A NEW ALTERNATIVE IN THE HYGROSCOPIC DILATATION OF THE CERVIX

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INTRODUCTION

In order to dilate the uterine cervix for various indications, laminaria tents (Laminaria japonica or Laminaria digitata) have been used for several years. However, this practice has been slowly abandoned, both for difficulties in finding the laminaria and some undesirable qualities (slowly occurring dilatation, side effects, etc.), especially since the prostaglandin analogs, that partially obviate to these disadvantages, have been made available.

It has been proposed lately to the Italian and European gynecologists the replacement of the old Laminaria japonica with a new one made with innovative materials and know-how.

It is probably useful, before going into details, to summarize the present knowledge on the structure of the uterine cervix. The most important advances have been made on the cervical biochemical properties. It is now known that the human uterine cervix is mainly a fibrous tissue composed by collagen fibers and ground substance, the latter comprised of proteoglycans containing glycosaminoglycans (previously known as acid mucopolysaccharides) bound to a protein core. The distal or vaginal portion of the cervix contains only 6% of smooth muscle, whereas the remainder contains an average of 29%[1].

In the '50's, Danforth demonstrated that the cervical function is related to connective tissue biochemical properties, rather than to smooth muscle physiology, since the human cervix is made of fibrous tissue covered by only a thin layer of smooth muscle[2, 3]. Later on, it has been shown that the main component of the cervical connective tissue is the collagen, particularly type 1 (70%) and 3 (30%)[4]. The collagen fibrils aggregate to form fibers by means of cross-links, and it is thanks to this protein that the cervix can modify its structure in different situations (pregnancy, hormonal treatment, diseases, etc.). It appears that locally acting substances such as prostaglandins facilitate these protein rearrangements[5]. This is particularly obvious during the first part of pregnancy when the mature collagen, that has many stable cross-links (peculiar of non pregnant women), undergoes molecular fragmentations that result in an increase of free collagen. It is therefore clear that during pregnancy both catabolism and synthesis of collagen are so high as to induce a complete reshaping of the organ, that will complete at the time of labor[6]. Finally, during the mechanical dilatation the ground substance, which is an interstitial matrix similar to a gel, retains water; therefore both collagen frame and matrix define the biochemical properties of the cervix[7].

Among the mechanical dilators, the Hegar or metallic dilators are the most widely used. In a recent survey in the USA, out of 300,000 terminations of pregnancy 95% were performed with this device, which carries several and often recurring side effects such as cervical injury, uterine perforation, cervical false passages, etc.[8, 9].

It has been shown that during the cervical dilatation according to Hegar, one finds very strong resistance at 9mm dilatation; beyond this point, the resistance decreases because of documented microscopic lacerations, particularly around the internal cervical os. If one keeps dilating, another point of strong resistance is found with the Hegar number 11[10].

It is more and more clear that future fertility, after cervical dilatation, is closely related to the proper execution of the procedure, especially in young or nulliparous women, or in those frequently undergoing terminations of pregnancy. Specifically, the metallic dilator implies a sustained, reiterated and potentially harmful mechanical stress[11-13]. In fact, this high incidence of cervical injuries must be considered liable for the increasing frequency of second trimester abortions, due to a variable degree of mechanical cervical incompetence[14, 15].

Among the methods developed to decrease or eliminate the adverse effects of Hegar dilators is the synthetic derivative of prostaglandin PGE2 sulprostone, administered parenterally on an in-patient basis[16]. This "pharmacological" dilatation has, however, clear limitations despite its few adverse effects (nausea, vomiting, diarrhea, abdominal pain). These symptoms directly depend on the duration of administration and the total dosage used to obtain an efficient uterine contractility and an adequate cervical ripening. One must also keep into account the cost and the need of a precise identification of high-risk patients in which the drug is contraindicated.

These are the patients with systemic diseases such as asthma, COPD, heart failure, severe hypertension, hepatic failure, renal insufficiency, decompensated diabetes mellitus, thyrotoxicosis, glaucoma, ulcerative colitis, spastic or hypoxic vascular diseases, coagulopathies, some CNS disorders, thalassemia, peptic ulcer. And also specific contraindications such as previous uterine surgery, third trimester pregnancy, hypersensitivity, acute gynecologic infections.

