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Research Article

Dexmedetomidine and Remifentanil for Lithotripsy at the Pediatric Age: A Prospective Randomized Double-blind Study

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Abstract

Background: Non-invasive but painful ambulatory urolithiasis treatment, extracorporeal shock wave lithotripsy [ESWL], necessitates immobilization in pediatric age. Appropriate anesthetic agent is crucial for convenient sedoanalgesia, remifentanil generally being used for this purpose. Although dexmedetomidine still not approved by FDA for any pediatric indication, increasing experience with its use in many pediatric scenarios led us to test for ESWL in pediatric patients. So, we compared the hemodynamic, sedative, analgesic and side effects with recovery profiles of dexmedetomidine and remifentanil for ESWL at the pediatric age.

Methods: In this prospective, double-blind study, seventy children under going elective ESWL were randomly assigned to a dexmedetomidine [Group D, n=35] or a remifentanil group [Group R, n=35].

Results: The procedure was well tolerated in both groups. Heart rate [HR] reduction at 10th and 20th minutes for group R [$p<0.05$], and at every measurement for group D [$p<0.001$] with significant low SpO2 values for group R compared to group D at 15 and 20 minutes [$p<0.05$] were observed. Ramsay scores increased within the individual groups [$p=0.001$], being higher in group R [$p=0.024$]. Pain scores were decreased compared to baseline in both groups [$p<0.001$]; being higher in group R at 5, 10 and 15 minutes [$p=0.0001$]. Respiratory depression and apnea observed in 20% of patients receiving remifentanil [$p=0.011$].

Conclusion: Both groups provided similar sedoanalgesic effects, yet dexmedetomidine offers comfortable and secure anesthesia with little systemic side-effects along with less respiratory problems suggesting relevance for conscious anesthesia during ESWL at the pediatric age.

ABBREVIATIONS

ECSWL: Extra Corporeal Shock Wave Lithotripsy; HR: Heart Rate; FDA: Food and Drug Administration; ICU: Intensive Care Unit; MAP: Mean Arterial Pressure; Spo2: Peripheral Oxygen Saturation; RSS: Sedation by Ramsey Sedation Score; WBFPAS: Wong-Baker Faces Pain Assessment Scale

INTRODUCTION

Extracorporeal shock wave lithotripsy [ESWL] is a non-invasive treatment method for urinary tract stones. More than 90% of urolithiasis patients are safely managed by this ambulatory treatment with high success and low complication rates [1]. In contrast to adults, only 1% to 3% of all urinary stones are detected in children; hence profound experience in ESWL treatment in this particular group is demanded at stone centers. Although now a days, no general anesthetic is routinely administered to adults for ESWL treatment; this is not the case with children. In many centers, children up to the age of 8 years treated by ESWL are routinely given a general anesthetic or preferably, if possible, analgesia with sedation [2].

The optimal anesthesia should be easy to administer and should have a high efficiency with minimal adverse effects. Adequate analgesia, satisfactory sedation, and rapid recovery are desirable in such ambulatory procedures [3]. For these purposes, various types of acting drugs have been used for different clinical interventions.

Remifentanil is a specific μ opioid agonist with a fast onset time, may be delivered by a continuous infusion, and is rapidly metabolized by esterases [4,5].

Dexmedetomidine is a selective α 2-receptor agonist, has sedative, analgesic and anti-shivering properties. In contrast to other sedatives, it does not cause respiratory depression [6].

Dexmedetomidine initially approved by Food and Drug Administration [FDA] for short-term sedation [<24 h] for adult patients in the intensive care unit [ICU] setting receiving

mechanical ventilation with endotracheal intubation, more recently has received FDA approval for monitored anesthesia care in adults. To date, although still does not hold FDA approval for any pediatric indication, given the favorable sedative and anxiolytic properties, there is an increasing body of clinical experience with dexmedetomidine in many pediatrics scenarios, including its intraoperative use as part of a balanced anesthetic technique; to provide sedation during mechanical ventilation, and anxiolysis for the non-intubated pediatric ICU patient; to prevent emergence delirium, and as an agent for procedural sedation [7]. Both dexmedetomidine and remifentanil have been used alone or in combination with the other sedative drugs for anesthetic purposes in different surgical procedures in adults [1,3,4,8]. No data available is comparing them at the pediatric age for treatment of urinary stones by ESWL.

The primary endpoint of this prospective, randomized, double-blind study was to investigate and compare the hemodynamic and analgesic properties, sedation levels, adverse effects and anesthesia recovery characteristics of dexmedetomidine and remifentanil in pediatric patients who underwent ESWL for urolithiasis. In other words, our hypothesis is to test whether dexmedetomidine can be safely used in pediatric extracorporeal shock-wave lithotripsy concerning sedation, analgesia and side effects.

