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Induction of Multiparous Women at Term Using Different Methods: Prostaglandin E2 (Dinopristone) Vaginal Gel, Intracervical Foley Catheter Insertion and Sweeping of Membrane: An Open-Label, Randomised Controlled Trial

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Abstract

Introduction: Induction of labour is defined as the methods of ripening the cervix to initiate labour process. This is a commonest obstetric intervention.

Objectives: To determine the time from induction of labour to active phase of first stage of labour, number of vaginal deliveries in each arm, number of instrumental deliveries, caesarian sections, maternal and fetal effects were considered.

Methods: The study was carried out as a randomized controlled trial at the New unit for Obstetrics and Gynaecology in Teaching Hospital Peradeniya. The study group consisted of 329 pregnant women and divided in to four arms as Prostaglandin, Foley induction, sweeping of membrane (ASM) and control arm.

Results: Mean age was 29.3 in the study group. Considering the ethnicity 62 %(n= 203) were Sinhalese, 21% (n= 72) were Muslim and 15% (n= 54) were Tamil. After the 48 hours of induction a favorable cervix was achieved in 77.3%, 64.8%, 63.5% and 55.6 % respectively among Prostaglandin induction, folley induction, ASM and in controls. But there were no significance (p= 0.12). But considering the time to start of induction to women goes in to active labour was significantly high in induction arm (p=0.026). Also there were no significance of number of vaginal deliveries (p-=0.83), forceps deliveries (p=0.65), and caesarian (P=0.47) among study group. Both maternal and fetal adverse outcome were very low and no significance.

Conclusion: The methods of induction are does not influence the mode of delivery and also the need for augmentation. But we found that significant difference of time taken from introduction of induction method to onset of active labour. Neither any method of induction is significantly associated with common side effects nor does it have negative impact on severe maternal or neonatal outcome.

Keywords: Gynecology; Proastaglandin; Sweeping of membrane; Obstetric intervention

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Abbreviations: IOL: Induction of Labour: CTG: Cardiotocography; SOL: Spontaneous on Set of Labour; PGE2: Prostaglandin E2; ASM: Artificial Separation Membrane; NICU: Neonatal Intensive Care Unit; CI: Confidence Interval; OR: Odds Ratio; SD: Standard Deviation.

Introduction

Induction of labour is defined as the methods of ripening the cervix to initiate labour process. It is a commonest obstetric intervention in worldwide [1]. The aim of labor induction is to achieve vaginal delivery before the spontaneous onset of labour. Augmentation is quick the labour process by oxytocin. From 1980s, rates of labour induction have steadily increased. According to statistics 20% to 30% of the labours are induced [1-3]. World health organization global survey on maternal wellbeing and perinatal health (included in 24 countries) assessment with comprising of three million deliveries, demonstrated that significant number of women had induction of labour. Sri Lanka was the highest which is 35% and African countries were the least which is 2 % [1].

Situations in which induction of labour indicated are post-term pregnancy, oligohydramnios, maternal heart diseases, pre-eclampsia and eclampsia, intrauterine growth restriction fetal death and twin pregnancy more than 38 weeks [4-9]. Also the rates of Labour induction are indicated for preterm gestations and pre mature rupture of membrane [10-12]. To induce any pregnant women her dates need be corrected at the beginning by first trimester ultrasound scan which usually done around the 12th week of pregnancy. Studies showed that it reduces unnecessary IOL in significant amount [13]. The odds of having vaginal deliveries after induction of labour usually be assessed by a "Modified Bishop Score" [14]. In the 1960, Edward Bishop has developed a five-component scoring system to determine the possibility for an uncomplicated pregnancy at full term with successful vaginal delivery mode.

Labour induction was traditionally done by artificial rupture of membrane (ARM). In 1950s oxytocin preparations were available. It was used as an adjunct after ARM. In1960s prostaglandin perorations became available, several routes were used. The commonest formulation in current practice is vaginal PGE2 gel or tablet. Currently there are various methods include pharmacological agents such as prostaglandins, misoprostol, cytotec and 16-dimethylprostaglandin E2 [15-20]. Mechanical methods are the membrane sweeping and membrane stripping, amniotomy or balloon cathetering, injection of saline, nipple stimulation, specially acupuncture, oils such as castor oil, herbals etc [21-25]. In an ideal method it would make the cervix softer and dilated without hyper stimulation.

