

RIPENING OF THE CERVIX USING THE BALLOON CATHETER

PRIOR TO INDUCTION OF LABOUR

236145

BY

CHIMA DHUONU

A DISSERTATION SUBMITTED TO THE UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE IN PARTIAL FULFILMENT OF THE
REQUIREMENTS OF THE DEGREE OF MASTER OF MEDICINE IN
OBSTETRICS AND GYNAECOLOGY.

THE UNIVERSITY OF ZAMBIA

LUSAKA

1989

DECLARATION

I hereby certify that this dissertation represent entirely the result of my own individual effort. The various sources to which I am indebted have been acknowledged in the bibliography. I also hereby state that this study herein presented, has not previously been submitted either wholly or in part for a Degree at this or any other University nor is it currently being submitted for the same purpose.

Signed.....

CHIMA ODUONU.

ABSTRACT

The unripe cervix sometimes presents a real problem when induction of labour is indicated. The efficacy and safety of the balloon catheter in preinduction cervical ripening is evaluated in the study. The balloon catheter was used in 68 patients at term with a mean pre-catheter Bishop Score of 2.8 ± 1.3

There was a significant change in Bishop Score with a mean post - catheter Bishop Score of 7.1 ± 2.2

The overall success rate using the balloon catheter was 84 percent. This instrument was found to be easy to use, efficacious, and safe with few minor complications.

ACKNOWLEDGEMENTS

I am grateful to Mr. Davy Chikamata for introducing this procedure to me; Mr. N. Sikazwe and Professor Mtimavalye for their continued advice and encouragement. Dr. George Tembo for his immense help in statistical analysis of the data.

I would also like to thank Fredah Chikuse, Dorothy Mwale, Emma Mutale for their untiring effort in typing this manuscript. Many thanks go to the patients themselves who consented to their inclusion in this study for without their consent, this whole project would not have been practically possible.

Finally, I want to thank my Supervisor Mr. David Clegg, for converting a difficult, continuously debated and controversial research topic into a readable, hopefully viable manuscript. I thank him so much.

Dedicated to my late mother

Rose Ohuonu

C O N T E N T S

| | <u>PAGE</u> |
|---|-------------|
| LIST OF TABLES | 1 |
| KEY-WORDS, DEFINITION OF TERMS AND ABBREVIATIONS | 2 |
| INTRODUCTION | 3 |
| AIM OF STUDY | 8 |
| MATERIALS AND METHODS | 11 |
| RESULTS | 15 |
| DISCUSSION | 25 |
| CONCLUSION | 33 |
| RECOMMENDATION | 34 |
| BIBLIOGRAPHY | 35 |
| APPENDIX | 37 |

LIST OF TABLES

| <u>TABLE</u> | | <u>PAGE</u> |
|--------------|---|-------------|
| I | REVIEW OF LITERATURE | 6 |
| II | MODIFICATION OF BISHOPS PELVIC SCORING SYSTEM BY CALDER ET AL 1974 ... | 13 |
| III | INDICATIONS FOR INDUCTION OF LABOUR ... | 14 |
| IV | POPULATION PROFILE | 16 |
| V | CHANGE IN BISHOP SCORE | 17 |
| VI | INDUCTION SUCCESS RATE | 17 |
| VII | CHANGE IN BISHOP SCORE - NULLIPAROUS COMPARED WITH MULTIPAROUS | 19 |
| VIII | DELIVERY OUTCOME | 22 |
| IX | REASONS FOR FAILED INDUCTION | 22 |
| X | DELIVERY RATES | 24 |
| XI | PERINATAL OUTCOME | 24 |

KEY-WORDS, DEFINITION OF TERMS AND ABBREVIATIONS

| | | |
|------------------|---|--|
| Balloon Catheter | - | Foleys two-way rubber balloon catheter |
| Pre-catheter | - | Before insertion of catheter |
| Post-catheter | - | After removing catheter |
| Cervix | - | Refers to uterine cervix |
| Ripe Cervix | - | Soft, short, thin, dilating and yielding cervix with Bishop Score of six and above |
| Unripe Cervix | - | Firm, long, tubular, closed and unyielding cervix with Bishop Score less than or equal to five |
| Compliance | - | Stretchability; the "give" of the cervix |
| S V D | - | Spontaneous vertex vaginal delivery |
| I U D | - | Intra Uterine fetal demise |
| I D I | - | Induction - Delivery - Interval (in hours) |
| S D | - | Standard deviation from the mean |
| P | - | Probability |
| UTH | - | The University Teaching Hospital |
| C S | - | Caesarian Section |
| Primi | - | Primigravida (Para 0) |
| Multip | - | Multigravida (para 1 and above) |

INTRODUCTION

Methods of Cervical Ripening

Often in Obstetric practice, there arises the need to induce labour. Whatever the indication, there is often a common pre-requisite: - A RIPE CERVIX. The problem of failed induction is primarily that of an unfavourable cervix (Calder 1977). A low cervical score is associated with a longer induction delivery interval and increases the need for Caesarean Section.

Varying methods have been employed in an attempt to ripen the cervix hence improving its inducibility. Such methods include the use of Prostaglandins in all its forms; (Shepard et al 1981, Wilson et al 1978, Karim and Sharma 1971;) Oxytocin infusions (Faris and Kahlenberg 1954, Wilson 1978); Estradiol preparations, (Gordon and Calder 1977); Laminaria tents (Toham et al 1979, Lackritz et al 1979, Manabe and Nakajima 1972). Little attention has been paid to the balloon catheter - a cheap, simple, relatively innocuous instrument.

The prostaglandins, oxytocin infusions, laminaria tents all have side effects.

Prostaglandins can cause profuse diarrhoea, vomiting and occasional hypertension during parenteral use; (rare these days). Cases of uterine rupture have been reported following their use. (Raymond et al 1979, Gierason 1981, Scott 1982, Budden 1982). However except for some vaginal irritation in some patients, prostaglandins (PGE₂) vaginal pessaries have been recently reported to be safe and remarkably free from side effects. Never-the-less prostaglandins are expensive and not easily available.

