

1. Intravesical electromotive drug administration technique: preliminary results and side effects – The Journal of Urology June 1998; Vol 159, No 6: p.1851-1856 –Riedl CR, Knoll M, et al – Municipal Hospital Lainz, Vienna, Austria

A total of 84 patients underwent 215 intravesical EMDA treatments for various bladder disorders during a 3-year period

PROCEDURE	PATIENTS	RESULTS
<p>Local anesthesia for endoscopic bladder surgery.</p> <p>Intravesical Volume: 100-150 cc</p> <p>Lidocaine 1% (3 pts), 2% (4 pts) or 2,6% (4 pts)</p> <p>Epinephrine 0.75 mg</p> <p>2.5 mg midazolam intravenously administered to 5 pts undergoing resection.</p> <p>Current: 15-23 mA</p>	<p>11 pts, 12 EMDA treatments.</p> <p>Performed 20 minutes EMDA treatment (5 pts) or 2 treatment cycles of 15 mins in case of more extensive transurethral procedures (6 pts).</p> <p>Complete TURBT was performed in 5 pts (up to 4 cm as well multifocal tumors), tumor coagulation in 3 and multiple forceps biopsy in 3.</p>	<p>Performance of transurethral bladder tumor resection was painless in 10 of 12 cases (83%). 1 pts reported tolerable pain from a cold forceps biopsy and 1 required general anesthesia because of intolerable pain.</p> <p>Mucosal erythema of the posterior bladder wall observed in 2 pts.</p>

<p>EMDA and hydrodistension for treatment of chronic noninfectious cystitis: IC (16pts), radiocystitis (6 pts), chemocystitis (3 pts), lupoid cystitis (1 pts)</p> <p>Drug solution: 150 cc 2% lidocaine, 0,75 mg epinephrine, 20 mg dexamethasone for 20 mins with maximum current of 22 mA</p>	<p>25 pts, 65 EMDA treatments (1-6/pts)</p>	<p>15 of 25 pts (60%) was free of symptoms for a mean of 6.6 months. 3 (12%) had partial response and 7 (28%) no improvement. Cystometric bladder capacity was increased by an average of 73% from 244 cc before to 421 cc after EMDA with significantly reduced urinary frequency. 6/17 pts respondents (35%) reported moderate and 3/17 (18%) severe discomfort during the first minutes of EMDA before local anesthesia was effected but pain was tolerable and never led to terminate the treatments.</p>
<p>Recurrence prophylaxis for NMIBC 40 mg mitomycin-C in 100 cc bidistilled water 15 mA/20 mins for 4 weekly treatments</p>	<p>2 pts NMIBC, 91 EMDA treatments. pTaG1 (1pts), pTaG2 (14), pT1G2 (2), pTaG3 (3), Cis G3 (2)</p>	<p>9/16 pts (56,5%) were free of recurrence for a mean of 14.1 months (included Cis G3 and 2 of 3 cases of pT1G3)</p>

<p>Detrusor hyperreflexia and or urge incontinence</p> <p>Drug solution: 15-50 mg oxybutynin hydrochloride in 100 cc saline 0.3%</p> <p>Since instillations of 100 cc often cause detrusor contractions and leakage, they initially instilled 50 cc and let the current rise to 8 mA. Current was reset to zero and restarted until pts were able to tolerate 8 mA and the it was raised to 15 mA for 20 mins.</p> <p>Best dosage: 30 mg oxybutynin and increased the dosage at 10 mg increments if no response is observed.</p>	<p>14 pts with detrusor hyperreflexia and or urge incontinence who did not tolerate or improve on oral anticholinergics. 29 EMDA treatments. Pts was monitored for systemic anticholinergic side effects (blood pressure, heart rate, symptoms) during and immediately after EMDA. Bladder symptoms were controlled after 1 day and 1 week.</p>	<p>In 11 pts (78,5%) EMDA of oxybutynin reduced detrusor hyperreflexia. Due to contraction and leakage,treatment was terminated in 3 pts. 3/11 pts showed long term (> 1 week) improvement of bladder symptoms, 4/11 pts less than 1 week.</p> <p>No local or systemic side effects were observed.</p>
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<p>Acontractile detrusor</p> <p>Drug solution: 15-30 mg bethanecol hydrochloride in 100 cc saline 0.3%.</p> <p>15-23 mA for 20 mins</p> <p>Initially used 15 mg bethanecol and increased the dosage at 5 mg increments if no response is observed.</p>	<p>14 pts with cystometric evidence of acontractile detrusors, 20 EMDA treatments.</p> <p>EMDA with saline and bethanecol instillations without EMDA were performed for control.</p> <p>Pts were monitored for cholinergic side effects during EMDA, immediately after, 1 day, 1 week and 1 months after treatments.</p>	<p>In 10/14 (71.4%) pts urodynamic examination showed detrusor contracting during EMDA of bethanecol treatments. Simultaneous cystometry during EMDA recorded intravesical pressure increase, starting about 5 minutes after the initiation of the procedure. Only the combination of intravesical bethanecol and current, and neither alone, increased intravesical pressure. During 20 treatments only once a pts experienced painful bladder contraction which stopped when current was turn off. No side effects were observed</p>
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N°pts/treatments	84/215
Bladder or urethral pain temporarily worsened (*)	10/215 (4.6%)
Severe complications (bladder ulcera)	1/215 (0.5%)
Minor complications (**)	23%
Sistemic side effect	0

