PAPER DETAILS

TITLE: Effectiveness of hydrodistention procedure under local anesthesia in the treatment of bladder pain syndrome/interstitial cystitis

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PAGES: 357-362

ORIGINAL PDF URL: https://dergipark.org.tr/tr/download/article-file/2114833

Effectiveness of hydrodistention procedure under local anesthesia in the treatment of bladder pain syndrome/ interstitial cystitis

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Cite this article as: Sarıkaya K, Şenocak Ç, İbiş MA, Sadioğlu FE, Çiftçi, Bozkurt ÖF. Effectiveness of hydrodistention procedure under local anesthesia in the treatment of bladder pain syndrome/interstitial cystitis. J Health Sci Med 2022; 5(2): 357-362.

ABSTRACT

Objective: We aimed to indicate the effectiveness of local anesthesia in the treatment of hydrodistention in women with Bladder Pain Syndrome/interstitial Cystitis (BPS/IC) in our study.

Material and Method: The data of a total of 77 female patients who underwent hydrodistention treatment for BPS/IC in our clinic between January 2015 and July 2021 were analyzed retrospectively. The patients were divided into two groups as local anesthesia (LA, n=41) and spinal anesthesia (SA, n=36) groups according to the type of anesthesia applied. The groups were compared by determining the preoperative and postoperative O'Leary symptom index (SI) and problem index (PI), minimum voiding volume (MinVV), maximum voiding volume (MaxVV), average voiding volume (AvgVV) and daily frequency.

Results: The mean age of the patients was 48.97 ± 11.09 years in the LA group and 45.19 ± 14.35 years in the SA group (p=0.197). There was no significant difference between the groups in terms of the preoperative European Society for the Study of Interstitial Cystitis (ESSIC) group (p=0.999). During the postoperative period, a median (IQR) improvement of 11.0 (2.0) points was observed in the SI of the LA group, while a median improvement of 11.0 (2.0) points were observed in the SA group (p=0.437). The median improvement in PI score was 8.4 (4.0) points in the SA group, while it was 7.0 (3.0) points in the LA group (p=0.415). There was no significant difference between the groups in terms of improvements in minVV, maxVV, avgVV and daily frequency (p=0.480, p=0.614 and p=0.910, respectively).

Conclusion: Hydrodistention treatment in women with BPS/IC can be performed safely and with high success rate under local anesthesia and it is well tolerated by the patients. Local anesthesia offers a minimally invasive treatment option as well as the advantage of avoiding possible complications of spinal, epidural or general anesthesia.

Keywords: Bladder pain, hydrodistention treatment, local anesthesia

INTRODUCTION

Bladder pain syndrome/Interstitial cystitis (BPS/IC) is a chronic disease characterized by the presence of persistent irritating micturition symptoms and chronic pain felt in the pelvic region (1). According to the most accepted theory, BPS/IC is developed due to a primary damage of the glycosaminoglycan (GAG) layer in the bladder urethelium (2). It significantly reduces the quality of life in patients due to depression, anxiety, insomnia, fatigue, dyspareunia and several sexual problems (3). According to the definition of European Society for the Study of Interstitial Cystitis (ESSIC) BPS/IC is characterized by chronic (>6 months) pelvic pain, pressure or discomfort perceived to be related to the urinary bladder accompanied

by at least one other urinary symptom such as persistent urge to void or urinary frequency ,and establishes a list of confusable diseases that must be excluded. With this definition, ESSIC recommends diagnostic cystoscopy and cystoscopy-guided biopsy and hydrodistention treatment, and grades BPS/IC based on these findings (4). The European Association of Urology (EAU) committee also approves this definition made by ESSIC and recommends hydrodistention treatment during cystoscopy (5). Hydrodistention performed during cystoscopy provides simultaneous diagnosis and treatment in patients with suspected BPS/IC, as well as facilitating the exclusion of other possible bladder pathologies. Hydrodistention during cystoscopy is classically performed under general, spinal