The efficacy of oxytocin in cervical ripening is doubtful. (Faris and Kahlenberg 1954, Wilson et al 1978); oxytocin infusion in the presence of intact membranes poses a rare but grave danger of amniotic fluid embolism; cardiovascular overload etc., its use in ripening the cervix is usually futile and imposes excessive demand on staff and patient alike. It is also time consuming. The unusually large doses of oxytocin required for preinduction cervical ripening may precipitate hyperbilirubinaemia in the new born. (Beazley and Alderman 1975; Friedman et al 1978, Buchan 1979.

As far back as 1900, Hermann Johannes Pfannensteil had performed caesarean hysterectomy following severe post partum haemorrhage in one patient in whom Laminaria mertreunyer had been employed to ripen the cervix prior to induction of labour. Aggress and Benedetti in 1981 reported a case of Intra Uterine fetal demise during the use of laminaria tent. Significant increase in maternal and neonatal morbidity has been observed by Kazzi et al 1982, using laminaria tent at term with unsatisfactory results regarding labour. Laminaria tents are expensive, not easily reusable; resterilization requires ethylene dioxide gas - a sophisticated and expensive process. They can get trapped in the cervix, attract infection into the uterine cavity and may fail to dilate the cervix. (Stubblefield and Borton 1978). We are then left with only two practical options viz the prostaglandins in all their forms and the balloon catheter.

TABLE I: REVIEW OF LITERATURE

EXPERIENCE WITH THE BALLOON CATHETER IN
CERVICAL RIPENING PRIOR TO INDUCTION OF
LABOUR.

| Author | n | Balloon Size Used (cc) | Success Rate Reported | Complication Reported |
|----------------------------|-----|---------------------------------|-----------------------------|--|
| Flowright et al, 1968 (10) | 19 | 50cc | ? | None |
| Malmnas et al, 1969 (7) | 131 | 40-100cc | 86% | None |
| Slavtchev et al, 1973 (10) | 53 | 50cc | ? | None |
| Bear et al 1973 (10) | 73 | 40-45cc | 75% | -Bleeding in 3 patients - Fever in patients |
| Leiberman et al 1977 (6) | 87 | 40cc | ? | ? |
| Embrey et al 1967/1978 (3) | 100 | 50cc | 84% | None |
| *Hewlett, 1980 (10) | 301 | 60cc | 92% | None |
| Semchyshyn, 1983 (10) | 51 | 40cc | 100% | None |

? - Not indicated in Literature

() - Numbers in bracket represent references - see bibliography

* - Unpublished Data

n - Number of Patients studied

LOCAL AND NATIONAL RELEVANCE OF THE BALLOON CATHETER

Obstetric practice in the third world is beset with numerous problems mainly non-availability of essential medical facilities and drugs; There is need for cheap and effective alternative technology where possible. The balloon catheter might be a cheap available and effective alternative to prostaglandins; hence there is the need to re-evaluate its role as an adjunct to induction of labour at least in our Zambian setting.

OTHER STUDIES

The balloon catheter has long been in use in Obstetric practice; not just as a channel for introducing extra - amniotic prostaglandins, but as an entity by itself in ripening the uterine cervix. As far back as 1967, Embrey and Mollison had successfully shown that the balloon catheter was able to achieve cervical ripening in 84 percent of their cases; Semchyshyn (1983) claimed a success rate of 100 percent. Other experience with the balloon catheter includes Malmnas (1969); Bear (1973), Leiberman et al (1977), Dawson (1972), Saunders J.R. (1972) to mention but few.

Ever since Semchyshyn published his paper in 1983 very little has been heard about the balloon catheter, hence the aim of this study. No such study could be found in the Zambian Literature.

AIM OF THIS STUDY

- (i) The hypothesis to be tested in this study is that the simple rubber balloon catheter is capable of improving cervical compliance prior to induction of labour, in term patients.
- (ii) To evaluate its efficacy and safety in cervical ripening as a probable possible future alternative to prostaglandins in Zambia.
- (iii) To attest the validity of other studies using our own Zambian patients.
- (iv) To be able to formulate a departmental or indeed a National Policy regarding induction of labour using balloon catheter for pre-induction cervical priming.

STUDY DESIGN AND METHODOLOGY

A prospective, descriptive study was carried out in the Obstetrics department of the University Teaching Hospital, Lusaka, to evaluate the efficacy and safety of the balloon catheter in ripening the cervix prior to induction of labour. Sixty-eight patients were recruited for this study during the period of November 1987 through June 1988.

SAMPLING AND SELECTION OF PATIENTS

This was a hospital based study and patient selection was on the basis of compliance and conformance sampling whereby only consenting patients conforming to the inclusion criteria were selected.

INCLUSION CRITERIA

Cases included in the study were as follows:-

- i. Term pregnancies, 37 weeks and above
- ii. A definite indication for induction of labour
(see table III)
- iii. Singleton pregnancy with cephalic presentation
- iv. Patients with no sign of labour or impending labour

- v. Patients with unripe cervix (Bishop Score ≤ 5).
- vi. Informed consent must be obtained.

EXCLUSION CRITERIA

- i. All patients below 37 weeks of gestation even with good indications for induction of labour.
- ii. Multiple pregnancies.
- iii. Breech presentation.
- iv. Patients with ruptured membranes.
- v. Patients in established labour or with signs of impending labour.
- vi. Patients with already ripe cervix with Bishop Score greater than or equal to six.
- vii. Cases of suspected placenta praevia.
- viii. Previous Caesarean Sections.
- ix. Patients with no informed consent.