(*) almost exclusively in pts with chronic cystitis

(**) mostly associated with catheterization

EMDA can safely and effectively be used for a variety of conditions with dexamethasone, lidocaine, mitomycin C, bethanecol and oxybutynin, taking advantage of increased drug administration without systemic side effects.

2. The stability of lidocaine and epinephrine solutions exposed to the electrical current and comparative administration rates of the two drugs into pig bladder wall- Urol Res 2003; 31: 169-176- Di Stasi SM, Giannantoni A, Navarra P. et al.

DRUG SOLUTION	OUTCOMES & METHOD	RESULTS
<p>Drug solution was the same as that used in clinical application: 50 ml lidocaine HCl 4% (NaCl-free), 1 ml di epinephrine HCl 1/1000, 50 ml water</p>	<p>To measure the duration of drugs stability (with mass spectrometry), the mixture was placed in open steel bowl and stored for up 7 days at room temperature in the lighting and in the dark and at 4°C in the dark.</p> <p>Transport rates with passive diffusion and with EMDA was determined: the solution was placed in two chamber cell with the donor compartments (drugs) separated from the receptor compartments (NaCl solution) by a viable pig bladder wall. This was subjected to the application of an electric current (20 mA and 30 mA) for 20, 30 and 45 min. The viability and structural features of</p>	<p>Lidocaine remained stable throughout the 7 days under all conditions, epinephrine remained stable under all condition during day 1 only and for 7 days when stored at 4°C in the dark.</p> <p>With the application of an electric current (30 mA for 45 min), both drugs remained stable. In bladder tissue, all lidocaine levels following electromotive administration is significantly exceeded the corresponding levels following passive diffusion: the ratio of tissue lidocaine levels, EMDA/passive diffusion was 6:1. Same results for epinephrine and tissue levels ratio was 9:1. There was no trypan</p>

	tissue were assessed with trypan blue exclusion test and histological examination	blue staining of epithelial, subepithelial or muscle cells indicating the viability of tissues. Histological examination of the bladder wall showed a normal structure.
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The combination lidocaine and epinephrine remains stable for 1 days and when exposed to 30 mA for 45 min. Electric current accelerates the transport rate of lidocaine and epinephrine. No tissue damage was detected histologically or by trypan blue test

TREATMENT OF INTERSTITIAL CYSTITIS AND BLADDER PAIN SYNDROME: EMDA AND HYDRODISTENSION OF THE BLADDER

3. Electromotive administration of intravesical lidocaine in patients with interstitial cystitis - Journal of Endurology October 1996; Vol 10, No 5:p.443-447 – Gürpınar T, Wong H. et al – Baylor College of Medicine, Houston, Texas

PROCEDURE	PATIENTS	RESULTS
<p>100 ml aqueous solution with lidocaine 1.5% and epinephrine 1:100,000</p> <p>15mA for 40 mins</p> <p>Blood sample were drawn before, at the middle (20 mins) and at the end of treatment and assayed for lidocaine: serum concentration remained below (<0.1µg/dL- 0.6 µg /dL) the typical therapeutic venous concentrations (1.5-5 µg /dL)</p>	<p>6 pts with long-standing IC (they have been treated from 3 to 20 years for IC but all remained significantly symptomatic)</p>	<p>Bladder volume increase in all patients. Quality of life (VSQL) score improved and voiding symptoms decreased as did suprapubic and perineal pain: in 4/6 pts (66%) these results have been durable (follow-up for 3 to 18 months). The procedure was well tolerated in all cases and the pts didn't experience pain or significant discomfort. No systemic side effects.</p>

EMDA treatment and bladder dilatation are safe, well tolerated and helpful

4. Intravesical Electromotive Drug Administration for the treatment of non-infectious chronic cystitis- International Urogynecology Journal 1997:8: p134-137- Riedl CR, Knoll M. Plas E. et al, Municipal Hospital Lainz, Vienna, Austria

