

Comparison of Pain Score After Giving Diclofenac Sodium Versus Nalbuphine in Patients Undergoing ESWL: Our Experience in SIMS/ SHL

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Submitted for Publication

12-04-2016

Accepted for Publication

12-04-2016

ABSTRACT

Treatment of urolithiasis has been revolutionized with the introduction of extracorporeal shock wave lithotripsy (ESWL) due to its simplicity, non-invasive nature, efficacy, and minimal morbidity. Pain experienced during ESWL is considered to be multifactorial including type of lithotripter used, frequency, voltage, age, and sex of patient. Various analgesic agents including opioids, nonsteroidal anti-inflammatory drugs, local anesthetic agents and a number of combinations have been used during extracorporeal shock wave lithotripsy by various techniques. **Objective:** Compare the mean pain score after giving Diclofenac Sodium versus Nalbuphine in patients undergoing extra-corporeal shock wave lithotripsy. **Study Design:** Randomized control trial study **Setting:** Department of Urology SIMS/SHL Lahore **Period:** 01.12.2012 to 01.05.2013. **Methods:** Total number of 150 (75 in each) patients were included in two groups (Diclofenac sodium group A SD 3.28+ 0.18, Nalbuphine group B SD 4.11 + 1.69). Inclusion and exclusion criteria strictly followed. Detailed history including (age sex address), informed consent, labs, bleeding profile, RFT, X-rays KUB, USG, IVU, and pregnancy test checked. Patients divided in two groups by lottery method. Injection Diclofenac sodium given deep intramuscular, while Nalbuphine HCL intravenous. Both groups were observed pain during ESWL. Data was analyzed by using SPSS version 10, SD, P value calculated. **Results:** A total of 150 (75 in each group) cases were enrolled after fulfilling the inclusion/exclusion criteria, majority of the patients in both groups were between 41-50 years i.e. 33.33%(n=25) in Diclofenac sodium group and 32%(n=24) in Nalbuphine group, mean and SD was calculated as 35.98±3.54 in Diclofenac sodium and 37.32±3.83 years in Nalbuphine group, 58.67%(n=44) in Diclofenac sodium and 52%(n=39) in Nalbuphine group were male while 41.33%(n=31) in Diclofenac sodium and 48%(n=36) in Nalbuphine group were females, mean pain score after giving diclofenac sodium versus nalbuphine in patients undergoing extra-corporeal shock wave lithotripsy was recorded as 3.09±0.54 in Diclofenac sodium and 4.93±0.79 in Nalbuphine Group, p value was computed as 0.05.

Conclusion: We concluded that on comparison of mean pain score after giving Diclofenac Sodium versus Nalbuphine in patients undergoing extra-corporeal shock wave lithotripsy, significant low pain score was recorded in patients treated with Diclofenac Sodium which may be used in future to control the pain.

Keywords: Extra-corporeal shock wave lithotripsy Extra-corporeal shock wave lithotripsy, mean pain score, Diclofenac Sodium, Nalbuphine

Article Citation: Inam QA, Hussain K, Ghous G, Butt MK, Irfan M, Rehman A. Comparison of Pain Score After Giving Diclofenac Sodium Versus Nalbuphine in Patients Undergoing ESWL: Our Experience in SIMS/ SHL. APMC 2016;10(4):261-265.

INTRODUCTION

In past urolithiasis used to be treated by open surgery. The treatment of urolithiasis has been revolutionized with the introduction of extracorporeal shock wave lithotripsy (ESWL) due to simplicity, non-invasive nature, efficacy and minimum morbidity¹. ESWL break stone into small

fragments that may then to be excreted. Main problem with this procedure is pain. Many drugs and methods have been used to control the pain felt during ESWL. The efficacy can be improved by reducing the pain and anxiety during ESWL. Newer generation lithotripters are less painful than old

version. Thus, the trend from general anesthesia and regional analgesia shifting towards sedative versus non-sedative. There is no consensus on analgesia protocol. The major issue is to provide the sufficient analgesic efficacy with minimum side effects. The use of opioid analgesics have complications such as significant respiratory depression, bradycardia, hypotension, nausea, vomiting, pruritus and prolonged recovery time. Therefore the reliable alternative for pain management is NSAIDS. In this randomized controlled study we compared the efficacy of diclofenac sodium versus nalbuphine injection for analgesia in patients undergoing ESWL².