MATERIALS AND METHODS

During the period of study, 68 patients were managed. The indications for induction of labour are presented in Table III. In the evening prior to the induction day, after obtaining an informed consent, the patient was put in a lithotomy position, the fetal presentation was noted and after swabbing the vulva and vagina with antiseptic solution, a vaginal examination was made to assess the cervix according to the modified Bishop Score (Table II) without sweeping the membranes and the findings were noted down in the questionnaire. With a Cusco's speculum, the cervix was then exposed and the anterior lip was grasped by a sponge holding forceps under sterile conditions. A second pair of sponge holding forceps was used to insert a 24 - 26ch gauge Foleys 2 - way catheter gently into the lower uterine segment, the catheter balloon having been tested prior to insertion. While maintaining the catheter in the lower segment, the catheter was ballooned gently with 60cc of saline or water for injection. The catheter was then pulled down slightly with little tension to ensure that the balloon was well anchored in the region of the internal os. The tail end of the catheter was then fixed to the patient's inner thigh with an ordinary strapping. The patient was then returned to her bed for observation.

RIPENING OF THE CERVIX USING THE BALLOON CATHETER

PRIOR TO INDUCTION OF LABOUR

236145

BY

CHIMA OHUONU

A DISSERTATION SUBMITTED TO THE UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE IN PARTIAL FULFILMENT OF THE
REQUIREMENTS OF THE DEGREE OF MASTER OF MEDICINE IN
OBSTETRICS AND GYNAECOLOGY.

THE UNIVERSITY OF ZAMBIA

LUSAKA

1989

DECLARATION

I hereby certify that this dissertation represent entirely the result of my own individual effort. The various sources to which I am indebted have been acknowledged in the bibliography. I also hereby state that this study herein presented, has not previously been submitted either wholly or in part for a Degree at this or any other University nor is it currently being submitted for the same purpose.

Signed.....

CHIMA ODUONU.

APPROVAL

This Dissertation of Dr. Chima Oluonu is approved
as fulfilling part of the requirements for the
award of the Master of Medicine Degree in Obstetrics
and Gynaecology by the University of Zambia.

Signed.....*Antonia Bagshawe*.....Date.....*4/7/90*.....*Asst. Prof.*

Signed.....*David R. Clegg*.....Date.....*11/5/90*.....

Signed.....Date.....

Signed.....Date.....

ABSTRACT

The unripe cervix sometimes presents a real problem when induction of labour is indicated. The efficacy and safety of the balloon catheter in preinduction cervical ripening is evaluated in the study. The balloon catheter was used in 68 patients at term with a mean pre-catheter Bishop Score of 2.8 ± 1.3 . There was a significant change in Bishop Score with a mean post - catheter Bishop Score of 7.1 ± 2.2 . The overall success rate using the balloon catheter was 84 percent. This instrument was found to be easy to use, efficacious, and safe with few minor complications.

ACKNOWLEDGEMENTS

I am grateful to Mr. Davy Chikamata for introducing this procedure to me; Mr. N. Sikazwe and Professor Mtimavalye for their continued advice and encouragement. Dr. George Tembo for his immense help in statistical analysis of the data.

I would also like to thank Fredah Chikuse, Dorothy Mwale, Emma Mutale for their untiring effort in typing this manuscript. Many thanks go to the patients themselves who consented to their inclusion in this study for without their consent, this whole project would not have been practically possible.

Finally, I want to thank my Supervisor Mr. David Clegg, for converting a difficult, continuously debated and controversial research topic into a readable, hopefully viable manuscript. I thank him so much.

Dedicated to my late mother

Rose Ohuonu

C O N T E N T S

| | <u>PAGE</u> |
|---|-------------|
| LIST OF TABLES | 1 |
| KEY-WORDS, DEFINITION OF TERMS AND ABBREVIATIONS | 2 |
| INTRODUCTION | 3 |
| AIM OF STUDY | 8 |
| MATERIALS AND METHODS | 11 |
| RESULTS | 15 |
| DISCUSSION | 25 |
| CONCLUSION | 33 |
| RECOMMENDATION | 34 |
| BIBLIOGRAPHY | 35 |
| APPENDIX | 37 |

LIST OF TABLES

| <u>TABLE</u> | | <u>PAGE</u> |
|--------------|---|-------------|
| I | REVIEW OF LITERATURE | 6 |
| II | MODIFICATION OF BISHOPS PELVIC SCORING SYSTEM BY CALDER ET AL 1974 ... | 13 |
| III | INDICATIONS FOR INDUCTION OF LABOUR ... | 14 |
| IV | POPULATION PROFILE | 16 |
| V | CHANGE IN BISHOP SCORE | 17 |
| VI | INDUCTION SUCCESS RATE | 17 |
| VII | CHANGE IN BISHOP SCORE - NULLIPAROUS COMPARED WITH MULTIPAROUS | 19 |
| VIII | DELIVERY OUTCOME | 22 |
| IX | REASONS FOR FAILED INDUCTION | 22 |
| X | DELIVERY RATES | 24 |
| XI | PERINATAL OUTCOME | 24 |

KEY-WORDS, DEFINITION OF TERMS AND ABBREVIATIONS

| | | |
|------------------|---|--|
| Balloon Catheter | - | Foleys two-way rubber balloon catheter |
| Pre-catheter | - | Before insertion of catheter |
| Post-catheter | - | After removing catheter |
| Cervix | - | Refers to uterine cervix |
| Ripe Cervix | - | Soft, short, thin, dilating and yielding cervix with Bishop Score of six and above |
| Unripe Cervix | - | Firm, long, tubular, closed and unyielding cervix with Bishop Score less than or equal to five |
| Compliance | - | Stretchability; the "give" of the cervix |
| S V D | - | Spontaneous vertex vaginal delivery |
| I U D | - | Intra Uterine fetal demise |
| I D I | - | Induction - Delivery - Interval (in hours) |
| S D | - | Standard deviation from the mean |
| P | - | Probability |
| UTH | - | The University Teaching Hospital |
| C S | - | Caesarian Section |
| Primi | - | Primigravida (Para 0) |
| Multip | - | Multigravida (para 1 and above) |

INTRODUCTION

Methods of Cervical Ripening

Often in Obstetric practice, there arises the need to induce labour. Whatever the indication, there is often a common pre-requisite: - A RIPE CERVIX. The problem of failed induction is primarily that of an unfavourable cervix (Calder 1977). A low cervical score is associated with a longer induction delivery interval and increases the need for Caesarean Section.