PROCEDURE	PATIENTS	RESULTS
<p>Drug solution: 150 ml lidocaine 2.6% with dexamethasone 20 mg and epinephrine 0.75 mg. 22 mA for 20 min. EMDA/cystodistension was performed on an out-patient basis in all patients, it lasts an average of 45 min and was easily performed by the medical staff.</p> <p>(*) CR group: 5/9 (55%) IC pts, 4/6 (66%) RD. Mean duration of complete remission was 5.4 months in IC group and 9.5 months in RC group.</p>	<p>17 pts with non-infectious chronic cystitis (NICC): IC (9), radiation cystitis (RD) (6), chemocystitis (1), lupoid cystitis (1). A total of 46 treatment (1-5 per pts) was performed: retreatments were performed at pts request whenever bladder symptoms recurred. For final evaluation, all pts compiled a questionnaire regards to their quality of life and their judgment as to the efficacy of the therapy.</p>	<p>Complete resolution of symptoms (*) for an average of 7,5 months was observed in 11 pts (65%), partial improvement in 4 (23.5%). Cystometric bladder capacity was increased by an average of 65%. No complications occurred. The treatment was excellently accepted: 16/17 (94%) stated that cystodistension with EMDA anesthesia is tolerable and they would undergo retreatment anytime. After a mean follow-up period of 10.8 months treatment was judged effective with a significant improvement of quality of life by 11/177 pts (65%).</p>

Complete resolution of symptoms in two-third of NICC patients for an average 7.5 months. EMDA treatment is effective, feasible, without serious side effects and cost effective

5. Electromotive drug administration and hydrodistension for the treatment of interstitial cystitis – Journal of Endourology June 1998; Vol 12, No 3: p. 269-272- Riedl CR, Knoll M, et al – Municipal Hospital Lainz, Vienna, Austria

PROCEDURE	PATIENTS	RESULTS
<p>-Pts with low-capacity bladders (<250 ml): solution of 100 ml of lidocaine 2% with dexamethasone 16 mg and epinephrine 0.5 mg. Electric current set at 15 mA for 20 mins</p> <p>- Pts with bladder capacity (>250 ml): solution of 150 ml of lidocaine 2.6% with dexamethasone 20 mg and epinephrine 0.75 mg. Electric current set at 22 mA for 20 mins</p>	<p>13 pts with diagnosed CI.</p> <p>Total treatment: 42</p> <p>As soon as bladder symptoms recurred, pts returned for retreatment.</p> <p>Retreatment 1 to 6 per pts</p> <p>(*) Complete responders: complete resolution of urgency, bladder pain and urinary frequency for at least 1 week</p> <p>(**) Partial responders: reduction of bladder symptoms for less than 1 week</p>	<p>8/13 (62%) pts reported complete resolution(*) of bladder symptoms lasting an average of 4.5 months.</p> <p>3 (22%) pts reported partial (**)</p> <p>improvement, while 2 (16%) aggravation of pain for several days (<4 days) after therapy.</p> <p>At 1 week post EMDA, cystometric bladder capacity was increased by an average of 66% and consequently urinary frequency was reduced as demonstrated by 45% decrease of nocturia.</p> <p>Cystodistension after EMDA was uniformly painless. Retreatments were effective in all cases for a similar or even a longer period of time.</p>

The combination of EMDA and hydrodistension shows some significant advantages: remission rates appear to be superior and there is no need for general anesthesia and hospital admission, which

reduces therapeutic costs and treatment time (about 1 hour including cystoscopy after EMDA). Moreover EMDA is easy to perform and has high acceptance by patients: in this series, 93% pts judged EMDA and hydrodistension well tolerable and said they would undergo retreatment any time.

6. Electromotive drug administration of lidocaine and dexamethasone followed by cystodistension in women with interstitial cystitis- International Urogynecology Journal 1997 8(3):p.142-145-Rosamilia A, Dwyer PL, Gibson J, Royal Women's Hospital Carlton, Victoria and Westmead Hospital, Sydney, Australia