MATERIALS AND METHODS

This prospective, randomized, double blind study was conducted under permission of Institutional Review Board of a tertiary academic care unit, Hacettepe University School of Medicine [Project #: 09/127, Decision #: LUT 09/127-117, 28.08.2009].

All parents were informed individually, and a written informed consent was obtained.

Children younger than two or older than age 16, or those who were ASA physical status> 2, or who had systemic, metabolic, cardiovascular, respiratory or neurologic diseases, allergies to any medications used in the study were not included. The final group was composed of 70 pediatric patients with urolithiasis scheduled for ESWL and using a computer-generated table of random numbers, and patients were randomly assigned to either Dex [Group D] or Remifentanil [Group R] groups [Figure 1].

The patients were allowed to take clear liquids up to 2 hours; solid food intake was with-held for at least 6 hours. After admission to the ESWL unit, 0.8mg/kg midazolam [Dormicum®, Roche, and Basel-Switzerland] were given per-orally for premedication. The time interval between the midazolam and the procedure starting was uniform for all patients, being 5 minutes before establishing vascular access for an anesthetic agent by a 24-gauge IV cannula through the dorsum of either hand. All patients received 3-5L / min oxygen via a nasal cannula throughout the procedure. After electrocardiogram, non invasive arterial blood pressure and pulse oximeter applications, baseline values were recorded, and 0.5mg/kg IV propofol was administered for anesthesia induction. After that, based on a computer-generated table of random numbers, patients received either a dexmedetomidine [Precedex®, Abbott Laboratories, IL, USA][Group D] or remifentanil [Ultiva®, GlaxoSmithKline, Zeist, The Netherlands] [Group R] infusion randomly. Drug preparations were done by a separate physician who did not participate in data recording. The patients and the parent's were informed but also blinded to the drug regimen. Dexmedetomidine was administered at a dose of 0.2-0.7 μg/kg/h, and remifentanil was given at 0.25-0.5 μg/kg/min, with calculated similar flow rates [mL/h], via the perfuser [Braun®, Melsungen AG, Germany]. Inadequate sedation was defined as the difficulty in completing the procedure because of movement, and additional propofol at a dose of 0.5mg/kg IV

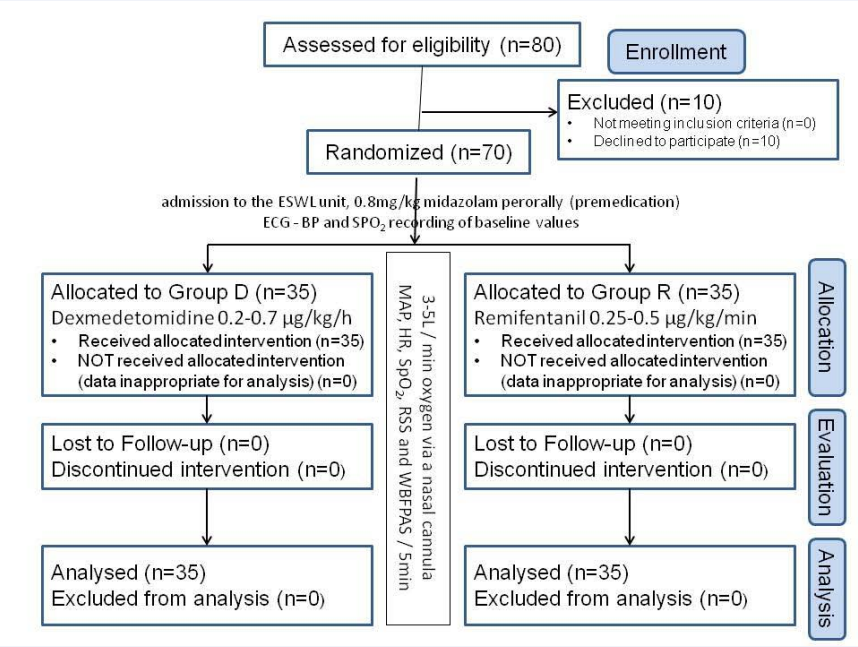

Figure 1 Flow diagram of the current study.

was used for these patients. The mean arterial pressure [MAP], heart rate [HR], peripheral oxygen saturation [SpO2], sedation by Ramseyn sedation score [RSS] [9] and pain intensity with "Wong-Baker Faces Pain Assessment Scale" [WBFPAS] [10] were determined preoperatively, at one minute after induction and in every 5 minutes throughout the procedure. Adverse effects such as hypotension, bradycardia, desaturation, apnea, nausea, and vomiting were timely recorded, anesthesia recovery time was documented. Criteria for the adverse effects were as followings: Hypotension, 20% decrease compared with baseline value; bradycardia, more than 20% deviation from the lowest age-adjusted normal values; desaturation, less than 90% SpO2 [11]. All ESWL procedures were performed with an electromagnetic lithotripter [Siemens Lithostar Modularis, Siemens AG, Germany] by the same urologist.