Varying methods have been employed in an attempt to ripen the cervix hence improving its inducibility. Such methods include the use of Prostaglandins in all its forms; (Shepard et al 1981, Wilson et al 1978, Karim and Sharma 1971); Oxytocin infusions (Faris and Kahlenberg 1954, Wilson 1978); Estradiol preparations, (Gordon and Calder 1977); Laminaria tents (Toham et al 1979, Lackritz et al 1979, Manabe and Nakajima 1972). Little attention has been paid to the balloon catheter - a cheap, simple, relatively innocuous instrument.

The prostaglandins, oxytocin infusions, laminaria tents all have side effects.

Prostaglandins can cause profuse diarrhoea, vomiting and occasional hypertension during parenteral use, (rare these days). Cases of uterine rupture have been reported following their use. (Raymond et al 1979, Giersson 1981, Scott 1982, Budden 1982). However except for some vaginal irritation in some patients, prostaglandins (PGE₂) vaginal pessaries have been recently reported to be safe and remarkably free from side effects. Never-the-less prostaglandins are expensive and not easily available.

The efficacy of oxytocin in cervical ripening is doubtful. (Faris and Kahlenberg 1954, Wilson et al 1978); oxytocin infusion in the presence of intact membranes poses a rare but grave danger of amniotic fluid embolism; cardiovascular overload etc., its use in ripening the cervix is usually futile and imposes excessive demand on staff and patient alike. It is also time consuming. The unusually large doses of oxytocin required for preinduction cervical ripening may precipitate hyperbilirubinaemia in the new born. (Beazley and Alderman 1975; Friedman et al 1978, Buchan 1979.

As far back as 1900, Hermann Johannes Pfannensteil had performed caesarean hysterectomy following severe post partum haemorrhage in one patient in whom Laminaria mertreunyer had been employed to ripen the cervix prior to induction of labour. Aggress and Benedetti in 1981 reported a case of Intra Uterine fetal demise during the use of laminaria tent. Significant increase in maternal and neonatal morbidity has been observed by Kazzi et al 1982, using laminaria tent at term with unsatisfactory results regarding labour. Laminaria tents are expensive, not easily reusable; resterilization requires ethylene dioxide gas - a sophisticated and expensive process. They can get trapped in the cervix, attract infection into the uterine cavity and may fail to dilate the cervix. (Stubblefield and Borton 1978). We are then left with only two practical options viz the prostaglandins in all their forms and the balloon catheter.

TABLE I: REVIEW OF LITERATURE

EXPERIENCE WITH THE BALLOON CATHETER IN
CERVICAL RIPENING PRIOR TO INDUCTION OF
LABOUR.

| Author | n | Balloon Size Used (cc) | Success Rate Reported | Complication Reported |
|----------------------------|-----|---------------------------------|-----------------------------|---|
| Plowright et al, 1968 (10) | 19 | 50cc | ? | None |
| Malmnas et al, 1969 (7) | 131 | 40-100cc | 86% | None |
| Slavtchev et al, 1973 (10) | 53 | 50cc | ? | None |
| Bear et al 1973 (10) | 73 | 40-45cc | 75% | -Bleeding 3 patients - Fever in patients |
| Leiberman et al 1977 (6) | 87 | 40cc | ? | ? |
| Embrey et al 1967/1978 (3) | 100 | 50cc | 84% | None |
| *Hewlett, 1980 (10) | 301 | 60cc | 92% | None |
| Semchyshyn, 1983 (10) | 51 | 40cc | 100% | None |

? - Not indicated in Literature

() - Numbers in bracket represent references - see bibliography

* - Unpublished Data

n - Number of Patients studied

LOCAL AND NATIONAL RELEVANCE OF THE BALLOON CATHETER

Obstetric practice in the third world is beset with numerous problems mainly non-availability of essential medical facilities and drugs; There is need for cheap and effective alternative technology where possible. The balloon catheter might be a cheap available and effective alternative to prostaglandins; hence there is the need to re-evaluate its role as an adjunct to induction of labour at least in our Zambian setting.

OTHER STUDIES

The balloon catheter has long been in use in Obstetric practice; not just as a channel for introducing extra - amniotic prostaglandins, but as an entity by itself in ripening the uterine cervix. As far back as 1967, Embrey and Mollison had successfully shown that the balloon catheter was able to achieve cervical ripening in 84 percent of their cases; Semchyshyn (1983) claimed a success rate of 100 percent. Other experience with the balloon catheter includes Malmnas (1969); Bear (1973), Leiberman et al (1977), Dawson (1972), Saunders J.R. (1972) to mention but few.

Ever since Semchyshyn published his paper in 1983 very little has been heard about the balloon catheter, hence the aim of this study. No such study could be found in the Zambian Literature.

AIM OF THIS STUDY

- (i) The hypothesis to be tested in this study is that the simple rubber balloon catheter is capable of improving cervical compliance prior to induction of labour, in term patients.
- (ii) To evaluate its efficacy and safety in cervical ripening as a probable possible future alternative to prostaglandins in Zambia.
- (iii) To attest the validity of other studies using our own Zambian patients.
- (iv) To be able to formulate a departmental or indeed a National Policy regarding induction of labour using balloon catheter for pre-induction cervical priming.

STUDY DESIGN AND METHODOLOGY

A prospective, descriptive study was carried out in the Obstetrics department of the University Teaching Hospital, Lusaka, to evaluate the efficacy and safety of the balloon catheter in ripening the cervix prior to induction of labour. Sixty-eight patients were recruited for this study during the period of November 1987 through June 1988.

SAMPLING AND SELECTION OF PATIENTS

This was a hospital based study and patient selection was on the basis of compliance and conformance sampling whereby only consenting patients conforming to the inclusion criteria were selected.