PROCEDURE	PATIENTS	RESULTS
<p>Drug solution: 2% NaCl-free lidocaine hydrochloride, 1.5 mg adrenaline, 16 mg dexamethasone in 150 ml sterile water. 30 mA (*) for 20-30 min</p>	<p>21 females with IC diagnosed. The time between initial diagnosis of IC and EMDA was 6 months to 14 years with a median of 3.5 years) Assessment was 2-day urinary diary and pain score (0-10 scale) performed before treatment and 2-and 6-monthly review.</p> <p>(*) Very high maximum output current: not recommended</p>	<p>18/21 pts (85%) had a good response (reduction of frequency and in pain score by 3 or more and) at 2 weeks, with 14 (63%) still responding at 2 months. An excellent response (pain score of 0) was obtained in 4/16 pts (25%) at 6 month review (pretreatment score:4-10) No pts asked for treatment to be terminated. Cystodistension was well tolerated in all cases. Cystometric bladder capacity was increased from an average of 200 ml before to an average of 600 ml after EMDA.</p>

There was a significant improvement in pain score at 2-month and 6-month review, with an improvement in urinary frequency at 2-month

7. Office bladder distension with Electromotive Drug Administration (EMDA) is equivalent to distension under General Anesthesia (GA)- BMC Urology 2005; 5:14 – Rose AE, Avezedo KJ, Paine CK – Stanford University Medical School, Stanford, California, USA

PROCEDURE	PATIENTS	RESULTS
<p>Two prospective protocols have been conducted to investigate the utility of EMDA anesthesia for office bladder:</p> <ul style="list-style-type: none"> -the first examined the role of EMDA distention in the initial diagnosis of IC; -the second examined the efficacy of EMDA distension in pts who had previously responded to a distension in the operating room with GA (*). <p>Median time elapsed between GA distension and EMDA distension was 10 months. (*) General Anesthesia</p>	<p>11 pts participating in two protocols of EMDA bladder distension who also underwent bladder distension under GA either prior to or after the EMDA procedure.</p> <ul style="list-style-type: none"> -first protocol: 2 pts who later went on to have a bladder distension under GA -second protocol: 9 pts <p>Most of the pts recruited for the study had already at least 3 previous IC therapies and many are considered “end stage” patients with ulcers and low bladder capacity.</p>	<p>The distension capacity achieved in the office was nearly identical to that in the operating room and the cystoscopic findings very similar.</p> <p>The median absolute difference in bladder capacity between GA and EMDA was only 25cc (5%).</p> <p>Cystometric bladder capacity was increased by an average of 135%</p> <p>Serum lidocaine levels were drawn from the 7 pts with bladder ulcers: all were less than 1.1µ/ml</p>

This study represents the first comparison between distension with EMDA vs general anesthesia: EMDA provides an equivalent degree of distension to the standard procedure performed in the operating room as essentially the same bladder capacity is achieved. These results confirms the feasibility of performing bladder distension in an office setting without risk and cost of general anesthesia

8. Pilot study of the feasibility of in-office bladder capacity distension using Electromotive Drug Administration (EMDA)- Neuology and Urodynamics 2005;24:1-7- Rose AE, Avezedo KJ, Paine CK – Stanford University Medical School, Stanford, California, USA

PROCEDURE	PATIENTS	RESULTS
<p>- First group of 10 pts underwent bladder distension under local anesthesia with instillation of 5 mg/kg alkalized lidocaine 4% buffered by 5 cc 8.4% sodium bicarbonate;</p> <p>- Second group of 11 pts had lidocaine EMDA anesthesia prior to distension.</p> <p>Drug solution: 75 cc lidocaine 4%, 2 cc epinephrine 1:1,000, 70 cc sterile water, 40 mg dexamethasone.</p> <p>Peak current 30 mA, rise rate 50 for 25 min</p>	<p>21 pts presenting with symptoms of urinary frequency , urgency and bladder pain were recruited.</p>	<p>In the alkalized lidocaine group, 6/10 distensions were aborted for intolerable pain after less than 5 min at only 40 cm H₂O. 4/10 completed the procedure.</p> <p>In the EMDA group, 7/11 distensions were completed using 60 H₂O for 7 min.</p> <p>Despite the lower pressure used in the alkalized lidocaine group, the median distension time was only 3 min compared to 7 min using EMDA and the cystometric bladder capacity was increased by an average of 75% compared of 135% with EMDA.</p>

EMDA provides a sufficient anesthesia to complete an office bladder distension

9. Electromotive-Drug-Administration (EMDA)-Verfahren: Eine innovative minimal-invasive Therapieoption bei Interstitieller Cystitis- 2007, Dissertation Saarland: Medizinische Fakultät der Universität des Saarlandes- Dilk O.

