

STUDY OF EFFECT OF PER RECTAL BUSCOPAN SUPPOSITORY (10 MG) ON DURATION OF ACTIVE STAGE OF LABOUR, FROM 3 CM CERVICAL DILATATION TO DELIVERY OF BABY

Jay Manoj Sheth¹, Bhumiika Himatbhai Bhagat²

¹Consultant / Private Practitioner, Department of Obstetrics and Gynaecology, Mumbai, Maharashtra.

²Consultant / Private Practitioner, Department of Obstetrics and Gynaecology, Mumbai, Maharashtra.

ABSTRACT

BACKGROUND

Term "active management of labour" means codified approach to manage women in labour. It aims at reducing discomfort and pain of mother, shortening duration of labour, and reducing cesarean section rate. Recently, much focus is around shortening duration of labour. It is the single factor which can reduce pain and discomfort of parturient lady. Role of Buscopan (hyoscine-N-butylbromide) as labour accelerant has not been evaluated despite the fact that same pathways which mediate pain also mediate cervical dilation.¹ Factors responsible for cervical dilatation, other than parasympathomimetic mediators, like spasmolytic effect and relaxation of pelvic muscles, smooth muscle relaxation of cervix, softening and ripening of cervix, etc. are also affected by Buscopan.²

Aims and Objectives: 1) Efficacy of Buscopan suppository in reducing duration of active stage of labour. 2) Safety of Buscopan suppository.

MATERIALS AND METHODS

Randomized controlled prospective study in primiparous women with singleton intra-uterine full-term pregnancy, who go into labour spontaneously, in tertiary care institute between 1st Jan 2009 to 31st Dec 2009. In the study group, 25 women were given single Buscopan suppository 10 mg, at 3 cm cervical dilatation, post-amniotomy. 25 women who were not given any medication were taken as controls.

RESULTS

Mean duration of active stage of labour in study group was ~104 minutes less than the same in control group. There was statistically significant shortening in duration of active stage of labour, by 104 (± 25) minutes (p value <0.05). There were no ill-effects seen in babies. All babies passed urine and stool well within physiological limit. No patient had any known serious complications of Buscopan.

CONCLUSION

It was concluded that Buscopan suppository effectively and safely reduces duration of active stage of labour.

KEYWORDS

Buscopan, Labour Duration.

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BACKGROUND

Goal of obstetrics is that every pregnancy should be wanted and culminate in healthy baby and healthy mother. Term "active management of labour" means codified approach to manage women in labour. It aims at reducing discomfort and pain of mother, shortening duration of labour, and reducing caesarean section rate.³

Earlier, main concentration was around induction and augmentation of labour. Duration of labour received little

attention until recently. Recently, much focus is around shortening duration of labour. It is the single factor which can reduce pain and discomfort of parturient lady, making parturition not unwanted due to long hours of labour.

Use of hyoscine-N-butylbromide (Buscopan) was initially studied as labour analgesic; effect on duration was just an incidental finding, studied in detail recently. Role of Buscopan as labour accelerant has not been evaluated despite the fact that same pathways which mediate pain also mediate cervical dilation.¹ Part of pain relief afforded by Buscopan may be due to shortening of duration of labour and thus making it less tiring.

Shortening of duration can be the single most important factor making tiring event of labour pleasant, reducing jeopardy of maternal health and baby due to prolonged hours of labour. Factors responsible for cervical dilatation, other than Para sympathomimetic mediators, like spasmolytic effect and relaxation of pelvic muscles, smooth

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Corresponding Author:

Dr. Jay Manoj Sheth,
#B-11, Ladiwala Bhavan,
S. V. Road, Kandivali (W),
Mumbai- 67, Maharashtra.
E-mail: drjaysheth@yahoo.com
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muscle relaxation of cervix, softening and ripening of cervix, etc. are also affected by hyoscine-N-butylbromide.^{2,3}

Aims and Objectives

1. To evaluate the efficacy of Buscopan suppository in reducing duration of active stage of labour.
2. To evaluate the safety of Buscopan suppository.

MATERIALS AND METHODS

To study effect of Buscopan on duration of labour, which supposedly enhances rate of dilatation of cervix; we were mainly concerned with active phase in 1st stage of labour.⁴

Because it was difficult to determine exactly when cervix becomes fully dilated, 2nd stage was also included in study, and end point was taken as delivery of baby. Thus, In this study, "active stage of labour"– term refers to active phase of 1st stage and 2nd stage of labour.