INCLUSION CRITERIA

Cases included in the study were as follows:-

- i. Term pregnancies, 37 weeks and above
- ii. A definite indication for induction of labour
(see table III)
- iii. Singleton pregnancy with cephalic presentation
- iv. Patients with no sign of labour or impending labour

- v. Patients with unripe cervix (Bishop Score \leq 5).
- vi. Informed consent must be obtained.

EXCLUSION CRITERIA

- i. All patients below 37 weeks of gestation even with good indications for induction of labour.
- ii. Multiple pregnancies.
- iii. Breech presentation.
- iv. Patients with ruptured membranes.
- v. Patients in established labour or with signs of impending labour.
- vi. Patients with already ripe cervix with Bishop Score greater than or equal to six.
- vii. Cases of suspected placenta praevia.
- viii. Previous Caesarean Sections.
- ix. Patients with no informed consent.

MATERIALS AND METHODS

During the period of study, 68 patients were managed. The indications for induction of labour are presented in Table III. In the evening prior to the induction day, after obtaining an informed consent, the patient was put in a lithotomy position, the fetal presentation was noted and after swabbing the vulva and vagina with antiseptic solution, a vaginal examination was made to assess the cervix according to the modified Bishop Score (Table II) without sweeping the membranes and the findings were noted down in the questionnaire. With a Cuscos speculum, the cervix was then exposed and the anterior lip was grasped by a sponge holding forceps under sterile conditions. A second pair of sponge holding forceps was used to insert a 24 - 26ch guage Foleys 2 - way catheter gently into the lower uterine segment, the catheter balloon having been tested prior to insertion. While maintaining the catheter in the lower segment, the catheter was ballooned gently with 60cc of saline or water for injection. The catheter was then pulled down slightly with little tension to ensure that the balloon was well anchored in the region of the internal os. The tail end of the catheter was then fixed to the patients inner thigh with an ordinary strapping. The patient was then returned to her bed for observation.

No premedication was given prior to the procedure. The next morning the catheter balloon was deflated and removed if it had not already been expelled spontaneously into the vagina. The cervix was then reassessed by the same observer and any change in Bishop Score noted in the questionnaire. (see appendix). The membranes were then ruptured in the ripe cases, and the appropriate dosage of oxytocin infusion was commenced where necessary. In the unsuccessful cases, the catheter was deflated, removed, to try again the next day.

TABLE II: MODIFICATION OF BISHOPS PELVIC SCORING
SYSTEM BY CALDER ET AL 1974

| | 0 | 1 | 2 | 3 |
|-----------------|-------------|--------------|----------|-------------|
| Dilatation (cm) | Less than 1 | 1-2 | 2-4 | More than 4 |
| Length (cm) | More than 4 | 2-4 | 1-2 | Less than 1 |
| Consistency | Firm | Average | Soft | - |
| Position | Posterior | Mid-Anterior | - | - |
| Level | -3 | -2 | -1 and 0 | +1 |

Range 0 - 12

Ripe Cervix \geq 6

Unripe Cervix \leq 5

TABLE III: INDICATIONS FOR INDUCTION OF LABOUR

| Indication for induction | No. of patients |
|--|-----------------|
| Pre-eclampsia | 40 |
| Post-maturity | 22 |
| Intrauterine fetal demise | 3 |
| Elderly Primigravida | 1 |
| Grandmultiparity with unstable lie | 1 |
| Gestational Diabetes with bad Obstetric History | 1 |
| | n = 68 |

RESULTS

DATA ANALYSIS

Statistical analysis of data was done by the computer using the Fisher T - test to calculate statistical significance of the difference between mean values.

The result of the 68 patients studied are presented. Table IV shows patients characteristics. Indications for induction of labour are shown in Table III.

POPULATION PROFILE

AGE: (See Table IV)

PARITY: Both primigravidae and multiparous women were studied. Total number of primigravidae was 23 and 45 multiparae. (See Table IV)

GESTATION: Gestation periods were calculated from last menstrual periods (See Table IV).

CHANGE IN BISHOP SCORE

The overall mean change in Bishop Score after introducing the catheter was 5.0 ± 1.8 . This was statistically significant. $P < 0.01$ at the 95 percent confidence interval (See Table V).

TABLE IV: POPULATION PROFILE

| Patient Characteristics | Mean \pm SD | Range |
|------------------------------|----------------|---------|
| Maternal age (years) | 25.8 \pm 5.6 | 16 - 37 |
| Parity | 2.1 \pm 2.1 | 0 - 9 |
| Gestational age (weeks) | 40.1 \pm 2.2 | 37 - 45 |

TABLE V: CHANGE IN BISHOP SCORE

| | n = 68 Mean \pm SD | Range |
|-----------------------------------|-------------------------|--------|
| Pre - Catheter Bishop Score | 2.8 \pm 1.3 | 0 - 5 |
| Post - Catheter Bishop Score | 7.1 \pm 2.2 | 2 - 12 |
| *Change in Bishop Score | 5.0 \pm 1.8 | 1 - 10 |

* $P < 0.01$ (Significant)

TABLE VI: INDUCTION SUCCESS RATE

| | No. of cases n = 68 |
|---|---------------------|
| Vaginal delivery following balloon catheter only | 12 (17.6%) |
| Vaginal delivery following balloon catheter plus oxytocin infusion .. | 45 (66.2%) |
| Total number of vaginal deliveries | 57 |
| Induction success rate | 57/68 (83.8%) |

Mean Bishop Score post catheter was 7.3 in primis and 7.0 in multips with a mean change of 4.9 ± 1.9 and 5.0 ± 1.7 respectively.

(see table VII)

DURATION OF CATHETER STAY

The mean length of stay of catheter in the lower segment was 14.3 hours with a standard deviation of 4.4 hours. The range was 4 hours - 23.2 hours.

