fibers are loosened, and the consistency of the cervix therefore softened, by an accumulation of fluid . The loosening process consists of three components, namely, separation of the individual fibers into a number of very fine fibrils, and actual fiber reabsorption and replacement by fluid. Finally, the vascularity of the cervix increases as pregnancy advances.

C-The Cervical Changes of Prelabor and Labor :

Prelabor refers here to the uterine activity that precedes labor and gives rise to the changes that are preparatory to labor. For the last four weeks of pregnancy, the pattern of uterine activity becomes closer closer to that which characterizes true labor. Labor-like contractions appear with increasing fre-