PROCEDURE	PATIENTS & OUTCOMES	RESULTS
<p>First drug solution: dexamethasone (40 mg in 10 ml), lidocaine 4% (NaCl free) in 50 ml, epinephrine 1/1000 2mg in 2ml. 15-25 mA, positive polarity.</p> <p>After emptying the bladder, the second drug solution was instilled: pentosan polyphosphate 200 mg in 150 ml distilled water 20-25 mA, positive polarity.</p> <p>Time of treatment: 20-35 mns.</p>	<p>78 pts with diagnosed IC were selected from 2004 to 2006 and treated with EMDA.</p> <p>All these pts had received other treatments in the past before EMDA.</p> <p>Urodynamic data were collected pre and post EMDA.</p> <p>For final evaluation pts compiled a questionnaire regards quality of life (improvement of symptoms: urgency-frequency, pelvic pain) and their judgement as to the efficacy of EMDA.</p>	<p>63 of the 78 patients replied to the questionnaire.</p> <p>84% of IC patients noticed an improvement of their symptoms: 48% of the effect was evident, 13% strong, 23% mild.</p> <p>80% of pts showed effects for at least 1 month, 38% for 6 months or more.</p> <p>49% had no post-therapeutic problems, 24% urinary tract infections, 11% hematuria.</p> <p>In 84% of EMDA treated patients the procedure was successful.</p>

EMDA improves patients' quality of life with a success rate of 83%

10. Instillation of hyaluronic acid via Electromotive Drug Administration can improve the efficacy of treatment in patients with interstitial cystitis/painful bladder syndrome: a randomized prospective study-Korean J Urology 2014; 55: 354-359- Gulpinar O et al - Ankara University Faculty of Medicine, Ankara, Ufuk University School of Medicine, Ankara, Turkey

PROCEDURE	PATIENTS & OUTCOMES	RESULTS
<p>Randomized prospective study. Patients were randomly assigned to two group</p> <p>-Group A: pts received hyaluronic acid directly with a catheter (40 mg acid hyaluronic retained for at least 60 min);</p> <p>-Group B: pts received hyaluronic acid with EMDA (40 mg acid hyaluronic in 40 ml saline solution, treatment time 25 min)</p> <p>The two group was similar in baseline parameters. In both groups instillation were performed weekly in the first month and then monthly after 2 months.</p>	<p>31(6 males, 25 females) pts with IC/BPS diagnosed were randomized to two groups similar for baseline parameters:</p> <p>-Group A: 15 pts</p> <p>-Group B: 16 pts</p> <p>They were followed for 24 months and the two group were compared at certain intervals.</p> <p>Primary endpoint of the study were VAS score, GRA (Global Response Assessment) and micturition frequency in 24 hours. Secondary endpoint were mean voided volume, number of nocturia episodes, IC symptom and problem scores.</p> <p>Follow-up: 24 months</p>	<p>There was a significant improvement in EMDA group at 6 and 12 months in term of micturition frequency, mean voided volume, number of nocturia episodes IC symptom and problem score, VAS score and GRA. The difference between the two groups was not significant at months 1 and 24.</p> <p>None of the patients experienced any serious adverse side effects and no patients refused treatment.</p>

Instillation of hyaluronic acid via EMDA increase the tissue uptake and improve the efficacy of the treatment

11. Improvement in the effectiveness of bladder instillation therapies in the treatment of interstitial cystitis by means of EMDA (electromotive drug administration): outcomes of a randomised, placebo-controlled, double blind trial. 2018; Münstermann N, Dilk O, Heinecke A, van Ophoven A; Mechernich, Homburg/Saar, Münster, Herne (Germany)

PROCEDURE	PATIENTS & OUTCOMES	RESULTS
<p>Randomized, controlled, double-blind trial.</p> <p>Drug solution: 40 mg dexamethasone, 20 mg butylscopolamine bromide, 100 ml 4% lidocaine, 2 ml adrenaline 1:1000, 100 ml water for injection.</p> <p>Patients were randomly assigned to two group:</p> <ul style="list-style-type: none"> -Group A: 25 pts received an EMDA instillation (rise 30 μA/s, intensity of current 20 mA for 30 min) administered twice (interval of 4 weeks) -Group B: 15 pts received the instillation alone without EMDA (same drug solution, identical duration of treatment but pulsed electric current was not 	<p>40 pts with confirmed IC were randomized to two groups.</p> <p>Group A: 25 pts. One pts was excluded, so become 24 pts</p> <p>Group B: 15 pts</p> <p>Total of 80 treatment: 50 with EMDA, 30 without EMDA.</p> <p>Primary outcomes: response rate to therapy. Pts who reported a marked improvement or freedom from symptoms in GRA(*) questionnaire were categorised as responders.</p> <p>Secondary outcomes: duration of relief from symptoms (duration of response) and change in: pain, urgency, micturition frequency and volume (bladder capacity)</p>	<p>The effectiveness of the treatment was assessed prior and at 2 and 6 weeks after the second EMDA instillation.</p> <p>Group A: 10/24 pts was responders 6 weeks after the second treatment.</p> <p>Group B: 2/15 pts was identified as responders.</p> <p>The EMDA treatment tended to lead to an improvement in terms of a reduction of urgency, micturition frequency and pain in comparison with instillation treatment alone.</p> <p>Serious adverse events did not occur with any of the total of 80 treatments.</p>