The multips tended to have shorter duration of catheter stay than the primis. In the shortest case the catheter stayed only for four hours before it was expelled and the patient went into spontaneous labour following expulsion of the catheter. The length of stay was recorded from time of inflating the balloon to the time of review next day when the catheter was removed or when spontaneous expulsion occurred.

TABLE VII: CHANGE IN BISHOP SCORE - NULLIPAROUS COMPARED
WITH MULTIPAROUS

| | Bishop Score before Catheter mean \pm SD | Bishop Score after Catheter mean \pm SD | Change in Bishop Score mean \pm SD |
|-------------------------|--|---|--|
| Nulliparous (n = 23) | 2.4 \pm 1.3 *(0-5) | 7.3 \pm 2.3 (3-12) | 4.9 \pm 1.9 (1-10) |
| Multiparous (n = 45) | 3.1 \pm 1.3 (0-5) | 7.0 \pm 2.1 (2-12) | 5.0 \pm 1.7 (1-9) |
| Total (n = 68) | | | |

Computed-T-Statistic = 0.6616 P > 0.05 Not Significant

* Figures in parentheses represent range of values.

SPONTANEOUS ONSET OF LABOUR

Twenty eight out of 68 patients i.e. 41.2 per cent of the patients went into spontaneous labour after varying hours from ~~the~~ time of insertion of the catheter.

(See Table ~~VIII~~). Those who went into spontaneous labour had mean duration of labour of 4.3 hours.

INDUCTION DELIVERY INTERVAL (See Table VIII)

The spontaneous labour and caesarean section cases were excluded from the calculation of the IDI. Mean IDI was 8.7 ± 4.1 hours; calculated from the time of artificial rupture of membranes to the time of delivery.

APGAR SCORE AND BABY WEIGHT (See Table XI)

The one minute apgar score and the baby weight was assessed and recorded by the attending midwife. The IUDs were excluded from Apgar Score assessment.

SUCCESS AND FAILURE

Success was measured in terms of improvement in Bishop Score following the catheter as well as successful induction leading to a vaginal delivery. A success rate of 84 per cent was achieved in this study.

SPONTANEOUS CATHETER EXPULSION RATE

The catheter was expelled from the cervix into the vagina in 94 per cent (64/68) of the cases in which the cervix was found to be ripe.

FAILED INDUCTION RATE (See Table IX)

Of the ten cases with failed induction only two cases had failed catheter as a contributing factor; the rest of the cases had significant improvements in Bishop Score following use of the catheter, but failed to progress for one reason or the other and hence sectioned. The indications for Caesarean Section are listed on table IX. One case was being induced for Postdatism only to discover later in labour that it was breech presentation and hence sectioned. Of the two cases of fetal distress one had cord round the neck three times. There were three cases in which the catheter was repeated twice at 24 hours interval. At the second attempt the cervix was found to be ripe in all but one case which was sectioned electively. (See Table VIII)

TABLE VIII: DELIVERY OUTCOME

| | No. of Cases |
|---|--------------|
| Spontaneous Labour and Delivery..... | 19 (27.9%) |
| Spontaneous Labour and Delivery Requiring Augmentation..... | 6 (8.8%) |
| Spontaneous Labour Requiring C S | 3 (4.4%) |
| Elective C S | 1 (1.5%) |
| Induction Resulting in S V D..... | 32 (47.1%) |
| Induction Resulting in C S | 7 (10.3%) |
| TOTAL (n) | 68 (100%) |

Mean IDI = 8.7 ± 4.1 hour: Range = 2 - 19 hours

TABLE IX: REASONS FOR FAILED INDUCTION

| | No. of Cases |
|---------------------|--------------|
| No. Progress..... | 7 |
| Fetal Distress..... | 2 |
| Others..... | 1 |
| TOTAL | 10 |

Failed Induction Rate..... 10/68 (14.7%)

INSTRUMENTAL DELIVERY (See Table X)

Seventy-five percent of patients delivered vaginally. Of these, five patients had vacuum extraction and two were delivered by forceps. The indications for the vacuums were eclampsia, fetal distress, and prolonged labour. The two forceps were done to assist second stage in two pre-eclamptic patients.

COMPLICATIONS OF THE BALLOON CATHETER

Overall complication rate was seven percent. Five patients out of 68 had varying degrees of minor complications. Two patients had small bleeds from the uterine cavity following insertion of the catheter. These bleeds were not alarming and stopped few minutes later. In one patient the membranes were ruptured accidentally during the procedure. However, the catheter was still left in situ and she was successfully induced the day after. The mother and baby were discharged in good condition. One patient developed a fever of 38.8° C post partum which responded to antibiotics but not to Chloroquine. Baby was in good condition. In one case, the balloon ruptured accidentally inside the lower segment. Another catheter was re-inserted. It is therefore of great importance to test the balloon first before introducing it into the uterine cavity to avoid such accidents, and also to ensure that sterile water is used always just incase one runs into such mishap as ruptured balloon.

TABLE X: DELIVERY RATES

| | No. of Cases | Rate |
|------------------------------------|-----------------|-------|
| Spontaneous Vaginal Delivery | 51 | 75% |
| Assisted Vaginal Delivery | 7 | 10.3% |
| Caesarian Section | 10 | 14.7% |
| Total (n) | 68 | 100% |

TABLE XI: PERINATAL OUTCOME

| | mean \pm SD | Range |
|----------------------------------|-----------------|-------------|
| Perinatal Deaths | Nil | |
| Apgar Score of Live Births | 8.4 \pm 1.3 | 2 - 9 |
| Birth Weight (kg) | 3.03 \pm 0.56 | 1.40 - 4.12 |

DISCUSSION

Previous studies have shown that the balloon catheter may be useful in improving cervical compliance prior to induction of labour.

The aim of this study was to ripen the cervix prior to induction of labour and not to induce labour.

The population size of 68 agrees with other studies (See Table I). The smallest population size was $n = 19$ (Plowright - 1968) and the largest series was that of Hewlet 1980 $n = 301$).

