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Hyoscine-N-butylbromide Versus Atropine as Labour Accelerant and Analgesic: A Randomized Clinical Trial

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Abstract: The aim of this study was to compare the efficacy of atropine and hyoscine-N-butyl bromide in reducing the pain and time length of the first stage of labour. In a single blind randomized clinical trial, 120 term pregnancies were enrolled from July 2009 to March 2011. A parallel design was used to randomly assign subjects into two equal groups including 60 participants in each group. Hyoscine-N-butylbromide was administered 40 mg intravenously in the first group and intravenous atropine was given in second group at a dose of 0.5 mg. The participants of the two trial arms were similar according to the distribution of background variables. The pain trend through the study follow up was found to be different between groups ($p<0.05$). Mean length of the first stage of labor was 218.5 min (SD: 81.4) in hyoscine versus 339 min (SD: 83.3) in atropine group ($p<0.001$). Mean 1st and 5th min APGAR score was similar in both groups. Drug side effects were less frequent in hyoscine group observed in 13 cases compared to atropine group observed in 56 cases ($p<0.001$). Hyoscine appeared to be preferable to atropine specially in reducing the length of first stage of pregnancy.

Key words: Labor, labor induction, hyoscine, analgesic, pregnancy

INTRODUCTION

Labour acceleration and active management is the practice of decreasing the total duration of labour without causing any adverse effects on the mother or fetus (O' driscoll *et al*., 1973). Several drugs are investigated to accelerate the labour or reduce the pain through the labour. Atropine and hyoscine are among these. Atropine although used earlier, has always been thought of to be replaced with an alternative drug having fewer side effects. Hyoscine-N-butyl Bromide (HNB) is an effective antispasmodic parasympatholytic agent and a known semisynthetic derivative of scopolamine. It has been shown to have analgesic effect in some medical situations. Fast pain reduction has been shown to be achieved by HNB in renal colic and also in patients with biliary colic using a 20 mg injectable dose (Tytgat, 2008). Nevertheless, no analgesic effect of a similar dose has been shown to exist after surgical or shock-wave procedures (Habib *et al*., 2001; Tytgat, 2008; Wilson *et al*., 1999). Contrary to hyoscine, atropine crosses the blood-brain barrier. So, in case of hyoscine no central action is anticipated and lower rate and severity of side effects may be encountered when compared to atropine at the therapeutically administered doses (Samuels *et al*., 2007). Although, the two drugs have been investigated for their effect on labour process, parallel comparison of these agents are rarely done in previous research attempts. The aim of this study was to compare the efficacy of atropine and hyoscine-N-butyl bromide in reducing the pain and time length of the first stage of labor.

MATERIALS AND METHODS

In a single blind randomized clinical trial, 120 term pregnancies were enrolled from July 2009 to March 2011. A parallel design was used to randomly assign subjects into two equal groups including 60 participants in each group. Hyoscine-N-butyl bromide was administered 40 mg intravenously in the first group and intravenous atropine was given in second group at a dose of 0.5 mg. The random sequence was generated using Randlist 11 statistical software package. The study setting was Alzahra University Hospital Delivery Ward in Tabriz, Iran. Sample size was estimated to ensure 90% statistical power and 95% confidence level to detect 10% of difference in analgesia from the 36% base for hyoscine-N-buutylbromide. The patients were kept masked to the type of treatment. The inclusion criteria were: (1) Age range of 18-35 years; (2) Term pregnancy between 37-41 weeks of gestational age; (3) Lack of risks and contraindication of vaginal delivery; (4) Cervical dilatation of 3-4 cm and 60-70% effacement; (5) Lack of specific comorbidities; (6) Cephalic presentation. Exclusion criteria were: Induction started cesarean section

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indications, premature rupture of membranes. Spontaneously started deliveries after being assigned to receive either HNB or atropine and undergoing the treatment protocol were followed through the delivery phase to be completed. The time period between injection time, at early active delivery phase and complete dilatation was considered as first phase of delivery. Pain severity was assessed using Visual Analogue Scale (VAS) to score the pain at a range of 1-10 points of scale. Pain was assessed every two hours up to six hours after injection. paretograph form was completed. Drug side effects, pregnancy outcomes and neonatal outcomes were investigated.

Statistical analysis was done using descriptive and bivariate analytical methods. Independent t-test, Man-Whitney U test and chi-squared test were used to analyze data. Repeated measurements analysis was also used to analyze pain scores measured repeatedly over study period. p-value<0.05 was considered as statistical significance level. Study protocol was approved by committee of ethics in Tabriz University of medical sciences.

RESULTS

The participants of the two trial arms were similar according to the distribution of background variables like age, gestational age, parity and some other variables as shown in Table 1. Small differences observed between groups were not found to be statistically significant.