A prospective study was conducted at Service d'Urologie, Hôpital Charles Nicolle, Rouen, France in 2006 and it was found that a significant difference was observed for pain with the two drugs used.² No such study has been conducted in Pakistan. Pain perception varies in different races, age and ethnicity.¹² Thus response to analgesia differs as well. By knowing that we would be able to improve the patient compliance in terms of hospital visits, time, money and better pain control during procedure that will ultimately lead to decrease patient load and visits in future.

METHODOLOGY

Type of study:

- Randomized Control Trial Study

Setting:

- Department of Urology, Services Hospital, Lahore

Duration of study: 01.12.2012 to 01.05.2013

Sample size:

- Sample size of 150 (75 in each) cases is calculated with 80% power of test, 95% confidence level and taking expected mean \pm Standard Deviation of mean pain score in both groups that is $3.28 \pm 0.18^{[8]}$ in Diclofenac Sodium group (group A) versus $4.11 \pm 1.69^{[10]}$ in Nalbuphine group (group B) in patients undergoing extracorporeal shock wave lithotripsy.

Sample technique:

- Non-probability: purposive sampling

Sample Selection:

Inclusion Criteria:

- Radio-opaque stones of size 2cm or less visible on X-Ray KUB film on Antero-posterior view in patients with upper urinary tract stones.

- Age ranging from 15 years to 60 years.
- Both male and female.
- Normotensive patients with B.P 111/80 to 129/80mmHg.

Exclusion Criteria:

- Obstructive Uropathy shown in Intravenous Urogram (IVU)
- Chronic Renal Failure shown in renal function tests (urea>60, creatinine>2) and ultrasonography (shrunken kidney).
- Pregnancy that was ruled out by ultrasound and pregnancy test.

Data collection procedure:

150 cases fulfilling the inclusion criteria were selected from the outpatient clinics of Urology department. For each patient detail history was taken including demographic information (age, sex, address) and administered Extracorporeal shock wave lithotripsy after taking informed consent, checking X-Ray (KUB), Urine C/E, Renal Function Tests, Intravenous Urogram (IVU), Coagulation Profile, Ultrasound (KUB) and pregnancy test was done. Any previous treatment history and presenting complaint was noted also. Stones were located in the kidney and ureter with ultrasound and X-Ray (KUB). Patients were divided into two groups randomly using lottery method based on type of analgesia that is Diclofenac Sodium 75mg was given intramuscularly and Nalbuphine HCL 10mg was given along with Metoclopramide 10mg intravenously to avoid nausea and vomiting before procedure. Extracorporeal shock wave lithotripsy was given with Lithotripter Modulith SLX-F2. The whole procedure and data collection was done by our team.

Both groups were observed for pain during extracorporeal shock wave lithotripsy at five, fifteen and thirty minutes. Exclusion criteria, was followed to address confounders and bias.

Data analysis:

Data was analyzed by using SPSS version 10 the data to be analyzed for the outcome variables. Quantitative data like age and pain score was presented in the form of mean \pm S.D. Qualitative data like gender was presented in the form of frequency and percentages. Outcome variables were compared between both groups in terms of mean pain score by using "T-test". Tolerant during procedure. P-value ≤ 0.05 was considered as statically significant.

RESULTS

A total of 150 (75 in each group) cases fulfilling the inclusion/exclusion criteria were enrolled to compare the mean pain score after giving Diclofenac Sodium versus Nalbuphine in patients undergoing extra-corporeal shock wave lithotripsy.