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or epidural anaesthesia. However, this situation not only increases the possible risks that may develop secondary to general anesthesia, but also leads to more hospitalization and loss of work. Therefore, performing the procedure under local anesthesia provides the patient with a more minimally invasive treatment option and provides the advantage of preventing risks that may develop secondary to spinal, general or epidural anesthesia (6). Lidocaine that instilled into the bladder before cystoscopy suppresses pain secondary to bladder tension by reducing c-fiber activity and allows hydrodistention (7). According to our literature research, it was obtained that there are very limited studies on the application of cystoscopy and hydrodistention under local anesthesia. In addition, it has been determined that there is not enough data in the literature regarding the comparative results of hydrodistention treatment performed under local anesthesia with hydrodistention performed under spinal or general anesthesia. Therefore, in the present study, we aimed to exhibit the efficacy and safety of hydrodistention treatment performed under local anesthesia by comparing the results of hydrodistention treatment performed under local anesthesia and spinal anesthesia in our clinic.

MATERIAL AND METHOD

Preoperative Evaluation

After the study approval was obtained from the ethics committee of Health Sciences University Keçiören Training and Research Hospital (Date:14.09.2021, No: 2012-KAEK-15/2369), the data of 77 female patients who were treated for hydrodistention due to BPS/IC in our clinic between January 2015 and July 2021 were retrospectively analyzed. All procedures were performed adhered to the ethical rules and principles of the Helsinki Declaration. Patients with urgency, pollakiuria (>7 urination in a 24-h period) and painful bladder symptoms for at least 6 months and who did not benefit from conservative treatment methods were included in the study. However, patients with a history of bladder outlet obstruction, bladder tumor, bladder stone, active urinary tract infection in urine culture, post-void residual urine volume (PVR) >50 ml, or neurogenic bladder were excluded from the study. In addition, those with an active vaginitis, endometriosis or uro-gynecological disorder such as cystocele, rectocele or severe stress urinary incontinence that will require surgery were also excluded from the study.

A detailed physical examination, including vaginal examination were performed following the clinical histories of the patients. Routine urinalysis, urine culture, urea, creatinine values, uroflowmetry and PVR measurements and urinary system ultrasonography of all patients were recorded. Symptom index (SI) and problem index (PI) scores were determined by evaluating all patients symptomatically using the O'Leary Sant questionnaire scale (8). In addition, the minimum voided volume (minVV), maximum voided volume (maxVV), average voided volume (avgVV) and 24-h frequency values of the patients were defined in detail. PI and SI scores, voided volume and 24-h frequency values were determined and recorded in the 3rd month following the procedure. The patients were divided into two groups as local anesthesia (LA, n=41) group and spinal anesthesia (SA, n=36) group according to the anesthesia type in which the procedure was performed.

Cystoscopy and Hydrodistention Procedure

Cystoscopy and simultaneous hydrodistention were performed in both groups using a 21 Fr rigid cystoscope (Olympus) and 30 degree optics. The glomerulation grade of the bladder was evaluated according to the criteria of the interstitial cystitis database study (9) and cold-cup biopsy was taken during cystoscopy if necessary. The ESSIC groups of the patients were determined according to the glomerulation grade, cystoscopy findings and biopsy criteria.

In the SA group, the bladder was filled with saline infusion and waited for 10 minutes until changes in the bladder mucosa were observed in routine cystoscopy. During the procedure, saline infusion was made at a height of approximately 80 cm from the patient with physiological flow. Subsequently, the bladder was emptied and a 16-18 Fr foley catheter was placed into the bladder and the procedure was terminated. All patients in the SA group were discharged on the 1st postoperative day following their urethral catheters removed. In order to provide an adequate local anesthesia for the procedure in LA group, 10 ml of 4% lidocaine was diluted with 40 ml of saline and instilled into the bladder using a 16 or 18 Fr foley catheter. In this way, the optimum local anesthetic effect sufficient for the procedure was obtained by waiting for about 10 minutes. Following local anesthesia, saline infusion was started to physiological flow from a height of approximately 80 cm to the patients and the infusion was continued until the pain level that the patients could tolerate a maximum degree during bladder filling. At the point where the patients could not tolerate the pain, the infusion was terminated and the amount of saline infused was recorded. Afterwards, the bladder was emptied and the procedure was terminated. No urethral catheter was inserted after the procedure in the patients in the LA group. The patients in the LA group were discharged after being followed up in the outpatient clinic observation room for approximately two hours. SI, PI, maxVV, minVV, avgVV and 24-h frequency values of the patients were determined before the procedure and at the 3rd month after the procedure, and the groups were compared.