applied. Physionizer was mute in both group at all times)	(*) General Response Assesment	
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Outcomes		Evaluation
Primary	Response rate to therapy	GRA questionnaire
Secondary	Micturition frequency	Micturition diary
Change in:	Micturition volume	
	Symptoms and perception of symptoms	Symptom score based on O’Leary/Sant IC index
	Pain	Visual Analogue Scales (VAS)
	Urinary urgency	Visual Analogue Scales (VAS)
	Duration of response	

EMDA is well tolerated and safe to administer, including with repeated treatments. EMDA achieves a clinically relevant prolongation and increase in the reduction of symptoms compared with simple instillation treatment

12. The care situation of patients with interstitial cystitis in Germany. Results of a survey of 270 patients. Urologe 5, 2013;52:691-702. Jocham D, Froehlich G, Sandig F, Ziegler A.

Using a comprehensive questionnaire the care situation of 270 pts (94% women, 6% men) with IC and bladder pain syndrome in Germany was recorded.

The average age of women was 53.5 years and that of men 67 years. The diagnosis of IC was made most frequently (62.22%) by biopsy and histological examination followed by urodynamics, potassium test, hydrodistension and cystoscopy. The average duration of the diagnosis was 9 years, 46.67% of the patients consulted a doctor more than 20 times before the diagnosis was made.

51.84% had to pass water more than 14 times per day. Frequency, nocturia and pain were the leading symptoms and 25% of the pts complained of urge incontinence.

In the self-assessment success 61,34 % considered EMDA the best intravesical procedure

13. German SK2 Guideline Diagnostic and therapy of Interstitial Cystitis (IC/BPS) - Responsible: German Society of Urology, Edition 1, version 1, September 30, 2018:30-31 (period of validity: 5 years)

3.5. Transurethrale Verfahren

3.5.4. Electromotive Drug Administration (EMDA®)

In one study, six IC / BPS pts were treated with EMDA® lidocaine and epinephrine administered at maximum distended bladder. Through this treatment, a significant increase in bladder capacity, a reduction in pain and the micturition frequency could be achieved. 66% of the treated pts described the efficacy as persistent (3).

Treatment of 21 female IC / BPS patients with lidocaine and dexamethasone by EMDA® showed good efficacy (reduction of frequency and pain) in 85% of pts two weeks after treatment. In 63% of pts, this effect lasted for two months. Complete pain reduction was also observed in 25% of pts six months after treatment (6).

In another study using the same technique and in which 13 pts with diagnosed CI were treated, it was shown that 62% of those treated reported a complete resolution of bladder symptoms. In addition, bladder capacity was increased by an average of 66% (5).

A study on the care situation of IC / BPS patients in Germany showed that 180 out of 270 study participants had used the EMDA® procedure for the treatment of the symptoms. When assessing the success of invasive treatment, more than 60% of those treated reported successful treatment (12).

Thus, the EMDA® method is the most effective invasive therapy in this study (9)...

Recommendation can be considered strong consensus (100%).

ELECTROMOTIVE DRUG ADMINISTRATION OF LIDOCAINE TO PRODUCE BLADDER LOCAL ANESTHESIA FOR THRANSURETHRAL SURGERY

14. Bladder and urethral anaesthesia with electromotive drug administration (EMDA): a technique for invasive endoscopic procedures. British Journal of Urology 1997;79, 414-420, Fontanella U.A, Saronno Hospital, Italy

METHOD	PATIENTS & OUTCOMES	RESULTS
<p>Lidocaine 4% (150 ml, NaCl free) is mixed with 150 ml of water and 3 ml di adrenaline (1mg/ml) added so that the final solution is: 2% lidocaine and 0.01 mg/ml adrenaline in 300 ml.</p> <p>Anxious pts were prescribed a benzodiazepine the night before surgery. Local anaesthetic gel is instilled into the urethra.</p> <p>Electric current applied: 25 mA for 25 min.</p> <p>Upon cessation of current, the catheter is removed and the patient enters the operating theatre within the next 5 min; if not, the drug solution retained in the bladder assists in</p>	<p>91 pts (68 men and 23 women). Total of 131 procedures. Pts were excluded if they had a history of reactions to local anaesthetic drugs, psychosis, alcoholism or active, inflammatory lower urinary tract infections.</p> <p>82 pts that underwent one to several invasive procedure (122 invasive procedures in total *) were asked to score their experiences with a simple pain scale:</p> <p>0= absent to minimal discomfort 1= discomfort to tolerable pain 2= intolerable pain</p> <p>9 underwent miscellaneous interventions all using rigid instruments</p>	<p>In 111/ 122 procedures the discomfort was minimal or absent. In 6/122 procedures pain was tolerable. In pain 5/122 was described as intolerable and the peration were abandoned.</p> <p>With the present method, the patient has a comfortable anaesthetic duration of 50-60 min. Serum lidocaine levels was innocuous.</p>

