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INTRODUCTION

Miscarriage is defined as the loss of an intrauterine pregnancy before 24 completed weeks of gestation. The WHO definition is the expulsion of a fetus or embryo weighing 500 grams or less and also a gestational age of less then 22 weeks of pregnancy. Recurrent miscarriage means three or more consecutive miscarriages. The risk of a further miscarriage after three consecutive miscarriages is 30-70%.

It can be divided into primary and secondary recurrent miscarriage depending on whether or not at least one previous successful pregnancy has occurred respectively. It may be recurrent first or second (mid trimester) miscarriage. Etiology involves various genetic, anatomic,

CERVICAL CERCLAGE; SIGNIFICANCE OF CERVICAL CERCLAGE

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ABSTRACT... Introduction: In Pakistan, cervical incompetence has been recognized as the leading cause of recurrent abortions in mid trimester. The elective cerclage based on history and clinical findings applied in second trimester overcomes the risk of emergency procedure. This problem is quite common in patients visiting IUH Faisalabad. Objectives: Assess gestational age at delivery after elective cervical cerclage application in mothers with recurrent mid trimester abortions. List the immediate and late complications of cerclage. Assess the fetal outcome after cerclage. Outcome Measures: 1. Percentage of mid trimester abortion in current pregnancy. 2. Frequency of prolongation of gestational age at delivery. 3. Complications of the procedure. 4. Birth weight of the baby. 5. Percentage of live births. 6. Fetal survival rate. Study Design: Interventional: Quasi experimental study. Setting: Department of Obstetrics and Gynaecology, Teaching Hospital IUH FSD, Period: Oct 2016 to July 2018, Subjects: Fifty patients with recurrent mid trimester miscarriage due to cervical incompetence. Methods: Patients were admitted through outdoor with history of previous mid trimester abortions possibly due to cervical incompetence. USG evidence of normal pregnancy with no obvious congenital anomaly was a pre requisite for cervical cercalge. Technique used was MCDonald's suture under general anaesthesia. Results: Effectiveness of cerclage was 90%; 78% had term deliveries, 12% preterm delivery and 5 spontaneous mid trimester abortions. There were 81% live births. The complications included cervical trauma after delivery (2%), spontaneous abortions (10%), pre term delivery (13%) and pre prom (2%). Conclusion: Elective cerclage at 12-14 wks of gestation in recurrent mid trimester abortions results in good fetomaternal outcome with almost no complications.

Key words: Cervical Incompetence, Elective Cervical Cerclage, McDonald's Stitch.

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infective, endocrine and immunology factors.^{8,9,10} Anatomic factors like uterine anomalies and cervical incompetence are involved mainly in recurrent mid- trimester miscarriage although some infections like syphilis and parvo virus B 19 are also a cause of late mid-trimester abortion.¹¹ The incidence of congenital uterine anomalies in women with recurrent (usually mid-trimester) miscarriage is 1-27% and include uterus didelphis, subseptate uterus and sub-mucosal fibroids.^{12,13}

Cervical incompetence whether congenital or acquired is a treatable cause of recurrent mid-trimester abortions.¹⁴ It incidence is 1-2% of pregnancies.¹⁵ It is defined as the inability to support an intra-uterine pregnancy because of

a structural or functional defect of the cervix.¹⁶ It may be inherent (due to diethylstilboestrol exposure in utero) or acquired due to obstetrical and surgical trauma such as cone biopsy, cauterization, amputation, or excessive cervical dilatation.¹⁷ Classically the patient presents with membrane rupture and relatively painless rapid labour in mid-trimester (usually after 16 weeks)¹⁸ Cervical cerclage has become the mainstay for the management of cervical incompetence. The diagnosis of cervical incompetence poses a difficult problem.¹⁹

