Original Article

Duration of Labour after Injection of Drotaverine Hydrochloride in Primigravida Presenting in Active Phase of Labour in a Tertiary Care Hospital

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ABSTRACT

Objective: To determine the mean duration of labour after injection of Drotaverine hydrochloride in primigravida presenting in active phase of labour in a tertiary care hospital.

Study Design: Cross sectional study

Place and Duration of Study: This study was conducted at the Department of gynecology and obstetrics Bacha khan medical complex Sawabi from January to July 2018.

Materials and Methods: A total of 123 patients were enrolled in the study after taking informed consent from the individual participant. Patients having age 20-36 years with singleton cephalic presentation of fetus as assessed on ultrasound and already in the active phase of labour having cervical dilation of 3-5cm with 2-3min uterine contractions for at least 30 seconds in every 10 minutes were included in the study. Data was collected using a pre designed proforma. Data analysis was done using SPSS version 20.

Results: Average age of the patients was 25.72years+3.67SD with range 20-36 years. Average gestational age of the patients was 37.26 years+2.29SD with range 33-41 weeks. The average total duration of average labor was 4.14±0.55SD.

Conclusion: Drotaverine hydrochloride in primigravida presenting in active phase of labour is effective to reduce the duration of labor

Key Words: Mean duration, labour, primigravida, active phase

Citation of article: Salman SG, Rafiq M, Hafeez S, Khan IR, Zartaj. Duration of Labour after Injection of Drotaverine Hydrochloride in Primigravida Presenting in Active Phase of Labour in a Tertiary Care Hospital. Med Forum 2020;31(11): 58-62.

INTRODUCTION

Labour is defined as process that results in the delivery of the baby. It is physiological process and can cause serious consequences during its prolongation. It can result in dehydration, infection, metabolic acidosis, fetal distress and increased intraoperative interventions.[1]

Spasms in the cervical smooth muscles is commonest cause of prolonged labour. Cervical muscle spasm is the most common cause of prolonged labour. It is because of over discharge of circular muscle of cervix. This over activity of cervical muscles is exaggerated in the presence of injury or inflammation, fibrosis in the cervical muscles or fear related tension syndromes.[2]

Obstetrician and laboring female both would like to complete the delivery process in shortest possible duration without compromising mother and fetal safety. Therefore, with early administration of oxytocin and amniotomy, antispasmodic agents may be used to accelerate the process.[3]

Labor is a process that involves multiple factors i.e uterine contractions, cervical ripening, dilation and delivery of baby and placenta in an ordered way. The fisrt stage of labor is a bit longer in primigravida as compared to multigravida, 12-16 hours and 6-8 hours respectively.

Calculating the time duration of labor is difficult and very subjective. Certain reasons are there that hinders the calculation of duration of labour. First is measuring cervical dilation and secondly the process of labor varies from patient to patient. Some females presents with strong and painful uterine contractions at 2cm of cervical dilation, whereas other females feels the same intensity of pain at 4cm of cervical dilatation.

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Received: February, 2020
Accepted: August, 2020
Printed: November, 2020

This affects the obstetrician's perception of induction of labor. Therefore, most of studies has defined the measurement of first stage of labor as the point of administering an antispasmodic till full cervical dilation. This intervention can be done at 3 to 6 cm of dilatation. This timing of the administration of antispasmodic agent varied from 3 cm to 6 cm cervical dilatation. Many studies have shown effectiveness of antispasmodics in increasing the rate of cervical dilatation during first stage of labor.

Second and third stage of labor was not influenced by using antispasmodics. Pain may be relieved but it is not certain that it has an analgesic effect.

Every mother and care taking obstetrician wants pain free labor and delivery. Strength and frequency of uterine contractions along with active cervical dilation are the factors that lead the progress of labor, but often active cervical dilation starts late even if uterine contractions are present. It can result in unrequired painful and prolonged labor which affects the health of mother and baby. Thus pharmacological drugs are used to augment cervical dilation in the presence of good uterine contractions that results in smooth delivery of baby. Different types of agents (both mechanical and pharmacological) are used, which can cause cervical dilatation. Early amniotomy and smooth muscle relaxants are used to shorten the duration of labor.

Drotaverine hydrochloride is a muscle relaxant that has different mode of actions. Drotaverine hydrochloride or isoquinolone 1,2,3,4-tetrahydro 6,7 diethoxy-1-(C-3, 4-diethoxy phenylmethylene) is a potent spasmolytic drug.[4]Drotaverine hydrochloride is a quinolone derivative and is a smooth muscle relaxant. It does not have habit forming or addictive nature because it lacks opioid analgesic and narcotic effects.[5]The mode of action of Drotaverine is inhibition of phosphodiesterase enzyme. It causes increase in cAMP levels which causes relaxation of smooth muscles by inhibiting muscle contractions.

The rationale of the present study is to evaluate the effect of shortening of duration of labour as in our set-up obstetrician do not give any drug or spasmolytic to shorten the duration of labour as long duration of labour may cause many complications to fetus as well as laboring mother. If mean duration of labour is shortened than before then we will implement the drug in future in our set-up to save time of obstetrician and laboring women.