Age distribution

Age distribution of the patients was done which shows that majority of the patients in both groups were between 41-50 years i.e. 33.33% (n=25) in Diclofenac sodium group and 32% (n=24) in Nalbuphine group, followed by 28% (n=21) in Diclofenac sodium and 29.33% (n=22) in Nalbuphine group were between 31-40 years, 17.34% (n=13) in Diclofenac sodium and 22.67% (n=17) in Nalbuphine group were between 15-30 years and 21.33% (n=16) in Diclofenac sodium and 16% (n=12) in Nalbuphine group were between 51-60 years of age, mean and SD was calculated as 35.98 ±3.54 in Diclofenac sodium and 37.32 ±3.83 years in Nalbuphine group. (Table No. 1)

Gender distribution

Gender distribution of patients shows 58.67% (n=44) in Diclofenac sodium and 52% (n=39) in Nalbuphine group were male while 41.33% (n=31) in Diclofenac sodium and 48% (n=36) in Nalbuphine group were females. (Table No. 2)

Mean pain score

Mean pain score after giving diclofenac sodium versus nalbuphine in patients undergoing extra-corporeal shock wave lithotripsy was recorded as 3.09±0.54 in Diclofenac sodium and 4.93±0.79 in Nalbuphine Group. (Table No. 3)

Table 1: Age distribution (N=150)

Age(in years)	Diclofenac Sodium (n=75)		Nalbuphine (n=75)	
	No. of patients	%	No. of patients	%
15-30	13	17.34	17	22.67
31-40	21	28	22	29.33
41-50	25	33.33	24	32
51-60	16	21.33	12	16
Total	75	100	75	100
Mean and SD	35.98±3.54		37.32±3.83	

Table 2: Gender distribution (n=150)

Gender	Diclofenac Sodium (n=75)		Nalbuphine (n=75)	
	No. of patients	%	No. of patients	%
Male	44	58.67	39	52
Female	31	41.33	36	48
Total	75	100	75	100

Table 3: Mean pain score after giving diclofenac sodium versus nalbuphine in patients undergoing extra-corporeal shock wave lithotripsy (n=150)

Mean pain score	Diclofenac Sodium (n=75)	Nalbuphine (n=75)
		3.09±0.54

P value= 0.05

DISCUSSION

Treatment of urolithiasis has been revolutionized with the introduction of extracorporeal shock wave lithotripsy (ESWL) due to its simplicity, noninvasive nature, efficacy, and minimal morbidity.^{8,9} Pain experienced during ESWL is considered to be multifactorial including type of lithotripter used, frequency, voltage, age, and sex of patient.⁸ Recent developments have made ESWL more effective, with minimal morbidity, making it possible to perform ESWL in an outpatient setting without the need for general or spinal anesthesia.^{9,10} Though avoidance of general anesthesia is beneficial to patients, there is a significant concern regarding jeopardizing treatment outcomes due to use of less potent analgesic methods.¹¹ Analgesics commonly used during ESWL include opioids, sedative hypnotics, nonsteroidal anti-inflammatory drugs (NSAIDs), and local anesthetic creams such as EMLA.^{11,12} Although opioids provide efficacious analgesia, they are associated with significant complications - respiratory depression, bradycardia, hypotension, nausea, vomiting, and prolonged recovery time.¹³

Pain perception varies in different races, age and ethnicity. Thus response to analgesia differs as well. However, we planned this study to determine any significant difference between two drugs i.e. Diclofenac Sodium and Nalbuphine. So that, we may be able to improve the patient compliance in terms of hospital visits, time, money and better pain

control during procedure that will ultimately lead to decrease patient load and visits in future.

In our study, mean pain score after giving diclofenac sodium versus nalbuphine in patients undergoing extra-corporeal shock wave lithotripsy was recorded as 3.09 ± 0.54 in Diclofenac sodium and 4.93 ± 0.79 in Nalbuphine Group, p value was calculated as 0.05 which is significant but not highly significant difference.

The findings of the study are in agreement with other studies who revealed 3.28 ± 0.18^8 in Diclofenac Sodium group (group A) versus 4.11 ± 1.69^{10} in Nalbuphine group (group B) in patients undergoing extracorporeal shock wave lithotripsy.

Another study,¹³ compared the efficacy of a eutectic mixture of local anesthetics (EMLA) cream, diclofenac sodium (DS) and EMLA in combination with DS (EMLA+DS) for pain management during extracorporeal shock wave lithotripsy (ESWL) and recorded that mean age was 44.4 ± 1.9 years. There was no statistically significant difference between groups regarding patient's mean age, shock waves, duration of ESWL and energy level values ($p > 0.05$). The mean pain score during ESWL was 3.90 ± 0.16 in the EMLA group, 3.28 ± 0.18 in the DS group and 3.05 ± 0.18 in EMLA+DS group ($p = 0.023$) and concluded that DS appears to be more efficient than EMLA in reducing pain during ESWL. Using EMLA+DS has no superiority in relieving pain compared to DS-only treatment.