Statistical Analysis

All statistical analyses were performed using the SPSS 24.0 (IBM Corp., Chicago) software for Windows. "Freguencies" and "descriptives" was used for descriptive statistics. For a normal distribution independent samples-t test was used as means and standart deviation. In the univariate analysis, Chi-Square Test was used for nominal data, while the Mann-Whitney U test was used for nonparametric variables. Median (minimummaximum) or median (Interquartile range) were used for continuous data. A p-value of <0.05 was considered as statistically significant.

RESULTS

The mean age of the patients was 48.97±11.09 years in the LA group, while it was 45.19±14.35 years in the SA group (p=0.197). According to the preoperative cystoscopy findings, the glomerulation grades of the LA and SA groups were found to be similar (Grade 0=9/5, Grade 1=17/22, Grade2=11/5 and Grade 3=4/4, p=0.293). Similarly, there was no significant difference between the groups in terms of preoperative ESSIC groups (p=0.999) (Table 1). While the preoperative median (IQR) O'Leary SI score of the LA group was 15.0 (2.50) points, it was 15.5 (2.75) points in the SA group (p=0.942). The median preoperative O'Leary PI score was 11.0 (3.50) points in the LA group and it was 12.5 (3.75) points in the SA group (p=0.093). There was no significant difference between the groups in terms of preoperative minVV, maxVV, avgVV and daily frequency (p=0.413, p=0.639, p=0.822 and p=0.305, respectively) (Table 2). In the evaluation performed at the 3rd month following hydrodistention, the median O'Leary SI score of the LA group was 5.0 (3.0) points, while the SI score of the SA group was similarly 5.0 (3.0) points (p=0.934). The postoperative median O'Leary PI score was 3.0 (2.0) in the LA group, while it was 4.0 (2.0) in the SA group (p=0.298). Similarly, no significant difference was found between the groups in terms of postoperative minVV, maxVV, avgVV and daily frequency (p=0.245, p=0.524, p=0.560 and p=0.315, respectively) (Table 3). A median 11.0 (2.0) point improvement was found in the LA group in the O'Leary SI score in the postoperative 3rd month, while there was a similar improvement of 11.0 (2.0) points in the SA group (p=0.437). It was also observed that there was no significant difference between the groups in terms of improvement in O'Leary PI scores (LA=7.0 (3.0) points vs SA=8.4 (4.0) points and p=0.415). While an average improvement of 60.7±29.6 ml was observed in the minVV of the LA group, it was 66.3±40.0 ml in the SA group (p=0.480). Similarly, there was no significant difference between the LA and SA groups in terms of mean improvement in maxVV and mean improvement

in avgVV (160.0 ± 80.0 ml vs 156.5 ± 70.5 ml and 116.0 ± 62.7 ml vs 113.6 ± 78.3 ml, p=0.460 and p=0.614, respectively). In addition, it was observed that the median improvement in daily frequency in the LA group was 7.0 (3.5) ,while it was 7.0 (3.0) in the SA group, and there was no significant difference between the groups (p=0.910) (**Table 4** and **Figure 1**).

Table 1. Preoperative patient's characteristics according to groups				
	Local (n=41)	Spinal (n=36)	р	
Age, mean±SD, years	48.97±11.09	45.19±14.35	0.197	
Glomerulation grade, n (%)			0.293	
Grade 0	9 (22.0)	5 (13.9)		
Grade 1	17 (41.5)	22 (61.1)		
Grade 2	11 (26.8)	5 (13.9)		
Grade 3	4 (9.8)	4 (11.1)		
ESSIC group, n (%)			0.999	
1X	4 (9.8)	3 (8.3)		
1A	6 (14.6)	5 (13.9)		
1B	3 (7.3)	4 (11.1)		
1C	6 (14.6)	5 (13.9)		
2A	3 (7.3)	2 (5.6)		
2B	6 (14.6)	7 (19.4)		
2C	9 (22.0)	7 (19.4)		
3A	3 (7.3)	2 (5.6)		
3B	1 (2.4)	1 (2.8)		
2B 2C 3A 3B *SD: Standard deviation. ESSIC	6 (14.6) 9 (22.0) 3 (7.3) 1 (2.4)	7 (19.4) 7 (19.4) 2 (5.6) <u>1 (2.8)</u> r the Study of Interstit	ial Cystitis	