In our study we used Dinoprostone gel, which is a synthetic PGE2 analogue. The exact mechanisms of the PGE2 are not completely understood, however, it may act via regulate intracellular cAMP and effect on cell membrane calcium ion transporters. This can causes dose-related side effects such as nausea, vomiting, and abdominal cramps. It also has a vasodilator action and can have hypotension episodes. PGE2 should not be used in women with hypersensitivity to PGE2 tablets, past cesarean delivery, past myomectomy and in cephalopelvic disproportion and suspected of fetal distress (Bleeding PV). All mechanical methods have the similar action which local pressure stimulates to release of locally acting prostaglandins and oxytocin's. The Foley catheter, cooks catheter used as the mechanical methods. We used Foley catheter as cooks were not available in our hospitals. During the induction process it insert in to endocervix by directly visualization or blindly locating the cervix with the fingers and guiding the catheter over the fingers, through endocervix and to the space between amniotic membrane and lower uterine segment. In our study we compare the cost effectiveness and the safety of the PGE2 gel, Foley catheter induction and sweeping of membranes with control group. By that we provide basis of an economic analysis to use of three induction methods. Our main objectives of this study are summarizing in below.

General objectives

To compare the effectiveness of prostaglandin E2 vaginal gel, intracervical Foley catheter insertion, sweeping of membrane with control group for the induction of labour at term in multiparous women.

Specific objectives

To determine the time period from the induction of labour to the active stage of labour with prostaglandin gel induction, Foley induction, sweeping of membrane.

To determine the failed induction rate with prostaglandin gel induction, Foley induction and sweeping of membrane.

To determine the lower segment caesarean section rate in each methods

To determine the rates of amniotic fluid stained with meconium developed in each methods

To determine the rates of labour augmentation in each induction methods

To ascertain the risk rates of uterine hyperstimulation and fetal heart rate (FHR) changes, in different induction methods
To determine the instrumental delivery rates in each method
To compare the maternal infections rates such as

chorioamnionitis, maternal morbidity (e.g. uterine rupture, Post-Partum Haemorrhage (PPH), Intensive care unit (ICU) admissions, sepsis in different methods.

Methodology

Study Design

The study was an open labeled randomized double blinded clinical trial to determine effectiveness of prostaglandin E2 gel, intracervical Foley catheter and sweeping of membrane for the induction of labour at term in multiparous women.

Study Setting

This study was carried out in New Unit for Obstetrics and Gynaecology in Teaching Hospital Peradeniya for nine months duration where around three hundred of deliveries occur per month.

Study Instruments

Data collection questionnaire, data extraction sheets in addition to the bed head tickets was used to collect data.

Study Population and Recruitment

The study was carried out as a randomized controlled trial at the New unit for Obstetrics and Gynaecology in Teaching Hospital Peradeniya. Recruitment of subjects was carried out from 1st of September 2013 to 1st of June 2014. Subjects were selected among those who admitted to ward with, uncomplicated multiparous women planned for induction of labour beyond 37 weeks of gestation, singleton pregnancy and cephalic presentation, intact membranes and unfavorable cervix (bishop score <6). Women less than 18 years, previous caesarian section, placenta anomaly, fetal congenital anomaly or known allergy to the products used for induction was excluded. The information sheets were given in the antenatal clinic. The verbal and written consent were obtained by the investigator.
Four study arms were as follows:

Group A - Dinoprostone 2mg gel inserted group

Group B - Intracervical Foley catheter induction group

Group C- Sweeping of the membrane alone group

Group D- Control arm

Randomization Schedule and Allocation

Randomization was generated by computer sequence with blocks and stratification. Randomization envelopes were identical and well covered to prevent the tampering. The allocation sequence was concealed till the intervention is assigned. Recruiters or the trial coordinator were not allowed to access the randomization sequence. Informed written consent was obtained from all the women who were recruited.