MATERIALS AND METHODS

Sampling method was non-probability (consecutive) sampling technique. Patients who were in the age group 20-36 years presenting to department/ ER having singleton pregnancy with cephalic presentation of the fetus (as assessed by ultrasound) and who were in active phase of labour with cervical dilation of 3-5cm with 2-3 uterine contractions for at least 30 seconds in every 10 minutes were included in the study. Patients having pregnancies with medical disorders like hypertension (BP > 140/90 mmHg) or diabetes (RBS > 180 mg/dl, FBS > 126mg/dl) were excluded and patients with borderline pelvis and cephalopelvic disproportion (assessed on pelvic examination) were also excluded from the study.

After explaining the purpose and benefit of the study and procedure, an informed consent was taken and information's were entered in a pre-designed proforma. Demographic data including gestational age was noted. These patients who were in active stage of labour were injected intramuscularly with forty milligrams (40mg) of Drotaverine hydrochloride. This injection was administered at 3-5cm of cervical dilation by a single trained staff nurse. Then patients were followed till delivery and duration of labour from time of injection till delivery was noted by the author herself. Data was analyzed using SPSS version 20. Data were stratified for stages of labour (1^{st}, 2^{nd}, and 3^{rd}).

RESULTS

Average age of the patients was 25.72years+3.67SD with range 20-36 years. Patients were divided into four categories according to age of patients. Out of which most common age group for primigravida presenting in active phase of labour was 24-28 years of age. Fifty (40.7%) patients were in the age range of 24-28 years. Frequency and percentages for age distribution is shown in table 1.

Table No.1: Age Wise Distribution of the Patients

Age (years)	Percentage/ frequency
≤ 23.00	35.8%(n=44)
24.00 - 28.00	40.7%(n=50)
29.00 - 33.00	22%(n=27)
34.00+	1.6%(n=2)

Table No.2: Mean Duration of Labor

	Count	Min.	Max.	Mean	Standard Deviation
1st Stage of Labour(in hr)	123	2.65	4.30	3.51	.54
2nd Stage of Labour(in hr)	123	.28	.75	.50	.12
3rd Stage of Labour(in hr)	123	.08	.17	.13	.03
Total Duration of Labour (in hr)	123	3.13	5.15	4.14	.55

Average gestational age of the patients was 37.26 weeks+2.29SD with range 33-41 weeks. Majority of patients have 36-39 weeks of gestational age. There were 27(21.95%) patients were of the less than or equal to 35 weeks and 18(14.63%) patients were in the range of more than 40 years of gestational age presenting in active phase of labour in a tertiary care hospital. (Fig 1)

Out of 123 primigravida presenting in active phase of labour in a tertiary care hospital. The average labour in 1st stage was observed 3.51 hour +0.54SD followed by the 2nd stage of average labour 0.50 hour+0.12SD while in 3rd stage, it was 0.13hour+0.03SD. Total duration of average labor was 4.14+0.55SD. (Table 2)

Gestational age wise distribution of duration of labor shows that duration of labor was almost same in all gestational age group. (Table 3)

Age wise distribution of duration of labor shows that age has no role over average duration of labor. (Table 4).

Table No.3: Gestational Age Wise Distribution of Duration of Labor Among Patients with Primigravida Presenting in Active Phase of Labour

Gestational Age (in weeks)		1st Stage of Labour(in hr)	2nd Stage of Labour(in hr)	3rd Stage of Labour(in hr)	Total Duration of Labour(in hr)
≤ 35.00	N	27	27	27	27
	Mean	3.5022	.4944	.1374	4.1337
	Std. Deviation	.55333	.11517	.02123	.55041
36.00 - 39.00	N	78	78	78	78
	Mean	3.5606	.5013	.1336	4.1954
	Std. Deviation	.49999	.12115	.02777	.51142
40.00+	N	18	18	18	18
	Mean	3.2828	.4811	.1250	3.8894
	Std. Deviation	.64408	.12616	.03053	.64701
Total	N	123	123	123	123
	Mean	3.5072	.4968	.1332	4.1371
	Std. Deviation	.53861	.11982	.02696	.54699

Table No.4: Age Wise Distribution of Duration of Labor Among Patients with Primigravida Presenting in Active Phase of Labour

Gestational Age (in weeks)		1st Stage of Labour(in hr)	2nd Stage of Labour(in hr)	3rd Stage of Labour(in hr)	Total Duration of Labour(in hr)
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	Mean	3.2828	.4811	.1250	3.8894
	Std. Deviation	.64408	.12616	.03053	.64701
Total	N	123	123	123	123
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	Std. Deviation	.53861	.11982	.02696	.54699

DISCUSSION

Number of cesarean sections, prolonged labor and labor duration can be reduced by actively managing labor. It will lead to successful delivery without having adverse maternal and fetal consequences.[6] There has been several randomized clinical trials done on safety of active management of labor, involving thousands of women. [7]Numerous studies reported that shorter duration of labor from time of admission with active management protocols can yield good results.[6, 8].

