European Journal of Molecular & Clinical Medicine

ISSN 2515-8260 Volume 09, Issue 03, 2022

ORIGINAL RESEARCH

EVALUATION OF EFFICACY AND SAFETY OF MISOPROSTOL FOR CERVICALRIPENINGANDINDUCTIONOFLABOURBYTWODIFFERENTROUTES

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ABSTRACT
BACKGROUND: Cervical ripening is one of the methods employed for induction of labour. Cervicalripening involves the usage of pharmacological agents or other means to soften, efface or dilate thecervix to increase the likelihood of a vaginal delivery. Induction of labour (IOL) is the process ofinitiatingcontractionsinpregnantpersonswhoarecurrentlynotinlabour,tohelpthemachievevaginaldelivery within 24 to 48 hours. **OBJECTIVE OF THE STUDY:** The objective of the study is tocompare the efficacy and safety of two different routes of regimen of misoprostol for cervical ripeningand induction of labour. **MATERIALS &METHODS:** This prospective comparative study, wasconducted in the Department of Obstetrics and Gynaecology at Adesh Medical College, for a periodfrom may January 2021 to June 2021. We enrolled 100 patients in our study. We divided the patientsintotwogroupsrandomlyintoGroupAandGroupB.GroupAweadministeredmisoprostolvaginallyandGroupBsublingually.Thedoseusedforboththegroupswas25µg.**RESULTS&CONCLUSIONS:** In our study, we found that there were no statistically significant differences indemographis, Bishops Score after induction, number of doses required, complications (foetal distress,meconium stained liquor and hyper stimulation), maternal side effects and neonatal Apgar Scoresbetweenthetwogroups.Therewerestatisticallyhighlysignificantdifferencesintheneedforoxytocinaugmentation between the two groups. Oxytocin augmentation was more in group B in patients ascomparedto patients in group A.
KEYWORDS: Induction,misoprostol,sublingual,cervicalripening,inductionoflabour

INTRODUCTION: Induction of labour is one of the most important procedures in today's obstetrics.Inductionoflabouristheartificialinitiationofuterinecontractionsbeforeitsspontaneousonsetfor thepurposeofdeliveryofthefetoplacentalunitusingmechanicalorpharmacologicalmethods.Thesuccessof labour induction largely depends on the cervical status or Bishop's score at the time of induction. Itis generally predicted that the patients with a poor Bishop's score at the initiation of induction havehigher chances of failure of induction. It has been a baffling problem since time immemorial and ismost debatable when done prior to attainment of maturity or at term in normal patient, just to deliverher at the convenience of patient and the doctor, as failure of induction or meconium staining of liquorfollowinginduction can leadto increased incidenceofcaesareansections.[1-3]
Asuccessfulinductionoflabourreferstovaginaldeliveryofhealthybaby,inanacceptabletimeframewith minimum maternal discomfort or side effects. Prostaglandin E2 has been the agent of choice forpre-inductioncervicalripeningforseveraldecadesandisoneofthepharmacologicagentsapprovedbytheUnite

dStatesFoodandDrugAdministrationforthisindication.However,ithasseveraldisadvantages:itisexpensive,requiresintracervicalapplication,andcontinuousrefrigeration.Inductionof labour with oxytocinisunlikelyto leadtovaginaldelivery inanunripecervix.[4-7]

Misoprostol (a prostaglandin E1 analogue) is a comparatively new agent for pre-induction cervicalripening and labour induction. It has excellent cervical ripening and uterotonic properties. Although,misoprostolcurrentlyisapprovedbyU.S.FDAforthepreventionandhealingofpepticulcersinducedby NSAIDs, in 2002, the U.S Food and Drug Administration approved a new label on the use ofmisoprostolduringpregnancyforcervicalripeningandfor inductionoflabour.Itiseconomical,stableatroomtemperature,withveryfewsideeffectsandcanbeeasilyadministeredthroughoral,sublingual,vaginal, buccal or rectal routes. Most clinical trials have used doses ranging from 25µg to 100µg,inserted intra-vaginally into the posterior fornix. Considering the routine use of both vaginal and oralroutes, uncertainty regarding the preferred dose and route, lack of accurate statistics, advantages anddisadvantages on the effectiveness of both methods, we designed this study to assess and compare theefficacy of sublingual misoprostol 50µg and vaginal misoprostol 25µg for induction of labour at term.Andtocomparematernalandneonatalcomplicationsandsideeffectsofthedrug.

OBJECTIVEOFTHE STUDY: The objective of the study is to compare the efficacy and safety of two different routesof regimen ofmisoprostolfor cervicalripening and induction of labour.

MATERIALSANDMETHODS: ThisprospectivecomparativestudywasconductedintheDepartment of Obstetrics and Gynaecology at Adesh Medical College, Ambala for a period from mayJanuary 2021 to June 2021 after obtaining institutional ethical committee clearance. After informedconsent, we enrolled a total of 100 subjects in our study, we divided them randomly into two groupsGroup A and Group B with 50 subjects in each group. Group A were given tablet misoprostol 25 µggivenvaginaandgroupBweregiventabmisoprostol25µggivensublingually.WeincludedSingletonpregnancybeyond37weeks'gestation,Vertexpresentation,Clinicallyadequatepelvis,Bishopscore<6, Reactive Non-stress test and Absence of uterine contractions. We excluded the pregnancies withMalpresentation,Presenceofuterinecontractions>=3/10min,Cephalo–pelvicdisproportion,Favourable cervix (Bishop score > 6), Previous Caesarean section or uterine scar, Multiple gestationandParity-5 ormore.