All women were allocated to four groups. We used stratified block randomization method. All the induction methods were carried out from 40+4 weeks of gestation according to the unit policy. The first method used was dinoprostone gel (dose -2mg).The first dose of PGE2 gel 2mg was inserted in to posterior fornix and observed for six hours. Fetal wellbeing assess by the CTG at three hours and five hours following insertion of prostaglandin. In intracervical Foley catheter induction, the balloon was inserted through internal os and bulb was dilated upto 60 ml of water. The remaining length was pasted on the woman's upper thigh. When the cervix dilated adequately and the catheter simply drops out. The Foley catheter was kept maximally for 48 hours. During that period fetal wellbeing was assessed by CTG and patients were observed for pyrexia, features of infection and dribbling (PROM).

The membrane sweeping was done at gestation of 40+4weeks. There after ASM was done daily until 41 weeks. CTG was obtained in two hours and six hours. Then the modified Bishop Scores were record by the SHO. All women had a same attention and care in the ward. Subsequent assessments carried out by senior house officer who initially assessed the women. The Pulse rate, Blood pressure, CTG, recorded at 3 hours, 6 hours and 12 hours after each method of induction. If any woman delivered in first two days after of therapy the Apgar scores were recorded. And all the other remaining women had assessments 48 hours after the therapy. If the CTG remained pathological and evidence of fetal distress, Lower segment caesarian section (LSCS) were done. Women who had very unfavorable cervix in 48 hours after the initial therapy, either cervical ripening carried out using different method or planed for LSCS according to the unit policy. The women who got favourable cervices were induced by amniotomy and intravenous oxytocin was given if need augmentation.

Inclusion Criteria

Multiparous women who were undergoing labour induction with a cephalic presentation (singleton), unruptered membrane, modify Bishop Score less than 8.

Exclusion Criteria

Primi mothers, women with malpresentation and unstable lie, women with a favourable cervix, contraindication for vaginal delivery, previous caesarean sections, not willing to participate in the trial.

Outcome Measures

Our main primary outcome was the time interval from the induction of labour to the delivery. Other are rate of fail induction and number of LSCS following failed induction. The secondary outcome were measured as the requirement of oxytocin for the augmentation, uterine hyperstimulation, delivery mode, blood loss in during the time of delivery, maternal fever,), perineal lacerations, Apgar scores, NICU admission.

Statistical Analysis

Analysis of the variance was used to compare between means of continuous variables. The statistical significant differences within the each groups considered when $p< 0.05$. We used the SPSS 20th edition for analysis. We have used the Chi Square Test, Fisher's Exact Limits, when compare the proportions of the dichotomous variables.

Ethical Consideration

Informed written consent was obtained from individuals prior to study after explaining the purpose and procedures of the study. It was explained to the participants that they will be free to opt out of the study at any point after recruitment without giving reasons and that it will not affect their social or medical benefits in any way.

Confidentiality of data will be ensured and no individual data will be exposed to a third party. Ethical clearance was obtained from the Ethical Review Committee, Faculty of Medicine of University of Peradeniya, Director of the teaching hospital Peradeniya. This study was registered at Clinical Trial Registry, Sri Lanka.

Results

There were 351 mothers had been recruited for the study? But ten women excluded from the analysis due to they had pre labor rupture of the membrane and another eleven were underwent emergency caesarian section due to fetal distress. So the total sample size were 329 in this study. No missing value for the primary outcome.

The most of the mothers were above age of twenty-five and mean age was 29.3 in the study group. Age group varies from 22 to 35 years. Considering the ethnicity 62% (n= 203) were Sinhalese, 21% (n= 72) were Muslim and 15% (n= 54) were Tamil.

In this study only consider the multigravida and we found majority of women in their second pregnancy. For the easy of the calculation and analysis we have taken only the mothers on their second pregnancy. Because it hard to found adequate sample size from parity more than three for calculation.

Four study arms were as follows(total=329)

- Group A - Dinoprostone 2mg gel inserted group(n=84)
- Group B - Intracervical Foley catheter induction group(n= 90)
- Group C- Sweeping of membrane alone group(n=80)
- Group D- Control arm(n=75)

The mean gestational age at the time of induction was forty weeks and three days. And we did not include patients with gestational diabetes, chronic diabetes, preeclampsia, gestational hypertension, growth restricted and fetal macrosomia. Most of the women were uncomplicated, not having chronic medical disorders and with average size baby who admitted for confinement.

Favorability of the cervix assess by the modified Bishops score which taken as equal or more than eight. After the 48 hours of induction a favorable cervix was achieved 77.3%, 64.8%, 63.5% and 55.6 % respectively among Prostaglandin induction, folley induction, ASM and control group. The majority of the induction arm have favourable cervix at the 48 hours, prostaglandin has the highest success rate than the other methods. But there are no significant difference of the favourability of the cervix. Data were represent in the table 1.