Traditionally the diagnosis of cervical insufficiency was based on the patient's history i.e. previous history of mid-trimester miscarriage in the absence of painful uterine contractions.^{20,22} Recently ultrasound or transvaginal ultrasound has been introduced.²⁰ When a cervical length of less than 25 mm is measured before 27 weeks therapeutic cerclage reduces pre-term delivery before 34 weeks.²¹ Vaginal ultrasound helps to detect early features of cervical incompetence (shortening or funneling) but neither USG nor HSG has been useful in diagnosis of cervical incompetence before pregnancy.²³

A short cervix (< 25mm) is associated with an 8% probability of spontaneous pre-term delivery < 35 weeks gestation in low risk parous women and 31% in high risk women. Cervical index Funnel Length +1

is calculated is $^{\rm Endocervical\,Length}$. If cervical index is ≥ 0.52 it is significantly associated with preterm birth increasing the relative risk of early birth by 6.4^{31} Cerclage can be applied electively (prophylactically) at 12-14 weeks gestation with removal at 37-38 weeks.

It can be selective (therapeutic) when cervical length measurement serially with transvaginal ultrasound in patients at high risk of cervical incompetence is less than 25mm before 27 weeks.²¹ It can be emergency cerclage, which is only applied when significant cervical effacement or shortening of the cervix is seen on serial weekly or biweekly transvaginal ultrasonography.²⁰ However two randomized controlled trials failed to show any significant improvement in perinatal

survival from ultrasound indicated cervical cerclage.²⁴ The MRC/RCOG Trial of elective cerclage reported a decrease in pre-term birth and very low birth weight babies delivery but the benefit was most marked in women with three or more mid-trimester miscarriage.^{23,25}

In Pakistan, cervical incompetence has been recognized as the leading cause of recurrent abortions in mid-trimester.²⁶ A study showed successful pregnancies in 75% compared to only 44% when cerclage was not applied and patients were managed only by bed rest, tocolytics and antibiotics.²⁷ This problem is quite common in patients visiting IUH. The Elective cerclage based on history and clinical findings applied in the second trimester (12-14 weeks) overcomes the risk of emergency procedure.²⁸ Emergency cerclage if undertaken after 18 weeks carries more risks of infections and other complications²⁹ and also it is technically difficult.

Selective and emergency cerclage although reduce the actual number of the patients subjected to surgical procedure but require serial transvaginal ultrasound. Elective cerclage based on history has the expected neonatal survival rate around 87% with properly selected patients.30 Elective procedure seems to over diagnose cervical weakness as a cause of midtrimester miscarriage but it is true only if we apply cerclage electively after one or two miscarriages. Cervical cerclage improves outcome only after 3 or more miscarriages.31 Different techniques like McDonald's stitch, shirodkar technique, abdominal cerclage and laparoscopic technique are used.32 McDonald's stitch is more widely used and less traumatic to the cervix.33 the overall success rate of the procedure is 70~80% (4). It is a simple procedure with a very few complications e.g. mild pyrexia, increased use of tocolytic therapy, increased hospital admission but no serious morbidity.34

In this study elective cervical cerclage (McDonald's stitch) is selected as salvage for patients with Cl. In this study, it was attempted to highlight that elective cerclage is more feasible as regards expenditure, hospital facilities and

patient compliance and a safe procedure with little morbidity. Effectiveness of this procedure was assessed in terms of prolongation of gestational age at delivery, maternal morbidity will be assessed by listing the immediate and late complications of the procedure and fetal outcome will be assessed in terms of birth of live baby, birth weight and condition of baby at birth and on discharge from the hospital.

OBJECTIVES OF STUDY

The main purposes of my study are to;

- Assess the gestational age at delivery after the elective cerclage application in mothers with recurrent abortions during mid- trimester.
- List the immediate and late complications of elective cerclage in mothers with recurrent mid-trimester abortions.
- 3. Assess the fetal outcome after the elective cerclage in mothers with recurrent abortions during mid-trimester.

MATERIAL AND METHODS

Setting

This study was conducted in Obstetrics and Gynaecology, IUH department Faisalabad.

Duration of Study

The study was conducted from Oct 2016 to July 2018.

