It would be desirable to provide improved methods for treating patients suffering from bladder pain and irritative voiding symptoms. In particular, it would be desirable to provide a means for providing a sustained treatment effect for several days or weeks or more beyond the active treatment period.

Summary

Improved methods of treating a patient having bladder pain and/or irritative voiding symptoms are provided. In one embodiment, the method includes administering to the patient's bladder lidocaine or another anesthetic agent continuously over a treatment period of 24 hours or more in an amount effective to achieve a therapeutic effect which is sustained beyond the end of the treatment period, as it has been discovered that a sustained treatment effect of bladder pain and irritative voiding symptom beyond the end of the active treatment period can be achieved by providing continuous intravesical treatment with lidocaine. Essentially any means of delivering the lidocaine into the bladder can be used so long as provides therapeutically effective amounts of lidocaine to the bladder continuously over the treatment period of 24 hours or more. The continuous lidocaine treatment over multiple days is also effective to improve bladder mucosal abnormalities (pathological and inflammatory features). This method of treatment not only provides the patient with pain relieve and a reduction in urgency during the treatment period, but also surprisingly provides an extended benefit well beyond the end of treatment. In another aspect, a method of treating a patient having bladder pain and/or irritative voiding symptoms is provided that includes administering lidocaine to the patient in an amount effective to achieve a measurable plasma concentration of lidocaine in the patient continuously over a treatment period of at least 24 hours.

In one aspect, there is provided the use of lidocaine in the manufacture of a medicament for use in the treatment of bladder pain and/or irritative voiding symptoms, wherein the medicament is to be continuously administered over a treatment period of from 2 to 28 days in an amount effective to achieve a therapeutic effect which is sustained beyond the end of the treatment period,

and wherein the continuous administration is into a patient's bladder at a mean average amount from 10 mg to 30 mg lidocaine (FBE) per day of the treatment period.

In one aspect, there is provided a drug delivery device comprising a medicament as defined herein, configured to release lidocaine when inserted into the bladder, wherein the drug delivery device is configured to release lidocaine continuously from 2 to 28 days, preferably from 3 to 21 days.

In one aspect, there is provided the use of lidocaine in the manufacture of a medicament for the treatment of bladder pain and/or irritative voiding symptoms, wherein the medicament is to be continuously administered to the bladder of the patient in an amount effective to achieve a therapeutic effect which is sustained beyond an end of the treatment period,

and wherein the lidocaine is to be administered continuously over a treatment period of from 10 to 28 days,

wherein a cumulative amount of the lidocaine (FBE) administered over the treatment period is between 150 mg and 1000 mg.

Brief Description of the Drawings

FIG. 1 is a plan view of an embodiment of a drug delivery device.

FIG. 2 is a plan view of the drug delivery device shown in **FIG. 1**, illustrating the drug delivery device inside a deployment instrument.

FIG. 3 is a cross-sectional view of the drug delivery device shown in **FIG. 1**, taken along line **3-3** in **FIG. 1**.

FIG. 4 is an illustration showing the size of an embodiment of a drug delivery device in comparison to an approximation of the bladder trigone region.

FIG. 5 illustrates examples of shapes for a retention frame of a drug delivery device.

We claim:

1. Use of lidocaine in the manufacture of a medicament for use in the treatment of bladder pain and/or irritative voiding symptoms, wherein the medicament is to be continuously administered over a treatment period of from 2 to 28 days in an amount effective to achieve a therapeutic effect which is sustained beyond the end of the treatment period, and wherein the continuous administration is into a patient's bladder at a mean average amount from 10 mg to 30 mg lidocaine (FBE) per day of the treatment period.

2. The use of claim 1, wherein the duration of continuous release is from 10 to 14 days.

3. The use of claim 1, wherein the cumulative amount of lidocaine (FBE) administration continuously over the treatment period is from 20 mg to 400 mg.

4. The use of claim 1, wherein the rate of lidocaine (FBE) released into bladder is from 15 mg to 30 mg day per day over the first 1 to 4 days of the treatment period and then tapers to a rate of from 15 mg to 3 mg per day over the remainder of the treatment period.

5. The use of claim 4, wherein the measurable plasma concentration of lidocaine does not exceed 65 ng/ml at a time of peak lidocaine exposure in the bladder.

6. The use of claim 1, wherein the rate of lidocaine (FBE) released into bladder is from 25 mg to 60 mg day per day over the first 1 to 6 days of the treatment period and then tapers to a rate of from 25 mg to 10 mg per day over the remainder of the treatment period.

7. The use~~medicament~~ of claim 6, wherein the measurable plasma concentration of lidocaine does not exceed 65 ng/ml at a time of peak lidocaine exposure in the bladder.