The most traditional osmotic dilators are the Laminaria japonica and Laminaria digitata tents. These seaweeds are found in North Atlantic and North Pacific oceans. The dried and compressed laminaria tents attain their maximal dilatation in 12 to 24 hours[17-19]. In this regard, Bentov and Stubblefield[20] stated that even though laminaria tents have many of the features of an ideal cervical dilator, the very slow expansion time would make a faster device preferable. One should also consider other undesirable qualities of laminaria tents, such as the risk of infections due to their incomplete sterilization (bacterial spores persist in the interstices of the seaweed). Moreover, they cannot be manufactured to precise specifications and sometimes their irregular surface brings about bleeding and pain at insertion and during cervical dilatation. Finally, it is not infrequent that the vegetable matter of which laminaria tents are composed crumbles during removal because of spontaneous intracervical lysis.

A new, completely different hygroscopic cervical dilator has been recently introduced in the USA and in some European countries; it consists of a new laminaria made with innovative technology.

TECHNICAL FEATURES

Dilapan is a new synthetic dilator, composed of a polyacrylonitrite polymeric hydrogel. It consists of a slender cylindrical stick with a string attached to one end in order to facilitate placement and removal (Figures 1 and 2). The only available size in Italy is 4x65 mm, while in USA smaller ones can also be found (3x55 mm and 4x55 mm). Each unit is individually sealed, resistant to humidity and sterilized with ethylene oxide.

PHYSICAL PROPERTIES

The hydrophylic properties of the polymer allow Dilapan to increase three to fourfold in diameter, up to 12 mm, over a period of 2-4 hours, without lengthening. Specific tests performed (expansion time, pressure reaction, resistance to tension) under normal use conditions and under a traction force of over 100 Kg show a clear-cut superiority over traditional laminaria tents. These features allow the use of Dilapan both in pregnant and nonpregnant women that have different degrees of cervical compliance.

MECHANISM OF ACTION

The Dilapan hydrogel absorbs fluids through a hygroscopic action and gradually, but quickly, increases its diameter dilating atraumatically the cervical canal with the the following rate:

1.5 hrs	8.7 mm
2.0 hrs	9.7 mm
2.5 hrs	10.2 mm
3.5 hrs	11.0 mm
5.00 hrs	12.7 mm
15-21.00 hrs	14.5 mm

Dilapan radial expansion is three to four times faster than that obtained with Laminaria japonica tents[21].

HYSTOPATHOLOGIC STUDY

Recently Robinson[22] studied the histopathologic effects of Dilapan in order to identify the cervical morphologic changes after prolonged treatment (12 hours) and the mechanism of cervical softening. According to this study, treatment with the new synthetic hygroscopic laminaria results in collagen depolymerization. Although the decreased cervical density could be due to a dilution effect caused by edema, the latter is not visible grossly or microscopically. On the other hand, the cervical dilatation cannot be be caused only by a direct physical effect as a

consequence of a positive pressure applied. Dilapan treatment apparently starts a chain reaction of fragmentations (probably in the ground substance of the connective tissue) that leads to collagen depolymerization.

At the same time, there is an increase in the amount of ground substance, in analogy with the physiologic microscopic changes of pregnancy.

CONTRAINDICATIONS AND WARNINGS

The use of synthetic laminaria is not advised during the course of genital tract infections. It should also not be used during the menstrual flow and beyond the 16th week of pregnancy. A careful insertion is important in order to avoid utero-cervical lesions or the dilator displacement into the uterine cavity or the vagina. Dilapan should not be left in situ for more than 24 hours. A proper insertion and removal technique does not usually carry any risk (such as broken or trapped laminaria), as long as one carefully seizes with the forceps only the distal ring, where the string is attached. However, in case the dilator breaks, its fragments can easily be aspirated.

CONCLUSIONS

Several studies have shown the high patient's tolerance, and the possibility to reach up to 12 mm dilatation in 3-4 hours with a single unit of Dilapan. In addition to an almost absolute safety, a less painful and more uniform expansion can be attained. Besides its use for minor outpatient gynecological procedures, Dilapan was appreciated for its low cost and hospital use suitablility. This is obvious if one considers that one extra day of hospitalization carries a cost 20 times higher than that of the amount of Dilapan needed for an individual procedure.