Favourability of cervix in 48 hours= N (%)	Mode of Induction			Control group	P value
	PGE2	Folley	ASM		
Favourble cervix	64(77.3%)	58(64.8%)	51(63.5%)	49(65.5%)	0.12
Unvarourable cervix	20(22.7%)	32(35.2%)	29(36.5%)	26(34.5%)	0.22

PGE2=Dinoprotone gel ASM= Artificial separation of membrane
Table 1: Method of induction versus favorability of cervix.

Considering the final outcome (mode of delivery), all had successful outcome. All the methods have more than sixty percent of vaginal delivery rate. Even control arm without any intervention has higher rate of vaginal delivery (64%). The outcome after induction represent in table 2.

Mode of delivery=N (%)	Mode of Induction			Control group	P value
	PGE2	Folley	ASM		
Vaginal Delivery	54(64%)	61(68%)	52(63%)	48(64%)	0.83
Forceps delivery	4(5%)	3(3%)	4(4%)	3(4%)	0.65
Vacuum delivery	1(1%)	3(3%)	1(1%)	2(2%)	0.81
Emergency LSCS	25(30%)	23(28%)	18(22%)	23(30%)	0.47

PGE2=Dinoprotone gel ASM= Artificial separation of membrane
Table 2: Mode of Delivery after induction of labour.

The main indication for LSCS was fetal distress. (p=0.043). In control arm it is equal in fetal distress, lack of progress in first stage and second stage (Table 3).

Indication for LSCS =N(%)	Mode of Induction			Control group	P value
	PGE2	Folley	ASM		
Fetal distress	15 (60%)	9 (40%)	6 (36%)	7 (30%)	0.043
LOP First stage	8 (32%)	8 (36%)	7 (40%)	8 (33%)	0.56
LOP second stage	2 (8%)	6 (24%)	5 (24%)	8 (33%)	0. 032

PGE2= Dinoprotone gel ASM= Artificial separation of membrane
LOP= Lack of progress LSCS= Lower segment caesarian section
Table 3: Indication for LSCS after Induction of Labor.

Majority of instruments deliveries done due to fetal distress at second stage in induction group. In control group it was equal in fetal distress and prolonged second stage. Prolonged second stage were consider when duration is more than one hours in active stage of the second stage of labour without epidural (Table 4).

Indication for Instruments= N (%)	Mode of Induction			Control group	P value
	PGE2	Folley	ASM		
Fetal distress	3 (60%)	3 (50%)	3 (60%)	2 (40%)	0.73
LOP second stage	2 (40%)	3 (50%)	2 (40%)	3 (60%)	0.65

PGE2=Dinoprotone gel ASM= Artificial separation of membrane
LOP=Lack of progress
Table 4: Indications for instrumental delivery after induction of Labor.

Most of the women were start of oxytocin for augmentation. This may due to routine start of oxytocin after amniotomy as a unit policy at that time. Oxytocin start at any stage of the labour (both first and second stage) was considered in here. And all the mothers were required analgesia and we not found any significance (Table 5). We do not routinely offer epidural, but intramuscular Pethidine as an analgesic method.

Indication= N (%)	Mode of Induction			Control group	P value
	PGE2	Folley	ASM		
Augmentation	67 (80%)	73 (82%)	66 (82%)	66 (88%)	0.786
Analgesia	77 (92%)	72 (80%)	70 (88%)	60 (80%)	0.876

PGE2=Dinoprotone gel ASM= Artificial separation of membrane
Table 5: Number of mothers need Augmentation (Oxytocin) and Analgesia.

Headache, dizziness, palpitations, vomiting and hypertonus of the uterus were recorded as side effects following each induction methods. Table 6 depicts the percentages of each complication following induction. We discovered that there is no significant association between side effects and mode of induction.