Table 2. Preoperative O'Leary scores and voiding parameters of the groups					
	Local (n=41)	Spinal (n=36)	р		
Semptom index, median (IQR)	15.0 (2.50)	15.5 (2.75)	0.942		
Problem index, median (IQR)	11.0 (3.50)	12.5 (3.75)	0.093		
Minimum voided volum, median (IQR), ml	50.0 (30.0)	50.0 (40.0)	0.413		
Maximum voided volum, median (IQR), ml	200.0 (65.0)	200.0 (107.5)	0.639		
Average voided volum, median (IQR), ml	130.0 (42.5)	127.5 (63.75)	0.822		
Daily frequency, median (IQR)	15.0 (3.5)	14.0 (4.0)	0.305		

*IQR: Interquartile range, SD: Standard deviation

Table 3. Postoperative O'Leary scores and voiding parameters of the groups					
	Local (n=41)	Spinal (n=36)	р		
Semptom index, median (IQR)	5.0 (3.0)	5.0 (3.0)	0.934		
Problem index, median (IQR)	3.0 (2.0)	4.0 (2.0)	0.298		
Minimum voided volum, median (IQR), ml	120.0 (65.0)	145.0 (107.5)	0.245		
Maximum voided volum, mean±SD, ml	365.3±64.7	356.7±69.9	0.524		
Average voided volum, mean±SD, ml	253.6±66.6	244.5±64.8	0.560		
Daily frequency, median (IQR)	7.0 (3.5)	7.0 (1.0)	0.315		
*IQR: Interquartile range, SD: Standard deviation					

Table 4. Improvement in O Leary scores and voiding parameters of the groups				
	Local (n=41)	Spinal (n=36)	р	
Semptom index, median (IQR)	11.0 (2.0)	11.0 (2.0)	0.437	
Problem index, median (IQR)	7.0 (3.0)	8.4 (4.0)	0.415	
Minimum voided volum, mean±SD, ml	60.7±29.6	66.3±40.0	0.480	
Maximum voided volum, mean±SD, ml	160.0±80.0	156.5±70.5	0.460	
Average voided volum, mean±SD, ml	116±62.7	113.6±78.3	0.614	
Daily frequency, median (IQR)	7.0 (3.5)	7.0 (3.0)	0.910	
*IOR: Interguartile range, SD: Star	ndard deviation			



Figure. Improvement in O'Leary scores and voiding parameters of the groups

DISCUSSION

Currently, due to the increase in the number of patients diagnosed BPS/IC, more studies are being conducted on different treatment modalities of the disease and the application forms of treatment vary. In addition, due to its negative effects on working life, depression, anxiety, chronic pain and sexual dysfunctions, especially in women, cause a significant decrease in the quality of life (10). Recent studies have drawn attention to the fact that BPS/IC seriously increases the rate of depression and anxiety in the chronic period, and therefore it is important to initiate treatment in the early period (11). Historically, various protocols have been applied in the treatment of BPS/IC, primarily medical therapy and intravesical instillation. Hydrodistention treatment was first applied by Dunn et al. (12) in 1977. Hydrodistention concomitant with cystoscopy is not only therapeutic, but also offers the advantage of excluding other bladder diseases and taking a simultaneous biopsy if necessary. Although the ESSIC and EAU guidelines recommend diagnostic and therapeutic hydrodistention in patients with BPS/IC, they do not offer any recommendations on procedural technique (4,5). On the other hand, AUA recommends that the hydrodistention procedure be performed under general, spinal or epidural anesthesia, for less than 10 minutes and under a low pressure of 60-80 cmH₂O (13). In line with these recommendations, in our study, saline infusion was applied into the bladder from a height of 80 cm from the patient and the infusion time did not exceed 10 minutes.