Recently the combined use of sulprostone and hygroscopic laminaria has been suggested in order to maintain a morphologically intact fetus for a pathologic exam[23]. In the same study it is recommended to use this association in the first trimester of pregnancy for the diagnosis of congenital malformations with the chorionic villi sampling (CVS) technique[23]. The association has also been shown to be extremely useful in order to decrease the prostaglandin dosage and related side effects. Finally, the predilatation with hygroscopic laminaria can be considered as an useful and ideal technique in primigravida with intact cervix, in order to avoid infertility problems secondary to recurrent cervical lesions that often occur after use of metallic dilators and prostaglandins[23, 24].

It is to be hoped that the studies under way, in Italy as well as in other countries, may provide new indications for the diagnostic and therapeutic use of the new hygroscopic laminaria, such as: colposcopic visualization of endocervix in cases of CIN; therapeutic dilatations in patients with expulsive dysmenorrhea unresponsive to treatment; as an intracervical device replacing the outdated "Petit's tube" in cases of primary cervical sterility, etc. In this way, cervical dilatation could become at the same time a less traumatic and more reliable procedure for the gynecologist.

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Figure 1. Before expansion. After 4 hours' expansion (12 mm).

Figure 2. Actual expansion at 4 hours in 0.9% saline solution.

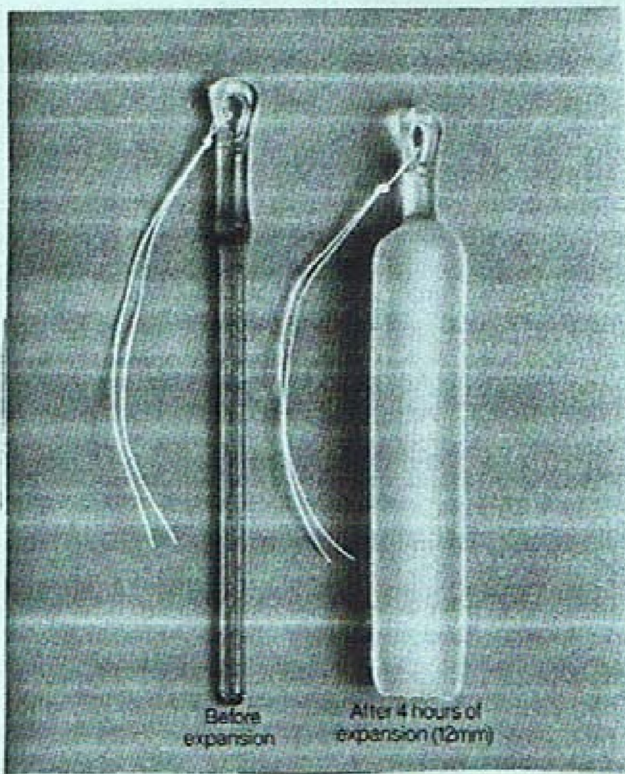

Figure 1

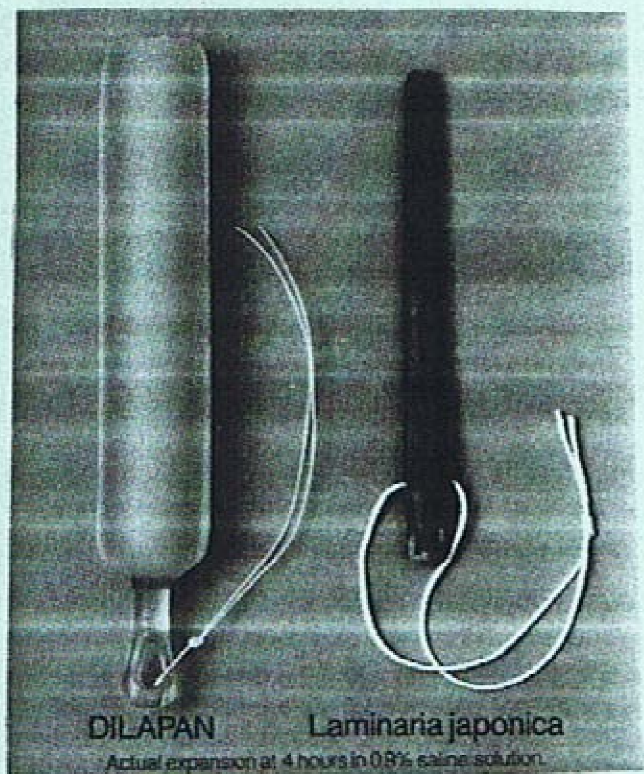

Figure 2

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