Comparative Study Between Elective Double Cervical Cerclage versus Conventional Cerclage in cases of Cervical Insufficiency

Thesis

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List of Abbreviations

CL	**:**	Cervical length
CRH	**:**	Corticotropin releasing hormone
FFN	**:**	Fetal fibronectin
H_2O_2	**:**	Hydrogen peroxide
ICSI	**:**	Intracytoplasmic sperm injection
IL	**:**	Interleukin
KOH	**:**	potassium hydroxide
MIAC	**:**	Microbial invasion of amniotic cavity
NICU	**:**	Neonatal intensive care unit
PMN	**:**	Polymorphonuclear neutrophils
PROM	**:**	Premature rupture of membranes
PTB	**:**	Preterm birth
PTD	**:**	Preterm delivery
PTL	**:**	Preterm labour
TAC	**:**	Trans abdominal cerclage
TAU	**:**	Trans abdominal Ultrasonography
TCO	**:**	Total cervical occlusion
TNF	**:**	Tumour necrosis factor
TVU	**:**	Trans vaginal Ultrasonography

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Introduction

"Cervical insufficiency" is defined as recurrent 2nd or early 3rd trimester delivery caused by the inability of the uterine cervix to retain a pregnancy in the absence of contractions of labor ***(Romero et al., 2006).***

Cervical insufficiency is one of the important causes of recurrent abortion and preterm labor. Preterm labor is the most common cause of neonatal morbidity and mortality. Infants born preterm are at increased risk of a range of adverse neonatal outcomes, including chronic lung disease, severe brain injury, retinopathy of prematurity, necrotizing enterocolitis and neonatal sepsis ***(Secher et al., 2007).***

Cervical cerclage is a procedure in which sutures are inserted around the uterine cervix in women suspected to have cervical weakness. The first use of this technique was initially published by Lash and Lash in 1950, and it involved a complicated cervical repair procedure that could only be performed prior to pregnancy ***(Noori et al., 2007).***

In 1955 V. N. Shirodkar (professor of Midwifery and Gynecology at the Grant Medical College in Bombay, India) reported an alternative method that could be performed during pregnancy. It involved reflection of the bladder away from the

cervix, enabling insertion of a stitch above the level of the cardinal ligaments. A simpler less invasive operation described by Ian Mc Donald (from the Royal Melbourne Hospital) in 1957 has been adopted by many. This involves insertion of a purse-string suture around the vaginal cervix. These two methods of cerclage cannot be used effectively in women with a severely deficient or damaged cervix. In 1965, Benson and Durfee published an alternative method of cerclage requiring transabdominal insertion of a suture at the level of the internal cervical os. Many series of such sutures have been published since then ***(Noori et al., 2007).***

Based on clinical indication, cervical cerclage can be classified as an elective procedure (based on previous history and/or investigation), a selective procedure (based on evidence obtained by ultrasound examination that shows shortening of the cervix) or an emergency procedure (when the cervix is dilated with the membranes seen or bulging through the cervical os) ***(Yanamandra et al., 2006).***

An association between infection and preterm delivery was established. The working hypothesis is that microorganisms in the lower genital tract (which maybe non-pathogenic in this environment) ascend into the uterus to cause inflammation and preterm birth ***(Norman, 2007).***

In most women it is impossible to determine whether weakness of the cervix or ascending infection is the primary cause in those with a previous history of an apparently incompetent cervix. All the previous cerclage techniques only deals with the mechanical factor of insufficiency, without dealing with the biochemical factor (infection) which may be the initiator of cervical shortening and dilation ***(Secher et al., 2007).***

There is a growing body of evidence that the cervix creates a barrier against infection. As most pregnancies continue to term despite the presence of opportunistic organisms with pathogenic potential in the vagina, it seems likely that local defense mechanisms are in operation within the amniotic fluid, fetal membranes, and the cervical mucus plug. The later, which becomes considerably thicker following conception, has been shown to be particularly important in this regard ***(Noori et al., 2007).***

In 2001, Hien et al. performed in vitro studies on cervical mucus plugs and demonstrated that intact cervical mucus plugs have antimicrobial activity against a wide range of gram-positive and gram-negative organisms and may contain diffusible factors with bactericidal properties ***(Noori et al., 2007).***

The mucus plug contains antibacterial, antifungal and antiviral products. In addition, innate and adaptive immune system appears to have a role ***(Secher et al., 2007).***

Total cervical occlusion (TCO) was first documented by Saling et al. in 1984 as an effective intervention for women at risk of preterm birth. The operation involved dissection of the external os epithelium in a similar fashion to conization. They then removed 2 cm of glandular epithelium lining the cervical canal. The raw area was sutured together to ensure adequate healing of opposed surfaces. As term drew closer, they attempted to recanalise the cervical canal by incising the scar tissue ***(Noori et al., 2007).***

In the last years a simpler, less traumatic technique was introduced, whereby the external cervical os is occluded using a continuous, nonabsorbable suture. This is inserted at the time of internal os cerclage. Such a suture, lacking any significant mechanical strengthening function, act by maintaining the cervical mucus plug within the cervical canal for a greater proportion of the pregnancy, thereby reducing the risk of infection due to ascending organisms and, hence, preterm birth. So, the double cerclage deals with both problems of incompetence (mechanical factor and infection) ***(Noori et al., 2007).***

Several uncontrolled studies were performed over the last 5 years and they showed that the combined suture improves the obstetric outcome compared with the single suture. However, confirmation of the value of the procedure can only be achieved with an appropriately designed prospective randomized trial. Such a multicentre trial is now underway, led by Niels Secher and his group, in Copenhagen ***(Noori et al., 2007).***

Because of the importance of this issue and the difference it would make in the treatment of cervical incompetence, it was decided to perform a similar randomized controlled trial.