

# CLINICAL TRIAL OF DILEX-C FOR DILATATION OF CERVIX FOR MEDICAL TERMINATION OF PREGNANCY

(A Comparative Study with Laminaria Tent)

by

SURENDRA PAWADE,\* M.B.,B.S., D.G.O.

and

P. BHATTACHARYA,\*\* M.D., D.G.O.

## Introduction

As the demand for termination of pregnancy is increasing, the obstetricians are on the lookout for a quick, safe and cheaper method of termination of pregnancy. For two stage evacuation laminaria tent was used for ages but it is expensive and is now not easily available. One of the newer method of slow dilatation of the cervix is by Isapgol tent ('Dilex-C'). This study was carried out to compare its efficacy with laminaria tent in relation to (1) Minimum time required for dilatation of the cervix, (2) whether further dilatation is easily achieved if required, (3) time taken for evacuation, (4) blood loss during the surgical procedure.

Isapgent is a new device introduced by LUCKNOW CENTRAL DRUG RESEARCH INSTITUTE INDIA (DILEX-C UNICHEM LABORATORIES LTD., BOMBAY). This is made from dried seed-husk of PLANTAGO-OVATA-FORSK (ISAPGOL), which is abundant in India. These seeds are rich in mucilage (a hemicellulose). These

preparation increases bulk by imbibing water, so when placed in cervical canal it absorbs moisture and swells, thus causing gradual dilatation of cervix. Dilex-C tent is 50-60 mm. long and of 3.5 mm. to 4 mm. in breadth. It is sterilized by gamma irradiation and supplied in sealed polythene packets and stable for any length of time.

Clinical trial was undertaken at Medical College and Hospital, Nagpur. There were 25,148 admissions in Obstetrics and Gynaecology Department from August 1980 to September 1981, out of which 802 cases demanded MTP (3.07%). In 802 cases, 302 were for first trimester abortion (38.03%).

Under this clinical trial of Dilex-C for cervical dilatation for MTP total cases selected were 144, which were divided into 4 groups, for correct evaluation of effectiveness of Dilex-C and depending on the span of time for which tent was kept in cervical canal prior to evacuation. In 80 cases Dilex-C were inserted and in 64 cases laminaria tent. One single tent was used in each case.

Group	Hours	Dilex-C	Laminaria Tent
A	24	20	20
B	16	20	20
C	8	20	20
D	4	20	4

\*Post Graduate Student, Department of Obstetrics and Gynaecology, Medical College, Nagpur.

\*\*Professor of Obstetrics and Gynaecology, Medical College, Nagpur.

Accepted for publication on 14-12-81.

Technique of insertion of Dilex-C in the cervical canal was same as in the case of laminaria tent. The patient was placed in the lithotomy position after evacuation of the bladder and examined bimanually and per speculum. A single tent was inserted into the cervical canal upto internal os. A dry gauze was placed at the vaginal vault through loop at string of Dilex-C. Antibiotics were given to each patient for 7 days.

Age of the patient varied from 15 to 45 years. 68.70% of patients came from the 21 to 30 years age group. 11.81% patients were unmarried. Period of gestation varied from 8 to 14 weeks. Maximum cases were in 10 weeks of gestation (50.70%). No local anaesthesia or analgesia was required during insertion of tent. Tent was removed after required time and intravenous 10 units Oxytocin in a drip of 5% dextrose was started in each case. Intravenous diazepam and pentothal was given in each case, except where trans-abdominal sterilization was to be done alongwith MTP, spinal anaesthesia was given. Intravenous methergine 0.4 mg. given after removal of products of conception with ovum forcep and before blunt curettage in all cases to achieve better haemostasis during procedure. Dilatation achieved was measured in each case in millimeter using Hegar's dilator. Dilatation of 8 mm. or more was considered satisfactory. Dilatation achieved, time required for evacuation and blood loss during procedure were noted (Table I).

Further dilatation was easy in each case of groups A, B and C. In group D further dilatation was easier in Dilex-C than laminaria tent which may be due to local action of Dilex-C on cervical glands and effect of more secretion of cervical mucus which helps softening of cervix. Cervical

dilatation achieved in later weeks of gestation is due to the hormonal effect on cervix which is easily dilated. Number of cases in which satisfactory dilatation was achieved (Table II).

#### *Complications (Table III)*

In Dilex-C group difficulty during insertion of tent occurred in 2 cases, one of the case was a primigravida with acutely anteverted uterus and second was a 11th gravida. In second case, insertion of Dilex-C was abandoned and a small size laminaria tent was inserted. This must be due to cervical fibrosis.

In laminaria group there was slight difficulty during insertion of tent in only 1 case of primigravida which required negotiation of cervical canal with uterine sound after that laminaria tent was inserted without difficulty.