Side effect= N (%)	Mode of Induction			Control	X^2 value	df	P value
	PGE2	Folley	ASM				
Headache	4 (5%)	3 (3%)	2 (2%)	2 (3%)	3.380	3	NS
Dizziness	2 (2%)	2 (2%)	0	1 (2%)	3.810	3	NS
Palpitations	2 (2%)	2 (2%)	0	1 (2%)	3.137	3	NS
Vomiting	4 (5%)	2 (2%)	2 (2%)	0	1.371	3	NS
Hypertonus	2 (5%)	0	2 (2%)	0	2.353	3	NS

PGE2=Dinoprotone gel ASM= Artificial separation of membrane
χ^2=Chi-square value DF=Degree of freedom P= p value NS=Not Significant
Table 6: Percentage of side effects and its association with mode of induction.

We analyzed the complications which occur during labour and post-partum period and there was no significant association with any method of induction (Table 7). We considered postpartum haemorrhage (PPH) as more than 500 ml in vaginal deliveries and 1000 ml in caesarian section.

Complication (%)	Mode of Induction			Control group	P value
	PGE2	Folley	ASM		
Maternal IP Pyrexia	3(4%)	4(4%)	3(4%)	2(3%)	NS
PPH	5(6%)	4(4%)	3(4%)	2(2%)	NS
Postpartum Blood Tx	2(2%)	2(2%)	0	1(1%)	NS
Postpartum Infection	1(1%)	2(2%)	2(2%)	2(3%)	NS

PGE2=Dinoprotone gel ASM= Artificial separation of membrane
PPH= Post-Partum Haemorrhage ICU=Intensive Care Unit
Table 7: Percentages of maternal complications following each induction method.

APGAR score at 5 minutes of birth, requirement of neonatal resuscitation following birth, meconium aspiration, need of admission to a special baby care unit were found to be same in each group. There is no significance of each group. The findings are summarized in table 8.

Effect on Neonate (%)	Mode of Induction			Control	p value
	PGE2	Folley	ASM		
Poor Apgar score at 5 minutes	3(4%)	2(2%)	2(2%)	2(3%)	0.67
Neonatal resuscitation	3(4%)	2(2%)	2(2%)	2(3%)	0.56
MAS	1(1%)	1(1%)	1(1%)	1(1%)	0.63
NICU	3(4%)	2(2%)	2(2%)	1(1%)	0.83

PGE2=Dinoprotone gel ASM= Artificial separation of membrane
NICU=Neonatal Intensive Care Unit Admission.
MAS- Meconium Aspiration Syndrome.
Table 8: Percentages and association between neonatal effects and induction.

Discussion

IOL rate in Sri Lanka is nearly 35% [1]. There are lots of logistic reasons for this high rate such as overcrowded in tertiary care center, fear of still birth after forty weeks of gestations, maternal request and their worries etc. Newer growing evidence showed that there if no difference of number of caesarian section due to failed induction at thirty nine weeks of gestation and forty one weeks of gestations. And also it found that there is no significant difference of maternal morbidity, mortality and neonatal morbidity and mortality. Other advantage that, it reduces the number of meconium stains amniotic fluid and their complications at term.

In our study, we mainly focused on effectiveness of various methods of induction for parous women. Due to logistic reasons we have collect the data from women on their second pregnancy with previous one vaginal delivery. The total of 329 mothers was included in this study group. There was no missing value for the primary outcome. The mean age was 29.3 in the study group. Age group was varied from 22 to 35 years. Considering the ethnicity 62 %(n= 203) were Sinhalese, 21% (n= 72) were Muslim and 15% (n= 54) were Tamil. All patients were equally distributed among the all four arms.

We found that induction of labour methods make cervix more favorable, but we couldn't found any significance among them (all were multips) when compare with the control arm. All the induction methods were introduced at mean gestation of forty weeks and three days according to the unit policy. Time from start of induction methods to the onset of active phase of labour shorter in prostaglandin arm. The mean time it taken to reach active phase was eighteen hours, thirty two hours, forty four hours and fifty two hours in prostaglandin group, Foley catheter group, sweeping of membrane group and control group respectively (p=0.26). It gave the idea that induction methods are really help for make the women go into to labour early. But if we consider the ultimate time limit as 48 hours, especially with Foley and sweeping of membrane, all have make cervix more favorable within this time. We recorded minor complication could arise during induction process such as headache, palpitation, dizziness, vomiting, uterine hypertonia. But there were no statistical significance of these results.