The reasons for admission in hyoscine group were pain (80%), vaginal discharge (16.7%) and decreased motility (3.3%). In atropine group the reasons for admission included pain (85%), vaginal discharge (10%)and decreased motility (5%). The differences were not statistically significant. Mean cervical dilatation was similar between groups both at admission and through the injection phase (Fig. 1).

Mean effacement at admission was 40.9 (SD: 21.1) in hyoscine group and 42 (SD: 22.5) in atropine group. The pain trend through the study follow up was found to be different between groups (p<0.05, Table 2).

Drug side effects were less frequent in hyoscine group observed in 13 cases compared to atropine group observed in 56 cases (p<0.001). Dry mouth was the most common side effect in both drugs observed in nine patients receiving hyoscine and 53 patients receiving atropine (p<0.001). Palpitations and nausea were other two side effects significantly more frequent among patients receiving hyoscine versus atropine group (p<0.01). Dizziness was similarly observed among two patients in both groups. Meconium stained amniotic fluid was observed to be as low as two deliveries in atropine group and four deliveries in hyoscine group without statistical significance. Postpartum hemorrhage was not experienced in onoe of the groups.

Mean length of the first stage of labor was 218.5 min (SD: 81.4) in hyoscine versus 339 min (SD: 83.3) in atropine group (p<0.001). Mean 1st min APGAR score was 8.9 (SD: 0.4) in hyoscine group compared to 8.88 (SD: 0.4) in atropine group but the difference was not statistically significant. The 5th min APGAR score was also similar in both groups (p-0.08).

Table 1: Baseline comparison of background variables between groups

Variables	Hyoscine group	Atropine group
Age (years)	25.0±4.750	24.9±0.500
Gestational age (weeks)	39.2±1.100	39.4±0.900
Parity	0.93±0.77	0.88±0.69
Grav	1.63±1.20	1.68±0.87
Abortion	0.2±0.480	0.08±0.28

Values are as Mean±SD

Table 2: Mean and standard deviations of pain score compared over time between the atropine and hyoscine recipients

	Hyoscine	Atropine
Baseline	5.13±1.66	7.09±1.34
2 h	7.08±1.48	7.71±1.23
4 h	8.5±1.02	9.32±0.97
6 h	8.67±0.92	9.77±0.57

Values are as Mean±SD

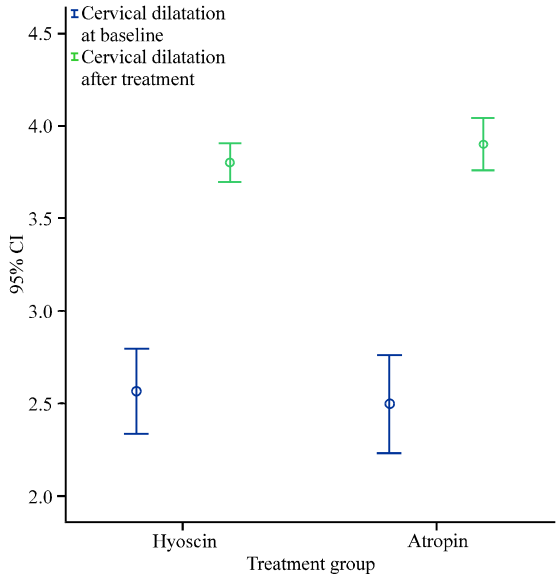

Fig. 1: Mean cervical compared between groups both at admission and after treatment

DISCUSSION

This study found the duration of the first stage of labor to be significantly shorter among women receiving Hyoscine-N-butylbromide compared to atropine. Mean length of the first stage of labour has been reported to vary from 124-319 in different studies using hyoscine (Aggarwal *et al*., 2008; Gupta *et al*., 2008; Samuels *et al*., 2007; Sirohiwal *et al*., 2005). The results of Aggarwal *et al*. (2008) was quite close to our estimate of the first stage of labor using hyoscine (Aggarwal *et al*., 2008). However, regarding the duration of the first stage of labor while using atropine our findings can be assumed as upper extreme compared to the previous Iranian research (Rabiei and Shabani, 2001). As the duration of the first stage of labor is dependent on methodological factors and other factors like parity, a comparison based on results of separate studies comparing atropine and hyoscine cannot be valid enough. We were able to retrieve one similar study that had compared hyoscine and atropine finding the two drugs not to show statistically significant effect on duration of the first stage of labor (Mortazavi and Rakhshani, 2004). This can be due to lower statistical power due to higher variability of factors or even methodological issues. Also, it should be considered that their study was only conducted on multipara women, thus the results may be different due to variation in parity.

CONCLUSION

Hyoscine appeared to be preferable to atropine specially in reducing the length of first stage of pregnancy.

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