Twelve patients from the Dilex-C group and 10 patients from laminaria tent group were complaining of slight pain in lower abdomen, which did not require any medication. Dysuria, difficulty in walking was not complained by the patients of both groups after insertion of tent and removal of tent. No difficulty was noticed during removal of tent in each group and cervical injury was not noticed with naked eye during the process in both the groups. One patient in which Dilex-C was inserted had a inflammatory reaction over the vaginal mucosa which was noticed during removal of Dilex-C. From previous history, similar type of reaction after some gynaecological examinations in past was obtained, this might be due to cetavelon lotion. Vaginal swab was sent for culture and sensitivity of micro-organism, which did not show growth of pathogenic organisms. No medication was

TABLE I

Group	Tent	No. of cases	Gestational weeks		No. of cases where difficulty encountered during removal of tent	Cervical dilatation achieved in mm.		No. of cases needed additional dilatation	Average time taken for evacuation	Average blood loss in ml.	No. of cases needed blood transfusion
			Range	Mean		Range	Mean				
A 24 hours	Dilex-C	20	8-14	10.7	Nil	7-20	10.0	18	8 mt.	45.9	1
	Laminaria	20	8-14	10.8	Nil	7-20	10.9	18	8 mt. 15 secs.	42.5	1
B 16 hours	Dilex-C	20	8-14	10.3	Nil	7-11	9.2	19	7 mt.	50	1
	Laminaria	20	8-12	9.3	Nil	7-11	9.5	20	6 mt.	22.5	Nil
C 8 hours	Dilex-C	20	8-12	9.9	Nil	8-10	9.0	20	6 mt. 15 secs.	36	Nil
	Laminaria	20	8-12	9.1	Nil	7-10	8.95	20	6 mt.	22.5	Nil
D 4 hours	Dilex-C	20	8-14	10.7	Nil	5-11	6.7	20	11 mt. 30 sec.	45.25	Nil
	Laminaria	4	8-14	11.5	Nil	6-9	8.0	4	10 mt.	50	1

TABLE II

Group	Hours	Tent	No. of cases	Percentage
A	24	Dilex-C	18	90
		Laminaria	19	95
B	16	Dilex-C	18	90
		Laminaria	20	100
C	8	Dilex-C	20	100
		Laminaria	18	90
D	4	Dilex-C	9	45
		Laminaria	3	75

TABLE III  
Complications

Sr. No.	Complication	Dilex-C		Laminaria Tent	
		No. of cases	Percentage	No. of cases	Percentage
1.	Difficulty during insertion of tent.	2	1.39	1	0.69
2.	Complaints/Complications during insertion of tent.				
	— Pain	12	8.34	10	6.94
	— Bleeding	1	0.69	Nil	—
3.	Complaints after insertion of tent.				
	— Dysuria	Nil	—	Nil	—
	— Difficulty in walking	Nil	—	Nil	—
	— Fever	Nil	—	Nil	—
	— Other	1	0.69	Nil	—
4.	Difficulty during removal of tent.	Nil	—	Nil	—
5.	Cervical injury.	Nil	—	Nil	—
6.	Uterine perforation.	Nil	—	1	0.69
7.	Uterine haemorrhage requiring blood transfusion.	2	1.39	2	1.39
8.	Incomplete abortion.	1	0.69	Nil	—

needed. She was discharged 2 days after per speculum examination, which revealed healthy vaginal mucosa.

Postoperative rise of body temperature was not noticed in any case after 24 hours of insertion and till first follow-up that is 7 to 10 days after MTP.

There was perforation of uterus in 1 patient where laminaria tent was inserted for 4 hours prior to evacuation which required laparotomy and closure of the rent. There was 1 case of incomplete abortion which required repeat evacua-

tion. She was a third gravida with previous two Full Term Caesarean Section deliveries.

#### Discussion

It was found from this clinical trial that in cases of Dilex-C the cervix becomes very soft and further dilatation is very easy. This must be due to its hygroscopic nature and also some chemical action of Isapgol on the cervical tissue.

Dilex-C is very cheap as compared to laminaria tent.

Easily available in India as it is manufactured in the country.

Has no disadvantage as compared to laminaria tent.

No allergic side effect was observed.

It is as effective dilator as laminaria tent (as shown in Table III).

Disadvantage—only one size is available and sometime the cervix may not allow thin size tent to be introduced. If two or three small Dilex-C is put in the swelling capacity may be more and cervical dilatation also will be more.

*Acknowledgements*

We are grateful to Dr. B. R. Solanki, Dean, Medical College, Nagpur and Dr. V. D. Shastrakar, Professor and Head of the Department of Obstetrics and Gynaecology, for allowing us to conduct this clinical trial.

We are also grateful to Unichem Laboratories Ltd., Bombay, specially to Mr. S. M. Karnik and Dr. Pandit for their help in supplying the Dilex-C for the trial.