We mainly compared 5 parameters between both the groups. These parameters include 1) number ofdoses(misoprostol)given2)needforoxytocinaugmentation3)uterineactivity(regular/hyperstimulation) 4) induction delivery time and 5) APGAR score. Statistical analysis was carried out byentering the data in Microsoft excel sheet and SPSS was used for comparison between the groups bychi-squaretestandpartialcorrelationcoefficient. P<0.05wasconsidered statisticallysignificant.

RESULTS AND DISCUSSION: In our study, we included a total of 100 subjects in the age group of20-30years.WerandomlyallocatedthesubjectsintotwogroupswithSubjectsineachgroup.GroupA were given misoprostol 25 µg given vaginally and Group B were given misoprostol 25 µg givensublingually. Most of the subjects were in the age group of 20-25 years in both the groups. There wasno statistically significant difference in age between the two groups. The indications for Induction oflabourincluded,PIH,MildOligohydromnias,MildIUGR,Post-datedandPROM.Out oftheseindications,themostcommonindicationforinductionof labor wasPIH inboththegroups.

Table1:Showsnumber ofdosesrequiredforinduction inboththegroups.

No ofdoses	GroupA(vaginal misoprostol)		GroupB(sublingual misoprostol)	
	No	**%**	**No**	**%**
1	8		7	
2	24		26	
3	12		10	

4	4		4	
5	2		3	

It is evident from the table 1 that the difference in the number of doses required in both the groups toproduceeffectoncervicalripening anddilatation wasstatistically notsignificant(p=0.967).

Table2:ShowsNeedforAugmentationbetweenthetwoGroups

Needfor Augmentation	GroupA (vaginalmisoprostol)		GroupB (sublingualmisoprostol)	
	No	%	No	**%**
Needed	34		12	
Not needed	16		38	
Total	50		50	

Itisquiteevidentfromthetable2that34patients needed augmentationbyoxytocinin25µgMisoprostol vaginal group as compared to 12 patients in 25µg Misoprostol sublingual group. Thedifference in both the groups for requirement of augmentation was statistically significant (p = 0.00)**.**The patients included in both the groups were those who achieved full cervical dilatation followinginductionandaugmentationoflabouraswellasthosewhounderwentlowersegmentcaesar eansection.

Table3:InductionDeliveryTimeWiseComparisonBetween theGroups

Need forAugmentation	Group A (vaginalmisoprostol)	Group B (sublingualmisoprostol)
Minimumtime	470minutes	420minutes
Maximumtime	920minutes	880minutes
Meantime	660	710
SD	112	120

Itisevidentfromtable3that,meaninductiondeliverytimewasmoreingroupBcomparedtoGroup A.Therewassignificantstatisticaldifferenceintheinductiondeliveryintervalbetweenthegroupswith(p= 0.42).

We also analysed uterine activity and APGAR score between the two groups, we found no statisticallysignificant differences in both the groups. The mean Apgar value at 1 and 5 minutes were similar inboth group.(data not shown) Also, no major maternal complications were seen in terms of fever,vomiting,diarrhoeaorbronchospasmin both thegroups.

Thisstudyshowsthatwomenwhoreceivemisoprostolvaginallyexperiencefasterinduction-todeliverytimes with less need for oxytocin augmentation when compared with a similargroup of womenreceiving oral misoprostol. These findings concur with those of others. Though the total number ofdoses of misoprostol required in vaginal groups was lower as compared to oral, when average wasderived, the difference was not statistically significant in our study which was in contrast to studiesdone by Wing DA et al, Janice SK et al, and Jindal et al. This may be due to the reason that sometimesthevaginaldosedidnotdissolutecompletelybythe timeofnextdosewhichincreasedtherequirementof dose. Induction to vaginal delivery interval was significantly lower in vaginal group as shown byJaniceetalandJindaletal,asvaginalmisoprostolisabsorbedrapidlyandeliminatedslowlyfrombodyma king it available to act for a longer time as compare to oral resulting in rapid progression of labour.Main fear with this drug is sometimes excessive uterine contractions and possibility of

uterine ruptureinbothscarredandunscarreduterus,however,byandlarge,useofthisdruginpreviouslyscarreduterusisalmostnegligibleandruptureisnotcommoninprimigravidaandinmultiparapatientsmisoprostolisusedverycautiously.Thesecomplicationsaredoserelated,higherthedose;moreisuterinestimulationbut shorter is the induction delivery interval.26 With 50µg vaginal misoprostol, incidence of uterinecontractileabnormalitieshasbeenreportedtobe4.9%, 9% and12% indifferentstudies.[14-16]

CONCLUSION: In our study, we found that there were no statistically significant differences indemographis, Bishops Score after induction, number of doses required, complications (foetal distress,meconium stained liquor and hyper stimulation), maternal side effects and neonatal Apgar ScoresbetweenthetwogroupsTherewerestatisticallyhighlysignificantdifferencesintheneedforoxytocinaugmentation between the two groups. Oxytocin augmentation was more in group B in patients ascomparedpatients in group A.

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