Study Design

Randomized controlled prospective study in primiparous women with single ton intra-uterine full-term pregnancy, who go into labour spontaneously, in tertiary care institute.

Duration of Study

1st Jan 2009 to 31st Dec 2009

Sample Size

Study group – 25 women were given single Buscopan suppository 10 mg, at 3 cm cervical dilatation.

Control group – 25 women were not given any medication.

Sampling Technique

Simple random method.

All registered primiparous women giving consent were allotted study or control group by simple random method.

Time of administration

Suppository was given per rectally at 3 cm cervical dilatation, post-amniotomy.^{2,5}

Inclusion Criteria

1. Primipara.
2. Spontaneous labour at term, 38 to 42 weeks (266 to 294 days).
3. Single-ton pregnancy.
4. Vertex presentation, station [-2] or below at onset of active stage of labour.
5. Cervical effacement \geq 50% at onset of active stage of labour.
6. Normal admission CTG.
7. Post-amniotomy – clear liquor and normal CTG.

Exclusion Criteria

1. Age of mother less than 20 years or more than 30 years.
2. Previous abortion, spontaneous or induced.
3. Previous preterm delivery.
4. Birth weight of first child less than 2.5 kg.
5. Presentations other than vertex.

6. Non-engaged head.
7. CPD.
8. Women with high risk factors, in previous or present pregnancy- like pre-eclampsia, ante-partum haemorrhage, Gestational diabetes, Anaemia, Heart disease, any medical or surgical disorder.
9. History of procedure involving dilatation of cervix other than previous normal delivery.
10. History of cervical/perineal tear in previous delivery.
11. Previous uterine scar.
12. Contraindications to vaginal delivery.
13. Meconium.
14. Any contraindication for Buscopan usage.

Method

Informed, written consent was taken from all women.

Detailed history was taken including demography details, presenting complaints, past / family / personal / drug / obstetric / immunization /menstrual history, etc. Data collection was done with pre-set questionnaire.

For all women on admission, general and systemic examination was done to rule out any medical or surgical disorder or high-risk factors, perineal shaving was done, enema was given.

Internal examination was done in all women by same doctor (to minimize inter-observer variation) to note dilatation, effacement, station, presentation, position, pelvic adequacy, membrane status and liquor, etc.

For all women, admission CTG was done, venous access secured prophylactically.

At 3 cm cervical dilatation, amniotomy was done in all women. Only women having clear liquor and normal CTG, post-amniotomy, were selected for study.

By simple random method, woman were allotted study and control group.

Women in study group were given 10 mg Buscopan suppository (stored in refrigerator) per-rectally.⁶ Women in control group were not given any medications.

All women were allowed to have liquid diet, at libitum. All women were confined to bed during active stage, allowed sit or move in bed.

All women were motivated to pass urine frequently. During second stage of labour, before crowning, bladder was emptied with the help of disposable catheter. And if amount of urine drained was found to be more than 200 cc, it was labelled as having urinary retention.^{7,8}

Labour progress was monitored with the help of WHO partograph. As per protocol of institute 2 hourly internal examination was done in all women to note progress of labour, every time by same doctor.

10 cc of 2% Xylocaine was infiltrated locally, and left medio-lateral episiotomy was given to all women before crowning.

Deliveries were conducted in dorsal position.

Following delivery of baby; cord clamped, cut and ligated using sterile procedure; and baby handed over to neonatologist. 500 ml of lactated Ringer's solution containing 10 IU of oxytocin was infused to all women.

Following delivery of placenta and after births, 0.2 mg methyl-ergometrine was given intravenously to all women. Local examination was done in all women to rule out any tear or extension of episiotomy. Episiotomy was sutured in three layers using 2-0 rapid Vicryl.

"Interval between amniotomy and delivery of baby was recorded as duration of active stage of labour."

All women were monitored for two hours following delivery of after births to diagnose timely any complication, should it occur, especially if there was any post-partum retention of urine.^{9,10}

All babies were examined by neonatologist to ensure that babies did not have any ill-effects due to Buscopan. Again they were examined after 24 hours and after 48 hours to see for any delayed effect, and other routine examination and immunization, as per institute protocol.^{6,11}

Statistical Analysis

Data collection was done with the help of partograph and pre-set questionnaire.