This shows agreement in pain score after Diclofenac Sodium administration for post ESWL pain.

Not much data is available regarding comparison of both the drugs, further trials in Pakistan are required to authenticate these findings, and it justifies the hypothesis of the study that "*there is a difference in mean pain score of patients undergoing extracorporeal shock wave lithotripsy receiving diclofenac sodium versus Nalbuphine.*"

However, on this preliminary data we may proceed with diclofenac sodium for controlling pain in patients undergoing extracorporeal¹⁴.

Further trials are required to authenticate the findings of the current study so that we may improve the patient compliance in terms of hospital visits, time, money and better pain control during procedure that will ultimately lead to decrease patient load and visits in future.

CONCLUSION

We concluded that on comparison of mean pain score after giving Diclofenac Sodium versus Nalbuphine in patients undergoing extra-corporeal shock wave lithotripsy, significant low pain score was recorded in patients treated with Diclofenac Sodium which may be used in future to control the pain.

REFERENCES

1. Ng CF, Thompson T, Tolley D. Characteristics and treatment outcome of patients requiring additional intravenous analgesia during extracorporeal shockwave lithotripsy with Dornier Compact Delta Lithotripter. *Int Urol Nephrol.* 2007;39(3):731-5.
2. Iqbal J, Pall M, Mette UK, Mandal AK, Bhukal I. Analgesia For ESWL: Comparing Two Analgesia Techniques. A Double Blind Randomized Study. *Int J Urol.* 2013;11:132-9.
3. Mazdak H, Abazari P, Ghassami F, Najafipour S. The analgesic effect of inhalational Entonox for extracorporeal shock wave lithotripsy. *Urol Res.* 2007;35(6):331-4.
4. Eryildirim B, Kuyumcuoğlu U, Tarhan F, Faydaci G, Uruç F. Comparison of three analgesic treatment protocols for pain management during extracorporeal shock wave lithotripsy. *Urol Int.* 2009;82(3):276-9.
5. Gupta NP, Kumar A. Analgesia for pain control during extracorporeal shock wave lithotripsy: Current status. *Indian J Urol.* 2008;24(2):155-8.
6. Mazdak H, Abazari P, Ghassami F, Najafipour S. The analgesic effect of inhalational Entonox for extracorporeal shock wave lithotripsy. *Urol Res.* 2007;35(6):331-4.
7. Wandner LD, Scipio CD, Hirsh AT, Torres CA, Robinson ME. The perception of pain in others: how gender, race, and age influence pain expectations. *J Pain.* 2012;13(3):220-7.
8. Morgan G Edward, Mikhail S Marged, *Clinical Anesthesiology* (Appleton and large) 3rd Edition, p-311.
9. Javed MS, Javed SH, Subhani GM, Saifullah M, Khan NI. ESWL: A Safe Modality for Treatment of Renal Stones. A Clinical Study at Kidney Center, DHQ Hospital, Faisalabad. *APMC* 2016;10(2):85-91.
10. Kehlet H. Postoperative pain. In: Wilmore DW, Brennan M, Harken A., eds. *Care of the surgical patient.* *Emerg Med J.* 2002; 19:565-70.
11. Kelly DF, Ahmad M, Brull SJ. Preemptive analgesia I: physiological pathways and pharmacological modalities. *Can J Anesth* 2001; 48:1000-10.

12. Chaussy C, Brendel W, Schmiedt E. Extracorporeal induced destruction of kidney stones by shock waves. Lancet. 1980; 2:1265–8.
13. Chaussy GC, Fuchs GJ. Current state and future developments of noninvasive treatment of urinary stones with extracorporeal shock wave lithotripsy. J Urol. 1989;141:782–9.

14. Salinas AS, Lorenzo-Romero J, Segura M, Calero MR, Hernandez-Millan I, Martinez-Martin M, et al. Factors determining analgesic and sedative drug requirements during extracorporeal shock wave lithotripsy. Urol Int. 1999;63:92–101.

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