Sample Size

In This study 50 patients underwent elective cervical cerclage.

Sampling Techniques

Non probability: Purposive

SAMPLE SELECTION

Inclusion Criteria

- The study included all the patients with suspected cervical incompetence based on previous obstetric history and clinical examination findings admitted through out patient department.
- 2. All patients had history of recurrent midtrimester abortions.

 Patients of recurrent mid-trimester abortions with history of McDonald's stitch application applied in any previous pregnancy whether successfully or not were also included in the study

Exclusion Criteria

Patients with following problems were excluded from the study:

- 1. Repeated first trimester abortions.
- 2. Second trimester abortions due to other causes like uterine abnormality, having structural abnormalities in the previous 2nd trimester miscarriage
- 3. Previous pre-term deliveries after 24 weeks of pregnancy.

Study Design

Interventional: Quasi-experimental

Data Collection Procedure

Patients were admitted through outdoor with history of previous mid-trimester abortions possibly due to cervical incompetence. Basic investigations were done. Ultrasonographic evidence of normal alive pregnancy with no obvious congenital anomaly was a pre-requisite before cervical cerclage application. Suitability for cervical cerclage application was assessed on the basis of history and USG Finding of the cervical length. Technique used was McDonald's suture. Cerclage was applied at 12-14 weeks gestation. Post operatively women were observed for 48 hours then woman was discharged for regular antenatal visits upto 37-38 weeks when in the absence of any indications for cesarean section the stitch was removed in hope of vaginal delivery. Gestational age at delivery in weeks of gestation indicated the success of the procedure, the more the gestational age; the more successful was the procedure. Maternal morbidity was assessed by listing immediate and late post-operative complications like complications of anaesthesia, bleeding, any trauma to adjacent structures, urinary or vaginal infections, fever, membrane rupture causing spontaneous miscarriage, PRE PROM or pre-term labour. Fetal outcome was assessed in terms of birth of the baby, birth weight and condition at birth and on discharge

from hospital.

DATA ANALYSIS

Data collected was entered in SPSS — 10 and analysed.

RESULTS

During two year of my study period at Independent University Hospital FSD. Patients with suspected cervical incompetence were selected for elective cervical cerclage (McDonald's Stitch).

Age

The mean age of patient was 25 years, range (18 — 35 years), 5patients were aged 18-20 years, 22 were 21-25 years, 20 were 26-30 years and 3 were 31-35 years as shown in Table-I.

Parity

Thirty six patients (72%) were Para 0, (all previous abortions), 2 patients (4%) were Para 1, 2 patients (4%) were Para 2, 4 patients (8%) were Para 3, 6 patients (12%) were Para >= 4 (Table-II). All 50 patients had previous 3 to 4 mid-trimester abortions. Previous McDonald's Stitch.

Type of Suture Applied

All 50 patients had McDonald's stitch applied electively at 12-14 weeks. Suture material used was black silk # 2/0.

Outcome of Pregnancy

Out of 50 patients, 39 patients (78%) had term deliveries. Six patients (12%) had pre-term deliveries. Five patients (10%) had abortions between 18 — 23 weeks of pregnancy. Effectiveness of Elective Cervical Cerclage The effectiveness of cerclage is shown in Table-III. It was successful in prolongation of pregnancy and prevention of mid-trimester abortions in 45 patients (90%). Five patients (10%) had spontaneous mid-trimester abortions despite McDonald's stitch. Of the remaining 45 patients, McDonald's stitch was able to prolong pregnancy upto term in 39 patients (78%) and upto 32-34 weeks in 6 patients (12%).

Mode of Delivery

Forty patients (80%) had normal vaginal deliveries.

Ten patients (20%) had elective lower segment caesarean sections. No instrumental delivery or emergency LSCS was done.

Perinatal Outcome

Five patients had spontaneous abortions. Out of 6 babies, born prematurely (32-34 weeks), 4 babies died due to prematurity. All 39 babies (78%) term babies were born with good Apgar score; so overall live birth rate was 80%. The birth weights of the new born are shown in Table-IV.