Statistical significance of difference in incidence of ill-effects between study and control group was calculated with the help of test for standard error of difference between two proportions.

Statistical significance of difference in duration of active stage of labour between study and control group was calculated by using unpaired "t" test.

RESULTS

All women involved in study were primiparous women with previous one normal delivery, birth weight of baby being more than 2.5 kg; without any previous abortions.

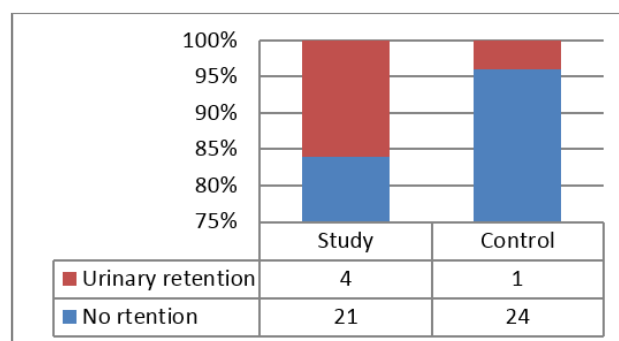
All women were in spontaneous labour at term, with vertex presentation. Station was ≥ -2 to ≤ 0 at beginning of active stage of labour. Effacement of cervix was $\geq 50\%$ at beginning of active stage of labour.

All babies born were normal at birth, APGAR being $\geq 9/10$ at birth, at one minute and five minutes; with normal course in first 48 hours.

No foetus suffered any ill-effects due to Buscopan.

All mother in either groups had no any ill-effects of Buscopan other than nausea, vomiting or urinary retention. However, there was no statistically significant difference in incidence of nausea and vomiting, which are common in labour.

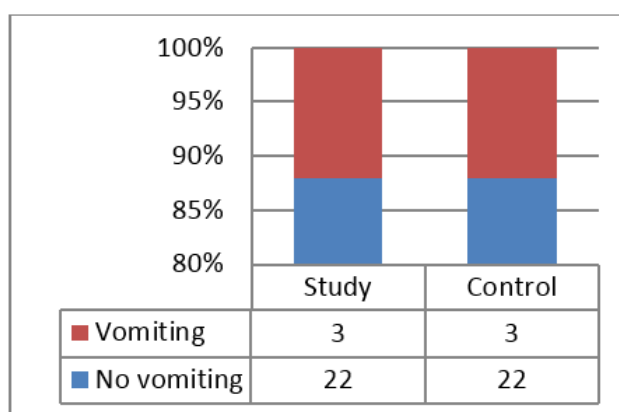
Four women in study group had retention of urine, incidence being 16%. Only one patient in control group had retention of urine, incidence being 4%. No patient had difficulty in micturition post-partum (everybody passed urine within two hours after birth).



Graph 1

Difference in incidence of urinary retention in study and control group was statistically not significant (p value < 0.05).

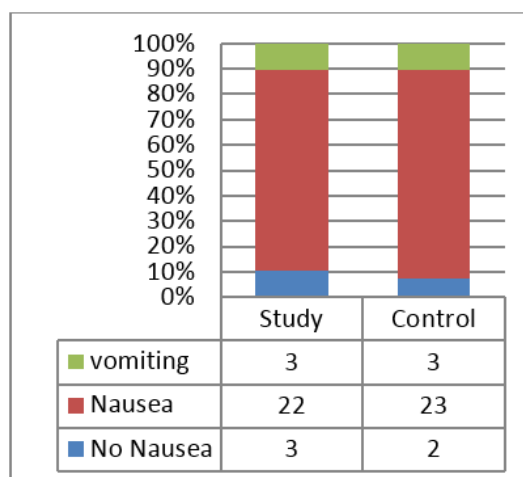
Three women out of 25 had vomiting in study as well as control group.