<p>maintaining the anaesthesia induced by EMDA. Before positioning the pts on the operating table, the urologist administered intravenous lorazepam: 2 mg in 83 pts (they remained fully conscious throughout their procedures and 4 mg in 8 younger and overly anxious pts.</p>	<p>(* Invasive procedures were: 27 bladder- mapping biopsies, 62 TURBT of bladder tumors, 21 transurethral incisions on the prostate or on bladder neck, 12 TURBT of the prostate</p>	
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EMDA with lidocaine provides safe, effective anaesthesia for most invasive endoscopic procedure in the lower urinary tract

15. Electromotive drug administration of lidocaine to anesthetize the bladder before intravesical capsaicin. The Journal of Urology June 1998 Vol 159, 1857-1861, Dasgupta P., Fowler C.J., Stephen R.L., Uro-Neurology Department, Institute of Neurology, London, UK

METHOD	PATIENTS & OUTCOMES	RESULTS
<p>Drug solution: 75 ml lidocaine hydrochloride 4% (NaCl-free) with 75 ml sterile water, 1,5 ml 1:1,000 epinephrine giving a final solution of 150 ml lidocaine 2% with epinephrine 1:100,000. 20 mA, rise rate 30 μA for 15 mns. Then bladder was drained and flushed and the capsaicin solution was instilled for 30 mns under urodynamic monitoring: 100 ml capsaicin 2 mmol/l in 30% alcohol in saline. Pts with positive urine cultures were treated with antibiotics before entering the study. Capsaicin instillation preceded by EMDA were repeated once in 2 pts and twice in 1 pt when the effect of the previous dose</p>	<p>8 pts (4 men and 4 women) with detrusor hyperreflexia due to spinal cord disease. Previous treatment of incontinence using a combination of oral anticholinergics and clean intermittent catheterization had failed. The discomfort caused by intravesical instillation of capsaicin restricted its use, the purpose of this study was studied the efficacy of using EMDA to anesthetize the bladder before capsaicin. Each pts score suprapubic pain with a 10-point scale at 5 mns after starting the capsaicin instillation and at the end of procedure (30 mns): 0: no pain at all 10: worst pain imaginable</p>	<p>The pain scores during capsaicin instillations after EMDA of lidocaine were much lower than those during capsaicin instillations after lidocaine alone. EMDA eliminated the hyperreflexic contractions of bladder occurring during capsaicin instillations, thus reducing the risk of urethral leakage. For 5 pts who had received previous capsaicin instillation after lidocaine alone the pain scores during capsaicin instillations after EMDA were 0.6 ± 0.4 at 5 mns and 0.4 ± 0.5 at the end. The pain score of 3 pts who received capsaicin after EMDA as initial treatment were 0,1,2 at 5 mns and 0,3,0 at 30 mns. Of the 8 pts, 6 (75%)</p>

diminished.	Of the 8 pts 5 had previous capsaicin treatments and the scores were compared to previous scores when intravesical lidocaine without EMDA had been used as local anesthesia before capsaicin.	responded to the treatment: 5 became completely continent and 1 had decreased episodes of urge incontinence during the day. The duration of benefit was 3 months in 3 pts, 6 months in 2 pts and 8 months in 1pts.
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Electromotive Drug Administration of lidocaine is a simple, safe and effective method of anesthetizing the bladder and reducing pain during subsequent intravesical capsaicin instillations

16. Electromotive drug administration of lidocaine as an alternative anesthesia for transurethral surgery. The Journal of Urology 1999; Vol 161, 482-485, Jewett Michael A.S., Valiquette L, Sampson Heather A., Katz J, Fradet Y, Redelmeier Donald A., University of Toronto, Canada