It has been postulated that the balloon catheter acts by separating the membranes from its flimsy attachment to the lower uterine segment thereby releasing endogenous prostaglandins which are in abundance in the membranes and decidua and which stimulate cervical ripening. Other researchers postulate that the catheter balloon acts as a presenting part and by its continuous pressure effect, stimulates uterine contractility which in turn causes effacement of the cervix and dilatation (Embrey and Mollison 1967). Other opinion suggest that by its mechanical pressure effect, the balloon stretches and weakens the cervical connective tissue in the region of the internal os hence increasing elasticity and compliance of the cervix causing it to dilate. To determine the true mechanism of action more sophisticated and biophysical studies are needed.

The size 24ch guage Foleys catheter used in this study has a diameter of 8.0mm which can be easily inserted through the cervix at term. The cervix has a potentially open canal even in cases where the os is clinically closed. None of the patients in this study required any analgesia or any form of pre-medication for insertion of the catheter. With 60cc of saline in the balloon, it assumes the shape of a sphere with a circumference of 15.5cm giving it a diameter of approximately 5.0cm. The balloon could change shape and diameter as it passes through the cervical cannal. Once it is expelled, the cervix is usually dilated enough to allow artificial rupture of membranes.

The tip end of the catheter is blunt, flexible and atraumatic such that chances of accidentally rupturing the membranes are remote.

The result of this study is in agreement with other studies. The 84 per cent success rate compared reasonably favourably to the 100 percent success rate of Semchyshyn 1983 and the 84 percent success rate of Embrey and Mollison 1967. Semchyshyn used balloon size of 40cc with a smaller diameter than the one used in this study. This could explain his 100 percent expulsion rate.

Malmnas et al 1969 in their series with 131 patients, had a success rate of 86 percent. Assisted vaginal delivery rate of 10.3 percent disagrees with the 22 percent forceps rate of Embrey and Mollison 1967. They had no vacuum delivery. Caesarean Section rate of 14.7 percent compares well with the 16 percent of Embrey 1967. Semchyshyn in his 51 cases recorded a low caesar rate of eight percent. i.e. four out of 51 patients compared to ten out of 68 in this study.

Surprisingly, Semchyshyn reported only one case of spontaneous labour following the catheter in his series, which contrasts sharply with the 41.2 percent (28/68) spontaneous labour rate in this study; (See Table VIII): The 20 percent spontaneous labour rate observed by Embrey and Mollison 1967 in their 100 cases almost agrees with the findings in this study. Other workers had encouraging results with the balloon catheter and varying success rates have been reported which are quite in line with the findings of this study (See Table I).

Contrary to Semchyshyn and Embrey, the balloon catheter in this study produced a more dramatic response in the primigravidae compared to the multiparae. Drammatic in the sense that the primigravidae who started off with very low Bishop Scores sometimes with os closed, had the os dilated the next day with membranes buldging allowing the

observer to do artificial rupture of membranes which was practically impossible prior to the insertion of the catheter. The primiparae recorded a mean change in Bishop Score of 4.9 ± 1.9 as opposed to 5.0 ± 1.7 in the multiparae. This difference was however not statistically significant. $P > 0.05$ (See Table VII).

Mean induction delivery interval was 8.7 ± 4.1 hours with a range of two hours to 19 hours. The IDI in this study on the whole tended to be longer than should be expected, one of the reasons being that IUDs were included in the calculation and with their membranes intact for longer time, labour tended to be much longer than usual. If the cervix is already at least three centimeters dilated before induction, the latent phase of labour should be shortened as was the case in other studies (Semchyshyn 1983)

Except for Embrey 1967, most other workers did not report on the actual duration of stay of the catheter. In this study, the longest time was 23.2 hours with no complications observed in the patient. It is advisable not to leave the catheter in situ for a long time for fear that it may act as a vehicle of infection into the uterine cavity. Hence it is of importance in the advent of failure, to deflate the catheter balloon, remove it and try again next day. Most of the complications encountered in this study were minor. The bleeding in the two patients were not serious. However this draws attention to the possibility of provoking bleeding in case of undiagnosed low-lying placenta; hence in suspected cases an EUA or Ultrasound scan could be useful in ruling out placenta praevia.

Accidental rupture of membranes is a remote but real possibility, and careful insertion technique could obviate this accident, especially in cases of IUD where membranes are usually fragile. However this mishap occurred in only one case out of 68. (See page 23). There were no cases of allergy to the rubber material with which the catheter is made.

All the live babies faired well with mean apgar score of $8.4. \pm 1.3$ excluding the still births. There was no case of trauma to the baby by the catheter, however there is the remote possibility of cord compression with the balloon in the lower segment or displacement of the presenting part by the balloon.

Except for Bear .1973, who reported fever in nine patients and bleeding in three patients, the rest of the other workers reported no complications in their series (Semchyshyn 1983, Embrey 1967, Malmnas 1969 (See Table I).

Confounding factors such as parity did not seem to be operative in this study since there was no significant change in actual post-catheter Bishop Score between primigravidae and multiparae.

The question is, could the catheter be the only factor pushing the 41.2 percent of cases into spontaneous labour? or could it have been a chance finding that even without the catheter these group of patients would have gone into labour anyway? This does not seem likely considering the Bishop Score with which they started off before inser tion of catheter. A careful case control study is needed to establish this fact.

To eliminate bias, a randomly selected population would have been the ideal thing but this type of selection was not possible here since only consenting patients were included and had to be induced. Also having the same observer perform the pre and post catheter cervical assessments could have been a source of bias. Other workers did not find this a source of worry.

The induction success rate of 84 percent was not measured in terms of Bishop Score change alone, but also in terms of outcome of labour. A case control study comparing the cases primed with balloon catheter with controls not primed with catheter, and employing much larger number of patients would have been ideal and might have given greater statistical significance. The idea of subjecting cases with unripe cervix to induction of labour seemed rather unethical and might have led to increased caesarean section rate for failed induction. (Calder 1977, Garret 1960). It would have been a good idea to compare and contrast the balloon catheter with the prostaglandins (PGE₂) pessaries if the latter was available in comparable quantity.