Graph 2

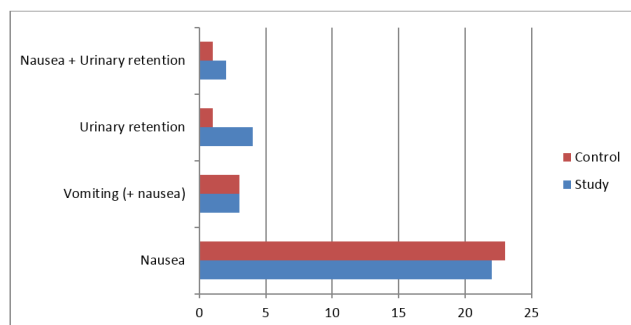
22 women in study group had nausea, out of which three women had vomiting, incidence of nausea being 88% in study group.

23 women in control group had nausea, out of which three women had vomiting, incidence of nausea being 92% in control group.



Graph 3

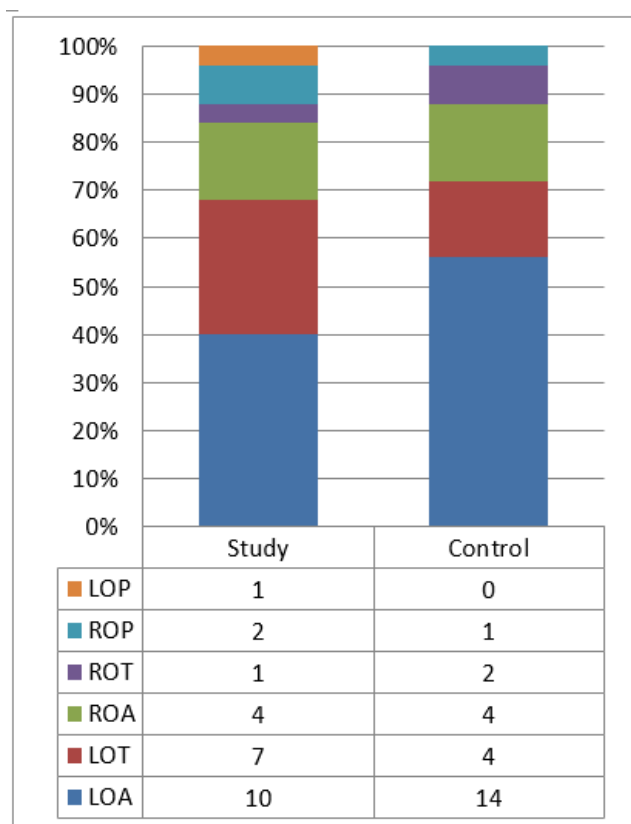
Difference in incidence of nausea in study and control group was statistically not significant (p value < 0.05).

**Graph 4**

Many women had nausea, however it can't be attributed specifically to use of Buscopan, as it is seen commonly in parturient women.

Less than 20% women had either vomiting or retention of urine.

Out of ill-effects suffered by women, only urinary retention can be assigned specifically to use of Buscopan, incidence of it being 12% more in study group than control group, however it was statistically not significant.

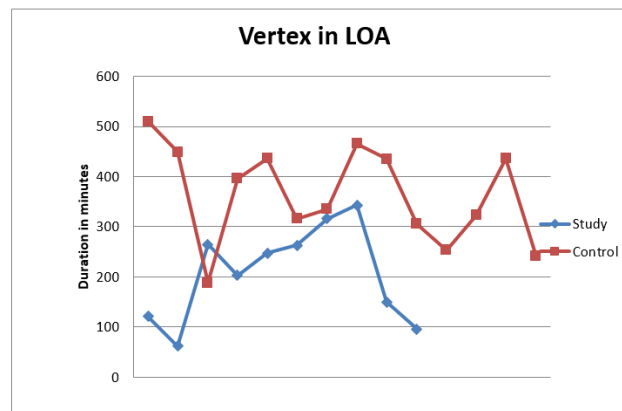
**Graph 5**

Above chart shows different positions of fetuses at 3 cm cervical dilatation, in study as well as control groups.

Duration of active stage of labour has been grouped and compared separately for different vertex position of foetus. This is because duration of labour as well as rate of cervical dilatation (slope of maximum acceleration) and descent of head is different for different vertex positions.

In study group, in 10 out of 25 women, fetuses were in left occipito-anterior (LOA) position. In control group, in 14 out of 25 women, fetuses were in LOA position.

Incidence of LOA was 48%, in this study.