We found that there was a significant different of time taken from induction of labour to onset of active labour when compared with the control arm. However no difference among each of the induction methods. We have taken the time duration until onset of active labour but not the delivery time. This was due onset of active labour to delivery time could affect by a lot of confounders. The time of active labour consider as cervical dilatation equal or more than four centimeters, or at least three good regular contractions for ten minutes duration. Majority of patients had vaginal deliveries which is more than sixty percent. Foley arm has the most successful vaginal delivery rate and it is sixty eight percent. Sweeping of membrane arm has the lowest rate, which is sixty three percent. Both the prostaglandin arm and control arm has the similar rate of caesarian section (30%), but none of them were significant. The Probaat trials also found the similar results [15,24,25].

The women who had emergency caesarian section were mainly due to the fetal distress in prostaglandin arm (62%). [40%-Foley, 36% - sweeping of membrane, 30% - control arm]. Caesarian section due to lack of progress in first stage is same in all the arms. Most of the section was due to lack of progress in the second stage found in control group and sweeping of membrane group. These results are compatible with some studies courted in the Cochrane data base [16,17]. A study done at Israel among 1376 grand multiparas (parity more than four) who underwent labor induction with low dose prostin were found that uterine rupture was 0.07%. Vaginal delivery could be achieved in ninety six percent of women, while three percent of the patients had emergency cesarean delivery. Also there was no relationship between parity and cesarean delivery rates [26]. Another study at Saudi Arabia with 64 grand multiparous women where labour induction with prostaglandin E2 was compared with spontaneous onset of labour found that there was no a significant difference between the time of duration of labor [27]. The membrane sweeping is a non-invasive procedure with no cost and can be done freely. By artificial separation of membrane it releases the local prostaglandin and other local chemicals and it leads to ripening of the cervix. Most of the studies found that good out come with sweeping of membrane alone for term pregnant women as an induction method [28-30]. The Cochrane systematic reviews includes nearly 70 RCTs, which comparing the mechanical method Intracervical Foley) with others found that the risk for caesarian sections were similar. (6 studies; CI 0.76 to 1.30). No events of severe neonatal and maternal morbidity and mortality were found. The advantage of mechanical method were decreased the risk of uterine hyperstimulation and fetal distress [31,32].

Due to our unit policy, we have start oxytocin for the augmentation just after amniotomy and so all the groups have the same number of augmentation rate. Recently Sri Lanka College of Obstetrics and Gynaecology have recommended that routine amniotomy has been discouraged. So results would have change if we use these protocols in current practice. Again the routinely labour ward staff has given intramuscular pethidine in labour ward. This would have contributed to the reason where no significance

difference which relevant to requirement of analgesia in labour. However, the other studies still did not have found significance difference of analgesic requirement [23-25].

Maternal intrapartum pyrexia, post-partum haemorrhages, post-partum endometritis, intensive care unit admission were recruited to the study and there were no significant difference of major complications during labour process and post-partum period with each method. There was neither significant maternal morbidity which leads to disability nor maternal mortality was recorded during the study period. Fewer neonates were had low APGAR score at five minute and some of them needed resuscitation. However, the number of neonates admitted to the NICU was low in the study group and no significance. However, we did not record the umbilical cord pH as no facilities where most of the other studies were done.

Conclusion

The method of induction does not influence the mode of delivery and the need of augmentation with oxytocin in multiuse. But we found that significant difference of time taken from introduction of induction method to onset of active labour. Neither any mode of induction is significantly associate with common side effects nor does it have negative impact on severe maternal or neonatal outcome. Analgesia requirement also same in each group. Each induction methods make favorable cervix at forty eight hours and it has same efficacy rate. APGAR score at five minutes, NICU admission was same in each group. Therefore we suggest prostaglandin, Foley catheter, sweeping of membrane have same efficacy to make cervix favorable and none of the methods have significant side effects on maternal well-being or fetal well-being.

Limitations of the Study

Since this is a large study with consist of four arms including the control arm it took long time to collection of data. The time duration from induction time to onset of active labour were taken from hours not from minutes. Admission to NICU may affect from other confounders as well. Amount of blood loss calculate from visual estimation, because there were no equipment to measure the exact weight correctly.

Conflicts of Interest

There are no conflicts of interest.

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This research did not receive any specific grant from funding agencies.

Suggestions

We suggest that this study can be done in a multiple unit in an island wide to collect more data and check for significance.

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