Complications after Elective McDonald's Stitch

Table-V and VI detail the frequency and types of complication observed after cerclage. Very few complications were encountered. Only one woman (2%) had cervical trauma after delivery requiring stitching, spontaneous abortion occurred in 5 women (10%), pre-term labour in 13% and PRE-PROM in one woman (2%).

Maternal Age (Years)	Number	Percentage
18-20	5	10.0
21-25	22	44.0
26-30	20	40.0
31-35	3	6.0
Total	50	100

Table-I. Distribution of study population according to age

Parity	Number	Percentage
0	36	72.0
1	2	4.0
2	2	4.0
3	4	8.0
>=4	6	12.0
Total	50	100.0

Table-II. Distribution of study population according to parity

Criteria	Number	Percentage
Abortion	5	10.0
Prolonged up to 32-34 wks	6	12.0
Prolonged up to term	39	78.0

Table-III. Effectiveness of cerclage

Birth Weight (Grams)	Number	Percentage
<1500 g	5	10.0
1500-2000	5	10.0
2000-2500	10	20.0
2500-3000	20	40.0
3000-3500	10	20.0
Total	50	100.0

Table-IV. Distribution of birth weight

Complications	Frequency	Percentage
Yes	13	26.0
No	37	74.0
Total	50	100.0

Table-V. Complication

Complications	Frequency	Percentage
Anaesthetic complications	Nil	0
Bleeding	Nil	0
Urinary / vaginal infection	Nil	0
Cervical Trauma after delivery requiring stitching	1	2.0
Spontaneous abortions	5	10.0
Pre term labour	6	12.0
PRE PROM	1	2.0

Table-VI. Post operative complications after Mc Donald's stitch

DISCUSSION

Awareness of cervical incompetence as a cause of recurrent pregnancy loss dates back to 15" century. Surrently there is a lot of presentation for accepting the fact because it is difficult to establish the diagnosis. The experience put forth by many authors differs widely, the diagnosis of cervical incompetence has been primarily based on the clinical history, as it is very difficult to define it on objective ground. According to several authors cervical cerclage is the procedure of choice for patients presenting with cervical incompetence in the mid-trimester. The frequency of cervical incompetence that required cerclage in my study was 0.6%, which is within 1% to 2% of the range given in literature.

The importance of current study was to see the effectiveness of elective cervical cerclage (McDonald's Stitch) in cases of recurrent midtrimester abortions in terms of prolongation of gestational age at delivery, perinatal outcome in terms of production of alive baby, birth weight, Apgar score and condition of baby at discharge and to see the immediate and late post-operative complications of McDonald's stitch. Our patient selection was guided by a consistent history of recurrent mid-trimester abortions and TVS finding for cervical length.^{37,38}

The study by Nalini and Urimila suggested that It could be the manifestation of an inherent weakness of the sphincter mechanism of the internal OS and most of the cases are acquired.³⁹ In one woman there was history of over enthusiastic first trimester D & C in 1 pregnancy by inexperienced personnel followed by recurrent pregnancy losses and in other the same history after instrumental delivery in first pregnancy subsequently leading to cervical incompetence. The mode of delivery in study group in this study as shown in Fig. - Ill is 40 patients (80%) by NVD and 10 patients (20%) by LSCS. These results are comparable to the figure of 73% by NVD and 20% by LSCS given by Chryssihopoulos et al.⁴⁰

In our study all caesarean sections were elective and there were no instrumental delivery in series of 50 patients. The mean age of patients in the study group was 25 years. As regards previous obstetric record all 50 patients had at least 3 previous mid-trimester abortions. Out of this 20 patients (40%) has history of previous 4 midtrimester abortions. 36 patients (72%) had only 3 or 4 mid-trimester abortions in their obstetric history. 14 patients (28%) had 1-7 previous preterm deliveries also in addition to recurrent midtrimester abortions in previous history. 6 patients (12%) had previous history of McDonald's stitch application in previous pregnancies. 2 of these patients had previous successful McDonald's stitch twice in their obstetric history. In 2 of these 6 patients with previous history of McDonald's stitch there was spontaneous mid-trimester abortion despite cerclage. The success rate of elective cervical cerclage (McDonald's stitch) in this study was 90% in terms of prolongation of pregnancy up to term or close to term and there was not significant difference (P= 0.079).