**Graph 6**

Mean duration of active stage of labour in study group women with foetus in LOA position was 206.6 minutes.

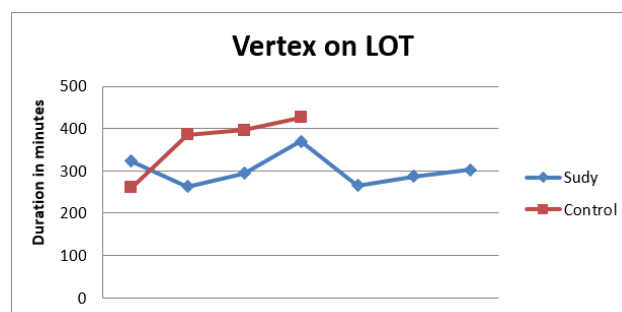
Mean duration of active stage of labour in control group women with foetus in LOA position was 363.57 minutes.

Mean duration of active stage of labour in study group was approximately 157 minutes less than the same in control group.

In study group, in 7 out of 25 women, fetuses were in left occipito-transverse (LOT) position.

In control group, in 4 out of 25 women, fetuses were in LOT position.

Incidence of LOT was 22%, in this study.

**Graph 7**

Mean duration of active stage of labour in study group women with foetus in LOT position was 300.71 minutes.

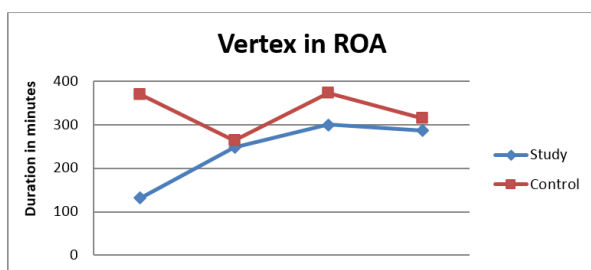
Mean duration of active stage of labour in control group women with foetus in LOT position was 366.75 minutes.

Mean duration of active stage of labour in study group was approximately 66 minutes less than the same in control group.

In study group, in 4 out of 25 women, fetuses were in right occipito-anterior (ROA) position.

In control group, in 4 out of 25 women, fetuses were in ROA position.

Incidence of ROA position was 16%, in this study.

**Graph 8**

Mean duration of active stage of labour in study group women with foetus in ROA position was 241.5 minutes.

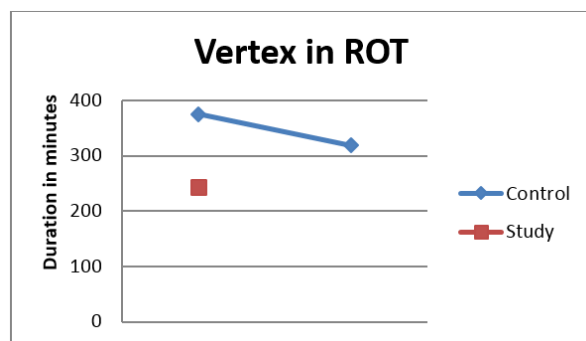
Mean duration of active stage of labour in control group women with foetus in ROA position was 330.25 minutes.

Mean duration of active stage of labour in study group was approximately 89 minutes less than the same in control group.

In study group, in 1 out of 25 women, foetus was in right occipito-transverse (ROT) position.

In control group, in 2 out of 25 women, foetuses were in ROT position.

Incidence of ROT position was 6%, in this study.

**Graph 9**

There was only one patient in study group and duration of active stage of labour was 243 minutes.

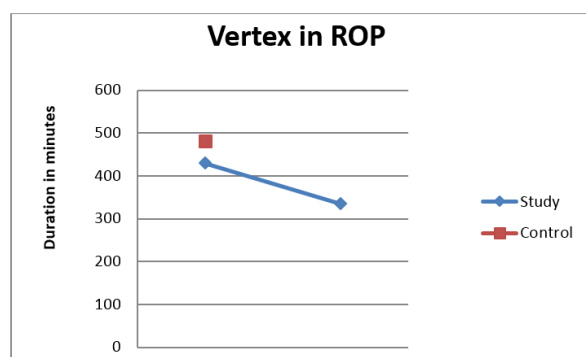
Mean duration of active stage of labour in control group women foetus in ROT position was 347 minutes.