There is a number of smooth muscle relaxants that are being used in labor. The purpose of which is mainly augmenting relaxation and dilatation of cervix. Drotaverine has significant muscle relaxing activity and lacks addictive nature, as it lacks opioid analgesic and narcotic effects.[5] Its mechanism of action is mainly inhibition of phosphodiesterase enzyme. It causes increase in cAMP levels which results in inhibition of smooth muscle contraction which leads to muscle relaxation. It also inhibits selected PDE isoenzyme PDE-IV (rolipram sensitive). Hence its side effects are less. It has more potent action in those tissues which are rich in PDE-IV isoenzyme.[9]

Drotaverine causes significant increase in cervical dilatation in primigravida.[10-13] It has no effect on 2nd and 3rd stages of labor in primigravida and also in multigravida. [13-17] It does not affect the mode of delivery when used in labor, it only shortens the duration of labour.[12, 14]

A study conducted by Sharma[12], concluded that duration of first stage of labour and rate of cervical dilatation in Drotaverine group was 194+57.04 minutes and 2.04+0.68 cm per hour and in our study it was 191.25+76.89 minutes and 2.48 cm per hour respectively, so results are comparable with other studies.

In our study mean age of the patients was 25.72 years which was ranged from 2428 years. Most of the pregnant patients presented in this age group. The average gestational age of our patients was 37.26 weeks which is comparable to other studies findings. The gestational age of majority of patients was 36-39 weeks. The average duration of 1st stage of labour was 3.51±0.54 hours. It was followed by 0.50±0.12 hours in second stage while shortest in 3rd stage of labour which was 0.13±0.03 hours.

In our study,4.12hour ± 0.551SD was the mean duration of first labor using Drotaverine hydrochloride. Our results were comparable with a same sort of study carried out by Anju Huria et al.[19]In that study they used Drotaverine and Valethamate, both of which significantly reduced the duration of first stage of labour. These drugs caused significant reduction in duration of first stage of labor as compared to control in nulliparous and multiparous both.

A study done by Kaur D and colleagues,[13] Mishra SL and other authors[11] and Sharma JB with his colleagues[12] concluded that Drotaverine is more potent as compared to valethemate in shortening the duration of labour.A study of 535 patients by Gupta and friends[17] was done by using Drotaverine injections during labor. They concluded that Drotaverine has more effective decreasing the time duration of labour. It does it so by inhibiting cervical muscles contractions during labour. This drug has more potency during membrane rupture.

A study by Thapa M et al concluded that duration of labor was significantly reduced after using Drotaverine intravenously. The mean duration from injection to delivery was 196.9 in primigravida and 196.9 in multigravida patients.[18] this decrease in duration of labor is caused by using Drotaverine injection that results in acceleration of first of labor. Yuel et al reported that Drotaverine is more potent than other smooth muscle relaxants (epidosin or buscopan) in cervical dialatation[19]. A study done by Majumder S et.al showed that their mean duration of first stage of labor was 176.67+/-91.69 min after using Drotaverine hydrochloride injection during labor.[20]

In a study done by Tewari K, they compared the effects of valethemate bromide with hyoscine butylbromide. They gave buscopan 20min apart in two divided doses and found that duration of labor was reduced by 5 hrs. and 12 minz.[21]

Samuels LA included 129 patients in his study out of which 69 received placebo and 60 received hyoscine butylbromide the mean time of duration of labor was 156 minutes in the drug group and 228 in placebo group. It showed significant decrease in duration of labor by 31.7%.[22]

A nonrandomized controlled study was done by Sirohiwal D, on 200 laboring patients. 100 patients at 3cm or more of cervical dilation, received antispasmodic agent and 100 patients didn't receive any drug. He concluded that duration of first stage of labor was 123.86 minz ±68.89 in first group and 368.05 minz ±133.0 in the controlled group. These findings were significant statistically.[23]

Our results are comparable with the studies done other colleagues in various institutes. We observed no peri-labor mortality or morbidity. All of our patients delivered normally with no progress to caesarian section or forceps assisted delivery.

CONCLUSION

We found from the results of our re-search that using Drotaverine hydrochloride injection in early stage of labor in primigravida patients decreases the duration of labor significantly. It also decreases the incidence of tears in cervical muscles that occur during labor. Its use can result in good maternal and fetal outcome.

However, more research is required specially randomized control trials on a larger sample that will yield the exact dosage and definitive outcome of using Drotaverine in accelerating the labor.

Author's Contribution:

Concept & Design of Study:	Seema Gul Salman
Drafting:	Maria Rafiq, Sania Hafeez
Data Analysis:	Isma Rafiq Khan, Zartaj
Revisiting Critically:	Seema Gul Salman, Maria Rafiq
Final Approval of version:	Seema Gul Salman

Conflict of Interest: The study has no conflict of interest to declare by any author.

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