



### Research report

## EVALUATION OF HYPOTENSION AND ALLERGIC REACTION WITH PARENTERAL DROTAVERINE IN A TERTIARY CARE HOSPITAL

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### ABSTRACT

**Background:** Drotaverine is an excellent anti-spasmodic and a vital drug for relieving spastic visceral pain. However, the incidence of hypotension and allergic skin reactions is a concern with drotaverin's use.

**Aim:** This study was intended to evaluate the risk of adverse effects with drotaverine in hospital patients.

**Method:** It was a retrospective cross-sectional study for the total cases on drotaverine inj. for the year 2017. Data collection form was used.

**Results:** 1 out of a total of 62 patients suffered hypotension after administration of drotaverine injection (0.016%). Patient suffering hypotension was on dimenhydrinate injection q8hrs. regularly. There was no case of allergic skin reaction with the use.

**Conclusion:** Use of drotaverine is safe with due consideration to mild risk of hypotension. Regular use of hypotensive drugs should be watched for while using drotaverine.

**Key Words:** Drotaverine, visceral pain, hypotension

### INTRODUCTION

Drotaverine hydrochloride is an analogue of papaverine with smooth muscle relaxant properties. It is a non-anticholinergic antispasmodic, which selectively inhibits phosphodiesterase IV and is accompanied by a mild calcium channel-blocking effect. Adverse effects with drotaverine hydrochloride, such as hypotension, vertigo, nausea, and palpitation, are mostly mild. It can be supposed that intravenous drotaverine hydrochloride might be a feasible antimotility alternative to intravenous hyoscine-N-butylbromide. Drotaverine is a cholinergic muscarinic antagonist, an antispasmodic, effective in treatment of spasm or twitches of the smooth muscles and pain. Drotaverine is primarily indicated in conditions like cervical spasm during labor, biliary spasm, cholangitis, cholecystitis, cholecytolithiasis, cystitis, nephrolithiasis, papillitis, smooth muscle spasm, stone formation, ureterolithiasis, urinary spasm, urolithiasis, vesical tenesmus. It is also used to relieve pain caused due to irritable bowel syndrome, headache and menstrual cycle. However, Drotaverine is contraindicated in conditions like cardiac, renal and hepatic insufficiency and 2<sup>nd</sup> & 3<sup>rd</sup> degree AV block. Intravenous drotaverine provides effective pain relief in more than two-thirds of patients with renal colic, with no serious side-effects. [1]

Several studies have been done showing use of drotaverine for acceleration of labor but is less effective in relieving of labor pains in addition atonic postpartum hemorrhage was seen more common[1, 2]. Intramuscular administration of drotaverine in dilatation phase of uncomplicated pregnancies was found to reduce the duration of cervical dilatation, total

funding for this research.

**Competing Interests:**

The authors declare no competing interests

Additional information is available at the end of the article.

duration of labor and incidence of cervical tears, with no change in stage 2 and 3 of labor[3]. In another study Intramuscular drotaverine decreased the time to spontaneous micturition and decreased the incidence of urinary bladder catheterization. [4]

As a smooth muscle relaxant, drotaverine will exacerbate existing hypotension symptoms in patients and cause such symptoms to appear where they are absent for some individuals, according to Biotavia. This side effect is particularly important to consider for those who have poor circulation or low blood pressure prior to taking the medication. For these patients, drotaverine can cause extreme hypotension leading to fainting and collapse.

The aim of this study is to evaluate incidence of hypotension and allergic reaction with Drotaverine. It enhances other spasmolytic effects (including M-cholinblockers), hypotension caused by tri-cyclic anti-depressants, quinidine, procainamide. It reduces the morphine spasmogenic activity, anti-parkinsonic properties of levodopa (tremor and rigidity increase are observed). [5]

**METHODOLOGY**

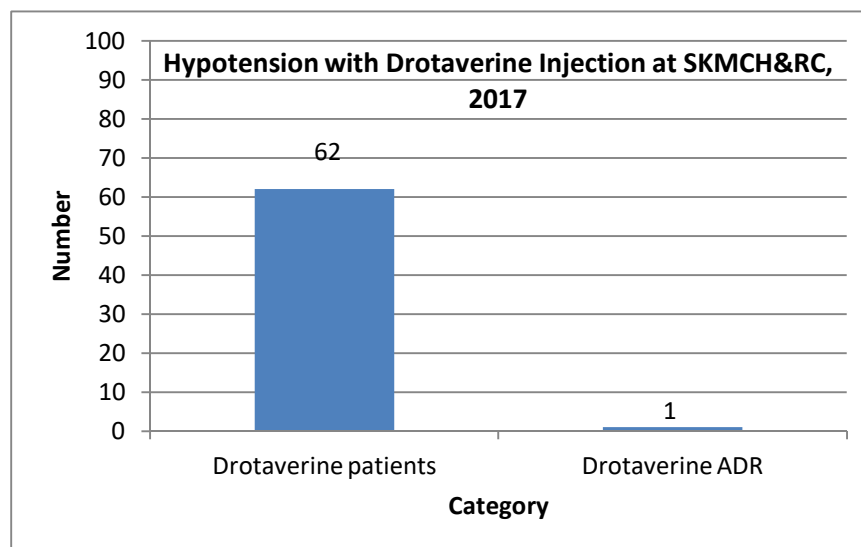
A retrospective cross-sectional study was designed by enrolling a total of 62 patients. Data collection form was used for gathering information.

**Inclusion criteria:** All the patients, irrespective of gender, ethnicity, above 18 years of age, were enrolled in the study.

**Exclusion criteria:** All the patients, below 18 years of age were excluded from the study.

**RESULTS**

One out of 62 patients experienced hypotension – an incidence of 0.016%



**DISCUSSION:**

Drotaverine is a very good therapeutic option for anti-spasmodic activity. With hyoscine injection withdrawn from international market, drotaverine is an excellent drug for spastic smooth muscle pain. Risk of allergic reactions and hypotension has been a concern with the use of this drug. Official literature mentions a <0.1% risk of hypotension. This particular

adverse effect is more significant with IV than I/M route of administration. Furthermore, rapid injection increases the risk of drotaverine adverse effects. There have been anecdotal reports of physicians concerned on safety of drotaverine in vulnerable cases in public sector. SKMCH received multiple reminders from Punjab drug control unit (PDCU) on concern over drotaverine safety. We evaluated in-house data for the year 2017. The drug is non-formulary at our institute; hence use is not very common. A total of 62 patients received parenteral drotaverine for the year 2017. 1 out of 62 (0.016%) suffered hypotension right after administration of IV injection. The patient suffered a single episode of B.P 90/60 – a drop from 125/70 earlier. NS (0.9%) was initiated immediately which normalized the B.P in next 40 minutes. Medication review revealed regular use of dimenhydrinate 50mg IV q8hrs for 2 days. Hypotension with drotaverine is expectedly enhanced with regular use of drugs with hypotensive potential e.g. anti-hypertensives, anti-cholinergics, tricyclic antidepressants etc.

Allergic skin reaction with drotaverine has been a concern in the anecdotal reports from public sector. There was no case of allergy reported with the drug at SKMCH for the year, 2017.

Drotaverine appears a good therapeutic option with acceptable adverse effect profile. Extra caution is recommended for use with hypotensive potential drugs. Parenteral injections should not be administered rapidly. I/M route is preferred over I/V in terms of safety profile.

## CONCLUSION

Parenteral drotaverine use is safe in adults. However, patients on medications like anti-hypertensives, anti-histamines and tri-cyclic anti-depressants should be observed cautiously while using drotaverine injection for the risk of hypotension.

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