Between our data and the success rate reported by Chanrackahul after 17-year study period of 50 patients which was 94.6 %⁴² Observational data

show that mid-trimester abortions occurred in 10% of patients; premature deliveries in 12% of patients and 78% of patients had term deliveries in the study group. These results co-relate very well with those reported by Bukhari (P> 0.05) in a local study carried out on 50 patients over a one-year study period carried out at Nishtar Hospital Multan. (27). The results are also comparable with those reported by Chryssikopoulos in a study carried out at Aretairon Hospital Athens, Greece, who reported a rate of spontaneous abortions of 10%, preterm birth 21% and term deliveries 69%. 40

Failure rate of procedure was 10 % i.e. 5 patients in this study had spontaneous mid-trimester abortion between 18-23 weeks of pregnancy despite McDonald's stitch. There was no case of abortion due to traumatic or accidental causes during study period of 1 year in 50 patients selected for the purpose of study. On the average there was prolongation of pregnancy up to 34 +/- weeks in this study. This is comparable with average prolongation of 35 +/- weeks in the work by Kurup M.⁴²

Post-operative complications were analyzed. There was only one case of minor cervical laceration after delivery, which was stitched. There was Pre-PROM in one patient. There were no complications like bleeding, severe infections, major cervical trauma or uterine rupture. These findings are consistent with those reported by Sobande (P>0.05), who showed that McDonald's stitch was not associated with any serious morbidity for the mother. In this study, the post cerclage survival rate of babies was 81%. This is comparable to that shown by Bukahri (27) but less than 90% shown by Sobande⁴³, 87% by Harger (30) and by Kurup (75), which was 85%. In this study, 77% of babies had a birth weight of more than 2000g which is almost equal to that showed by Sobande which was 76.6%.

As compared with Shirodkar technique, McDonald's stitch is technically easier, associated with less intra and post-operative complications (Table -V) and easier to remove. McDonald's stitch carried out electively is much better than

emergency cerclage, as emergency cerclage carries more complications and technically also becomes difficult. (29). Selective cerclage is based on serial TVS, which requires resources, expertise and good patient compliance. It can save unnecessary intervention. But in this study a group of patients with recurrent mid-trimester abortions was selected. Selective cerclage holds good in patients with history of one or two previous abortions.

Large numbers of patients visiting IUH come from rural areas, are poor and non-compliant and come to the hospital mostly when they are a case of recurrent abortions as seen in this study. Elective cervical cerclage by McDonald technique is a very good remedy for such cases. It is simple cost effective and beneficial procedure in terms of fetomaternal outcome for these patients. There is no doubt that education of the public is needed. The wrong beliefs especially about repeated abortions in our rural community should be eradicated by counseling that recurrent abortions are quite treatable and timely intervention can save the families from disastrous trauma of repeated pregnancy loses.

CONCLUSION

Recurrent miscarriage is a frustrating situation for a couple. Cervical incompetence is a major cause of recurrent mid-trimester abortions. It is treatable. If early intervention in form of cervical cerclage is done in patients with suspected cervical incompetence prolongation of pregnancy up to term or close to term can be achieved. Elective cervical cerclage at 12-14 weeks of gestation in recurrent mid-trimester abortions by McDonald's technique results in a very good fetomaternal outcome with a very few or almost no complications. It is feasible, cost effective and requires less patient compliance. Elective cerclage based on previous obstetric history of patients can replace emergency and selective cervical cerclage procedure in a poor community like ours.

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