METHODS	PATIENTS & OUTCOMES	RESULTS
<p>Multicenter study: 3 centers and 3 groups of pts participated to the study.</p> <p>Drug solution: 100 ml Lidocaine 4% (NaCl free), 100 ml sterile water and 2 ml epinephrine (1mg/ml) for a final concentration of 1:100,000</p> <p>Current applied: 25 mA for 20-25 min</p> <p>1 to 2 mg sublingual lorazepam were administered as an anxiolytic to 50% of the biopsy and 90% of the transurethral bladder tumor resection/fulguration pts.</p> <p>Anaesthetic gel was instilled into the urethra.</p> <p>A numeric pain score was measured before during and after the</p>	<p>94 pts enrolled.</p> <p>Outcomes: to assess safety, efficacy and cost-effectiveness of EMDA/lidocaine.</p> <p>Group 1 also included 6 pts with concurrent bladder tumor and interstitial cystitis who required bladder biopsy and hydrodistension, respectively.</p> <p>Group 1: 45 pts who required cold cup bladder biopsy with (27) or without (18) electromotive intravesical lidocaine (comparison trial of EMDA/lidocaine vs no anesthesia)</p> <p>Group 2: 43 pts undergoing transurethral resection/fulguration who were offered EMDA/lidocaine as an alternative to general</p>	<p>For group 1 pain levels were significantly less intense for EMDA group than the control group during insertion of the cystoscope, biopsy and coagulation.</p> <p>For the group 2 median pain scores for the entire procedure were 0 (except for mild pain during cutting, 1.4). EMDA/lidocaine for bladder biopsy and transurethral bladder tumor resection/fulguration was associated with higher patient satisfaction compared to previous treatments. 86% pts stated that they would be willing to repeat procedure.</p> <p>Group 3: 3 experienced more discomfort than those</p>

<p>procedures (biopsy, fulguration and resection) using an 11-point numeric rating scale with end points labeled 0 (no pain) and 10 (worst possible pain).</p>	<p>or regional anesthesia Group 3: 6 pts with benign prostatic hyperplasia (BPH)/carcinoma of prostate undergoing transurethral resection who agreed to be treated with EMDA/lidocaine.</p>	<p>undergoing bladder procedures. The remaining 3 pts had remarkably pain-free procedures. The cost per pts was less with EMDA/lidocaine than with conventional general and spinal anesthesia.</p>
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The anesthetic technique with EMDA/lidocaine offers advantages in terms of effective, safety and cost while providing near equal levels of anesthesia for patients requiring transurethral bladder biopsy, resection or fulguration.

17. Electromotive drug administration of lidocaine to anesthetize the bladder before botulinum-A toxin injections into the detrusor. Spinal Cord 2004; 42, 338-341. Schurch B, Reitz A., Tenti G., Swiss Paraplegic Center, Balgrist University Hospital Zurich, Department of Urology, University Hospital Zurich, Switzerland

METHODS	PATIENTS & OUTCOMES	RESULTS
<p>Drug solution for EMDA: 75 ml lidocaine hydrochloride 4% (NaCl-Free) with 75 ml sterile water and 1.5 ml 1/100000 epinephrine giving a final solution of 150 ml lidocaine 2% with epinephrine 1/100000 epinephrine. Urethra was lubricated with 20 ml lidocaine 2% gel. Current applied: 25 mA for 20-25 min 300 u of botulinum-A toxin (Botox®) was injected at 30 sites sparing the trigone.</p>	<p>28 pts (17 males, 11 females) with neurogenic detrusor overactivity but preserved bladder sensibility. Group of 10 pts: received conventional lidocaine instillation to anesthetize the bladder prior to the injection of Botox®. Group of 28 pts: received received EMDA enhanced lidocaine instillation prior to the Botox® injection. Pts scored the injection pain on a 10-point rating scale. Cost of the EMDA procedure were compared to general and spinal anesthesia.</p>	<p>For pts who underwent the injection of Botox® after conventional lidocaine instillation the mean pain score was 4.0. For pts who underwent EMDA enhanced lidocaine instillation the mean pain score after Botox® injection was 0.5. The Botox® injection after EMDA caused a slight pain in 12 pts and 16 pts reported no pain; no side effects and mucosa lesions were observed. Pts who had already undergone Botox® injection after conventional lidocaine instillation reported a remarkable reduction</p>

		or even the absence of pain and would prefer the EMDA-enhanced lidocaine instillation in the future. Local anesthesia using EMDA saved around 15% of the costs.
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EMDA enhanced instillation of lidocaine provides a sufficient anesthesia of the bladder wall that ensures a painless botulinum-A toxin injection into the detrusor muscle. This method may avoid general or spinal anesthesia with considerable cost reduction and avoidance of anesthesia-related risk and complications. EMDA a simple and safe procedure.