Duration of active stage of labour in study group was 104 minutes less than the same in control group.

In study group, in 2 out of 25 women, foetuses were in right occipito-posterior (ROP) position.

In control group, in 1 out 25 women, foetus was in ROP position.

Incidence of ROP position was 6%, in this study.

**Graph 10**

Mean duration of active stage of labour in study group women with foetus in ROP position was 382.5 minutes.

There was only patient in control group foetus in ROP position and duration of active stage of labour was 482 minutes.

Mean duration of active stage of labour in study group was approximately 100 minutes less than the same in control group.

Only one patient in whole study was having foetus in left occipito-posterior (LOP) position, which was included in study group and duration of labour was 381 minutes.

Statistical Analysis

Study Group-

Mean (duration of active stage of labour) = 261.04 (minutes)

Standard deviation = 91.07

N = 25

Control Group-

Mean (duration of active stage of labour) = 364.56 (minutes)

Standard deviation = 86.05

N = 25

Standard Error (of difference between two mean) = 25.06

Degree of freedom = 48

Difference in mean duration of active stage of labour amongst two groups was 103.52 minutes.

Using 'Unpaired - t test', difference in duration of active stage of labour between study and control group was found to be statistically significant (P value < 0.05), i.e. difference was less than 5% likely to be due to any chance error.

Using test for standard error of difference between two proportions, it was found that difference in incidence of side-effects of Buscopan between study group and control group was not statistically significant (Z < 1.96).

DISCUSSION

Buscopan has been in usage for more than half a century in varying doses (10mg, 20mg, 30mg, 40mg) and varying routes (intramuscular, intravenous, rectal, oral). Corsen et al, studied various uses and modes of action of Buscopan in obstetrics and gynaecology, and found that most prompt action occurred with intravenous and per rectal (suppository) routes, optimal time of administration was at 2.5-3 cm cervical dilatation and no significant side effects were observed with up to 30 mg dose².

In present study, there was shortening of mean duration of active stage of labour noted in women who were given Buscopan suppository as compared to those who were not given. Difference noted was approximately 104 minutes.

There were no any ill-effects of Buscopan noted on neonates. There was normal APGAR in all neonates.¹¹

There were no any ill-effects of Buscopan seen in any women. Few women had difficulty in micturition, difference in incidence between either group was not statistically significant. There was no incidence of dystocia, and no patient crossed action line on partogram.^{12,13,14}

Buscopan has been used as cervical spasmolytic, analgesic and for shortening of labour. Results of different studies conducted in last two decades are corroborated with our study.

Bhattacharya et al, studied effect of 20 mg Buscopan intramuscularly on 100 primigravidae and found that mean labour time was shortened by 3 hours 40 minutes and 81% delivered within 8 hours.⁹

Samal et al, showed shortening of labour by 2 hours 42 minutes with 88% women delivering within 8 hours. Neonatal outcomes were similar in two groups.¹⁰

Tewari et al were first to use dose of 40 mg intravenously, but in two divided doses 20 minutes apart, and found labour to be shortened by 5 hours 12 minutes compared to controls.¹⁵

A recent from Jamaica showed shortening of first stage of labour by 32%, without any adverse effects on mother or neonate, with 20 mg intravenous dose.

Whatever adverse effects noted are at high intravenous doses. However, controlled intravenous administration may obviate risk of adverse effects. Rectal route is popular for following reasons – safety, rapid onset of action (similar to intravenous route) and lesser dosage required as hepatic metabolism is by passed.¹⁶

Limitations of this study is that it is not double-blind study. Also due to small sample size and short study period, outcomes like foetal heart rate abnormalities, long term neuro-developmental outcomes, maternal side effects may not have surfaced.

CONCLUSION

Mean duration of active stage of labour in study group was ~104 minutes less than the same in control group.

There was statistically significant shortening in duration of active stage of labour, by 104 (± 25) minutes (p value < 0.05).

There were no ill-effects seen in babies. All babies passed urine and stool well within physiological limits.

No patient had any known serious complications of Buscopan.

Few women experienced difficulty in micturition, though statistically not significant.

Overall patient compliance was good as Buscopan also has spasmolytic and analgesic effects.

It is concluded that Buscopan suppository effectively and safely reduces duration of active stage of labour.

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