Until today, hydrodistention treatment has been performed under spinal, epidural or general anesthesia in many centers and successful results have been reported. In a study conducted by Yamada et al. (14) which included 52 patients, it was reported that hydrodistention treatment under epidural anesthesia was 70% effective for more than three months and no serious complications were encountered. In another review study conducted by Ens et al. (15) it was reported that hydrodistention treatment provided 54% to 90% symptomatic relief within 6 to 9 months and no serious complications were observed in similar studies. Ahmad et al. (16) reported that after hydrodistention and intravesical hyaluronic acid (40 mg/50ml) treatment administered under general anesthesia in a total of 23 patients, they found immediate improvement in the symptoms of 17(74%) of the patients. In the same study, they were indicated that the healing of ulceration and resolution of inflammation were occurred in all responders. Similar to the literature data, significant improvement was found in the O'Leary SI and O'Leary PI scores of the local and spinal anesthesia groups at the end of the third month in our study, and no difference was found between the groups in terms of improvement scores.

Although many cystoscopic interventions have historically been successfully performed under general, spinal or epidural anesthesia, urologists have managed to perform many cystoscopic procedures under local anesthesia in order to perform these procedures more minimally invasive (17-19). Offiah et al. (20) performed intravesical lidocaine instillation in a total of 24 female patients with BPS and investigated whether the symptoms have a peripheral versus central mechanism. According to this study, there was a statistically significant volume increase following lidocaine treatment: maximal cystometric capacity (MCC) 192-261 ml post lidocaine (p=0.005.) In another study, Aihara et al. (21) reported the results of hydrodistention treatment administered under local anesthesia to a total of 30 patients, 27 of whom were women and 3 were men. In this study, it was reported that the patients could tolerate hydrodistention treatment well under local anesthesia and that all patients could be infused with >200 ml of saline. In addition, in the same study, they emphasized that 21/30 (71%) patients benefited from the treatment one month after the treatment, and significant improvement was found in the O'Leary SI and O'Leary PI scores (p<0.0001 and p<0.0001, respectively). According to

the same study, a median 60 ml increase in minVV, 55 ml in maxVV and 60 ml increase in avgVV was detected in the postoperative third month (p<0.0001, p<0.0005 and p<0.0001, respectively), and in addition, a median 4.5 (0-11) time decrease has been reported in 24-h urinary frequency (p<0.0001). In our study, the results of hydrodistention treatment applied under local anesthesia and spinal anesthesia were compared. In our study, no significant difference was found between local and spinal anesthesia groups in terms of improvement in O'Leary SI and O'Leary PI scores. In addition, there was no significant difference between the groups in terms of median increase in minVV, maxVV, avgVV and the median decrease in daily voiding frequency. Our outcomes are consistent with the literature data, and no serious complications such as severe bleeding, bladder perforation or hypersensitivity reaction secondary to local anesthesia were observed in any patient. These results support the idea that hydrodistention therapy can be effective and safely performed under local anesthesia. Hydrodistention treatment performed under local anesthesia provides similar improvement rates that performed under spinal anesthesia.

The most important limitation of our study is its retrospective nature. In addition to the results at the end of the third month, the absence of long-term follow up results is another important limitation. On the other hand, because the VAS pain scores of the groups were not obtained in the early postoperative period, the fact that the groups were not compared in terms of postoperative pain scores can be considered as another limitation.

CONCLUSION

The results of hydrodistention treatment performed under local anesthesia are similar to hydrodistension treatment performed under spinal anesthesia. The procedure performed under local anesthesia provides similar improvement rates to that performed under spinal anesthesia in terms of the increase in the patients' O'Leary SI, O'Leary PI and voiding volumes, as well as the decrease in daily voiding frequency. Local anesthesia avoids the possible complications of spinal or general anaesthesia, allowing hydrodistention to be performed at less cost and with minimal working loss. However, the hypersensitivity reaction that may develop secondary to local anesthesia should be kept in mind, and it should be known that additional spinal or general anesthesia may be needed in cases where the patient cannot tolerate the procedure due to pain. There is a need for randomized controlled studies that compare the local anesthesia with spinal, epidural or general anesthesia and include longer follow-up periods in this respect.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was initiated with the approval of the Health Sciences University Keçiören Training and Research Hospital Ethics Committee (Date:14.09.2021, Decision No: 2012-KAEK-15/2369).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version

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