

Valethamate bromide: Is there any proof of efficacy and safety for its use in labor?

Gitanjali B

Section Editor

It has often been said that medicine is an art based on conjecture and improved by murder. Valethamate bromide is a drug widely used all over India by obstetricians for facilitating cervical dilatation in the first stage of labor.^[1] It is sold under many brand names such as Epidosin, Dilaton, Valosin, Valamate, Osdil etc. Even though this drug is available in India for more than a quarter of a century, it is still not listed in the Indian Pharmacopoeia. None of the well established textbooks of pharmacology from North America and the United Kingdom mention the drug, though one popular textbook from India makes a mention.^[2] Reliable sources of information like the British National Formulary also do not list it. A Google Scholar search on the term produces ten hits and a PubMed search on the molecule throws up just seven articles with only two clinical trials published in peer reviewed indexed journals. This seems to be the total quantity of information from the web sources. Yet, it is listed in the Tamil Nadu Medical Services Corporation procurement list as the item with the drug code 460.^[3]

This raises an interesting question. How and why is this drug so popular when there is so little information of its safety and efficacy? It is obvious that the drug is being used mainly due to three reasons. First, cervical ripening and dilatation is a natural

feature of labor and using drugs to hasten the process may be beneficial in crowded labor rooms to facilitate the reduction in time spent in monitoring women in labor rather than any sound medical reason. Second, there are also no “new” drugs for this indication since evaluating drugs in pregnant women has its own share of problems and ethical concerns. Therefore, continuing to use something which was introduced when the criteria for using drugs were less stringent is easy. Third, the promotional pressures from the pharmaceutical companies are relentless. Obstetricians may be duped to believe that they are indeed using a drug which is listed in the Indian Pharmacopoeia (I.P.)

The carton of Epidosin lists three ingredients on it [Figure 1]. One is valethamate bromide and the other two are normal saline and water for injection. It is interesting to note that both saline and water have I.P. listed next to their names. What is missed by the undiscerning mind is that there is no I.P. next to valethamate bromide. This is perhaps why many practicing obstetricians have failed to question the very basis for the use of this drug. Is it efficacious? There are no studies which prove it, and the meagre data shows that it is ineffective.^[4,5] One study which mentions that valethamate is as effective as drotavrine^[6] is an unblinded, underpowered trial which has used inappropriate statistical tests for data analysis, while another study comparing the same drugs says it is less efficacious than drotavrine but has more side effects.^[7]

Is it safe? Not really, since two studies have recorded adverse events of moderate intensity^[4,5] and one study noted mild events.^[7] This brings us to the question, whether it should be used in pregnant women at all since both the efficacy and safety have not been adequately documented. The answer to this question can only be an emphatic “no”. The World Health Organization (WHO) has brought out guidelines outlining

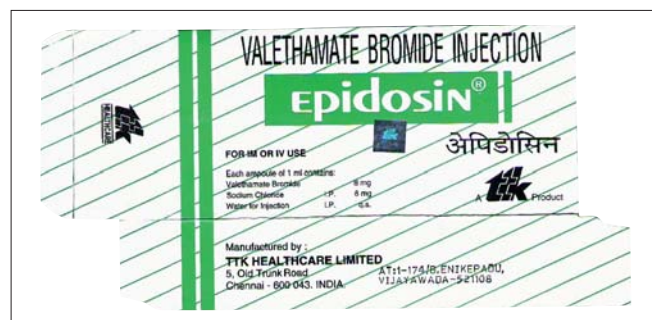


Figure 1: A photograph of the carton of Epidosin (valethamate bromide)

Address for correspondence:

Gitanjali B, Department of Pharmacology, JIPMER, Pondicherry-605 006. Email: gibatatman@gmail.com

DOI:10.4103/0976-500X.64528

Gitanjali: Valethamate bromide

the criteria for the selection of drugs for any indication and valethamate bromide does not satisfy even one of them. It is hoped that obstetricians will stop using this drug in pregnant women until there is convincing evidence of its efficacy and safety and it is listed in the Indian Pharmacopoeia. Essential medicine lists and procurement lists should not list this drug which does not have the evidence to support its continued use in pregnant women.

REFERENCES

1. Madhu C, Mahavarkar S, Bhav S. A randomised controlled study comparing drotaverine hydrochloride and valethamate bromide in the augmentation of labour. Arch Gynecol Obstet 2009; DOI 10.1007/s00404-009-1188-8.
2. Tripathi KD. Essentials of Medical Pharmacology. 6th ed. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd; 2008.
3. <http://www.tnmisc.com/tnmisc/new/html/services.php#> [accessed on 13th November 2009]
4. Kuruvila S, Jasper P, Peedicayil A, Mathai M. A randomized controlled trial of valethamate bromide in acceleration of labor. Int J Gynaecol Obstet 1992; 38:93-96.
5. Yilmaz B, Kart C, Kelekci S, Gokturk U, Sut N, Tarlan N, Mollamahmutoglu L. Meperidine versus valethamate bromide in shortening the duration of active labor. Int J Gynaecol Obstet. 2009 Nov;107:126-9. Epub 2009 Aug 6.
6. Ajmera SK, Shah PK, Shinde GA. Bombay Hospital Journal. Comparative Study of Drotaverine v/s Valethamate in Cervical Phase of Labour. [webpage on internet] Available at: http://bhj.org/journal/2006_4802_april/html/org_res_305-309.html [cited on: 2009 Nov 13]
7. Sharma JB, Pundir P, Kumar A, Murthy NS. Drotaverine hydrochloride vs. valethamate bromide in acceleration of labor. Int J Gynaecol Obstet 2001; 74:255-60.

Source of Support: Nil, Conflict of Interest: None declared

Author Help: Online submission of the manuscripts

Articles can be submitted online from <http://www.journalonweb.com>. For online submission, the articles should be prepared in two files (first page file and article file). Images should be submitted separately.

1) First Page File:

Prepare the title page, covering letter, acknowledgement etc. using a word processor program. All information related to your identity should be included here. Use text/rtf/doc/pdf files. Do not zip the files.

2) Article File:

The main text of the article, beginning with the Abstract to References (including tables) should be in this file. Do not include any information (such as acknowledgement, your names in page headers etc.) in this file. Use text/rtf/doc/pdf files. Do not zip the files. Limit the file size to 1024 kb. Do not incorporate images in the file. If file size is large, graphs can be submitted separately as images, without their being incorporated in the article file. This will reduce the size of the file.

3) Images:

Submit good quality color images. Each image should be less than **2048 kb (2 MB)** in size. The size of the image can be reduced by decreasing the actual height and width of the images (keep up to about 6 inches and up to about 1800 x 1200 pixels). JPEG is the most suitable file format. The image quality should be good enough to judge the scientific value of the image. For the purpose of printing, always retain a good quality, high resolution image. This high resolution image should be sent to the editorial office at the time of sending a revised article.

4) Legends:

Legends for the figures/images should be included at the end of the article file.