Other methods of ripening the cervix such as vaginal PGE₂ pessaries have in many studies been reported to be extremely safe and remarkably free from side effects, but they are expensive especially for us in developing countries working under difficult conditions. Their supply is erratic. This calls for a search for cheaper alternatives of achieving cervical ripening when the need arises which often does. Sims (1985) in his article (11) went to the extent of saying that the balloon catheter method of cervical priming has been abandoned. This may be true but we still need to look out for appropriate alternative technology, and in this context the balloon catheter could be a safe and effective alternative to prostaglandins. This requires further study.

The grand-multiparous patients requiring induction, may benefit so much, in that the latent phase of labour is greatly shortened and the amount of oxytocin needed for induction is greatly reduced.

Except for the remote possibilities of cord compression by the balloon and accidental rupture of membranes causing cord prolapse (no cases reported), the balloon catheter poses no immediate danger to the fetus. The goodness of the balloon catheter lies in its reusability, repeatability and resterilizability. If the procedure fails the first attempt, it can be removed and tried again without any harm to the patient.

CONCLUSION

It is high time Obstetricians in the developing countries stopped relying on expensive, usually unavailable facilities for patient management and began searching for much cheaper and readily available alternatives. It is only through research of this nature that we could come up with this much needed alternative technology.

The balloon catheter in this study significantly improved Bishop Score before induction from 2.8 ± 1.3 to 7.1 ± 2.2 ($P < 0.01$). This instrument was found to be relatively safe, easy to use and free from major complications or side effects. It is cheap, readily available and reusable.

Having said all this, there is urgent need for carefully designed studies in the near future, to evaluate further the efficacy and safety of this tool in a much greater detail.

Before that time comes, the balloon catheter may prove a useful alternative to the expensive and usually non-available prostaglandins which are currently in vogue.

RECOMMENDATION

- (i) There is need for randomized, double blind, case control comparative study with PGE₂ vaginal pessaries.
- (ii) Obstetricians in developing countries should lay more emphasis on the search for cheaper alternative tools rather than rely on expensive, usually unavailable methods.

BIBLIOGRAPHY

1. Agress R.L. Benedetti T.J.: Intra - Uterine Foetal death during cervical ripening with laminaria tent - American J. Obstet Gynaecol 141: 587, 1981
2. Dawson W.G; Foley - Catheter induction of labour - Br. Med Journal 4: 492; 1972
3. Embrey M.P; Mollison BG: The unfavourable cervix and induction of labour using a cervical balloon - J. Obstet Gynaecol. British and Commonwealth 74: 44, 1967
4. Kazzi G.M. Bottoms S.F., Rosen. M.G; Efficacy and safety of Laminaria digitata for pre-induction ripening of the cervix. Obstet Gynaecol 60: 440, 1982
5. Lakritz R. Gibson M., Frigoletto F.D: Pre-induction use of Laminaria tent for the unripe cervix - American J. Obstet Gynaecol 134: 349, 1979
6. Leiberman J.R., Piura B. Chaim W. Cohen A: The Cervical Balloon method of induction of labour - Acta Obstet Gynaecol, Scandinavia 56: 499, 1977

7. Malmnas C. Induction of labour in second and third trimester of pregnancy by a cervical balloon and intrauterine oxytocin infusion - Acta Obstet Gynaecol Scandinavia 48: Suppl 3: 18, 1969.
8. Raymond Z: Sandler, et al; Uterine rupture following vaginal PGE₂ gel - American J. Obstet Gynaecol 134: 348 1979
9. Saunders J.R: Foley - Catheter Induction of Labour - Br. Med. Journal 4: 237, 1972
10. Semchyshyn S: Induction of cervical compliance by balloon catheter in late pregnancy:- International J. Obstet Gynaecol: 21: 319 - 325, 1983
11. Sims CD: Induction of labour - Methods - The Management of labour - ed by John Studd;- Blackwell scientific publications P113, 1985
12. Wilson PD. A comparison of four methods of ripening the unfavourable cervix - British J. Obstet Gynaecol 85: 941, 1978

RIPENING OF THE CERVIX WITH THE BALLOON
CATHETER PRIOR TO INDUCTION OF LABOUR A PROSPECTIVE STUDY

1. CASE NO:
2. DATE :
3. FILE NO:
4. WARD/FIRM: -
5. NAME OF PATIENT:
6. AGE IN YEARS:
7. (a) PARITY: _ (b) GRAVIDA:
8. GESTATION IN WEEKS:
9. INDICATION FOR INDUCTION:
10. CERVICAL ASSESSMENT:

| | PRE-CATHETER | POST-CATHETER |
|----------------------------|--------------|-------------------------|
| a) STATION | | |
| b) CONSISTENCY | | |
| c) POSITION | | |
| d) LENGTH | | |
| e) DILATATION | | |
| f) BISHOP SCORE | | |
| g) (i) TIME INSERTED | | (ii) TIME REMOVED |
11. DIFFERENCE IN BISHOP SCORE:
12. POSITION OF CATHETER ON REVIEW:
13. DURATION OF CATHETER STAY:
14. SPONTANEOUS ONSET OF LABOUR: YES NO
15. MODE OF INDUCTION: (a) ARM (b) ARM PLUS OXYTOCIN (c) SRM
16. OUTCOME OF LAPOUR (a) SVD (b) VACCUM (c) FORCEPS (d) CAESAR INDICA
17. INDUCTION DELIVERY INTERVAL:
18. APGAR SCORE AT BIRTH:
19. WEIGHT OF BABY:
20. COMPLICATION ATTRIBUTABLE TO CATHETER:
21. REMARKS:

UNIVERSITY OF ZAMBIA LIBRARY

D

236145

THESIS

Ohu

DR CHIMA CHUONU

PRINCIPAL INVESTIGATOR