STATISTICAL ANALYSIS

For calculation of sample size, we selected 0.05 and 0.20 [power is 80%] for α and β-levels, respectively. The standard deviations in both groups were chosen as equal to 14 [HR]. Required sample size was calculated as 64 for detecting the mean difference of at least ten between two independent samples. NCSS-PASS 2005 software was used to calculate the sample size.

Statistical analyses were performed by the Statistical Package for Social Sciences [SPSS]

Release 15.0 for Windows, SPSS Inc., Chicago, IL, USA. Whether or not the data had normal distribution was assessed with the Kolmogorov-Smirnov test. The independent t-test and Mann-Whitney U Test was used to compare the groups for normal and non-normal distributed variables. The relationships between two categorical variables were discovered by Chi-square test. Group-time interaction and the change in the group over time were assessed by ANOVA with repeated measures. Friedman test was used to compare evolving discrete numerical variables. Statistical significance was accepted at $p < 0.05$.

RESULTS AND DISCUSSION

Results

Demographic characteristics were similar for each randomized group [Table 1]. The patients were enrolled from October 2009 to April 2010. Overall, 70 patient's have completed the study, 35 in each group D and R all eligible for analysis.

Hemodynamic parameters compared to baseline levels, the decrease of MAP by the time were statistically significant in both groups during the procedure [p<0.001]. However, both the group-time interaction and the comparison of D and R groups, independent from phase, were similar [p>0.05, Figure 2a]. HR of patients in Group D was lower than the baseline in time after sedation [p<0.001]. It was also decreased in Group R but was significant only at 10 and 20 minutes post-sedation [p<0.05] compared to preoperative baseline values. When D and R groups were compared, lower HR was significant in Group D at 20 minutes [p=0.02] [Figure 2b]. SpO2 values were lower in Group R at 15 and 20 minutes when compared with Group D [p<0.05] [Figure 2c].

Regarding sedation levels; RSS were increased gradually throughout the procedure in both groups [p=0.001]. Furthermore, there was a difference between the group comparison [p=0.024]. The rise of RSS was faster in Group R, and this was significant at 10 minutes after the start of the procedure [p=0.008] [Figure 3]. Inadequate sedation requiring additional IV propofol was observed in four children in Group R [11%], and seven children in Group D [20%]. The difference between the number of the patients requiring additional propofol and the amount of the rescue drug were not significant [p=0.51 for each].

Concerning pain assessment; WBFPAS pain levels were lower in both groups post-sedation [p<0.001]. The difference between the D and R groups were significant at 5, 10 and 15 minutes and were high in Group R compared to Group D [p=0.0001, 0.0001 and 0.003, respectively] [Table2].

When we evaluated the recovery time and adverse effects; the anesthesia recovery time in Group D was shorter without significance [p=0.121]. Respiratory depression and apnea were seen in 20% [7/28] of patients in Group R [p=0.011]. Additional adverse effects such as post-sedation nausea, vomiting or bradycardia, tachycardia, hypotension, and hypertension were not observed in either group.

Discussion

For the treatment of urinary tract stones, ESWL is a safe, non-invasive and cost-effective method [1,12]. The treatment may be associated with significant pain, coming through the skin and the deep visceral fascia, depending on the strength of the shock waves delivered [4,13]. Although the pain is less with new generation lithotripters, sedation and anesthesia are still needed for maximal patient comfort and sufficient therapy especially for pediatric

Table 1: Demographic Data of the Patients included in the Study.

	Group R (n=25) (mean ± SD)	Group D (n=25) (mean ± SD)	p
Age (years)	4.8 ± 3.7	5.7 ± 3.9	*0.35*
Weight (kg)	19.1 ± 13.1	20.7 ± 13.6	*0.61*
Height (cm)	102.3 ± 23.9	106.9 ± 24.8	*0.43*
Gender	n%	n%	
Female	17 (48.6)	*17* (48.6)	*0.594*
Male	18 (51.4)	18 (51.4)	

Abbreviations: Group R: Remifentanil group; Group D: Dexmedetomidine group; SD: standard deviation; n: number of patients.

Table 2: Pain levels in according to Wong Baker Faces Pain Assessment Scale.

Time (minute)	Group R Median [range]	Group D Median [range]	p
0	0 [0-0]	0 [0-0]	1
5	2.06 [0-4]	1.23 [0-2]	***0.0001***
10	1.30 [0-4]	0.5 [0-1]	***0.0001***
15	0.4 [0-2]	0.06 [0-1]	***0.003***
20	0.03 [0-1]	0 [0-0]	*0.31*

Abbreviations: Group R: Group D: Dexmedetomidine group

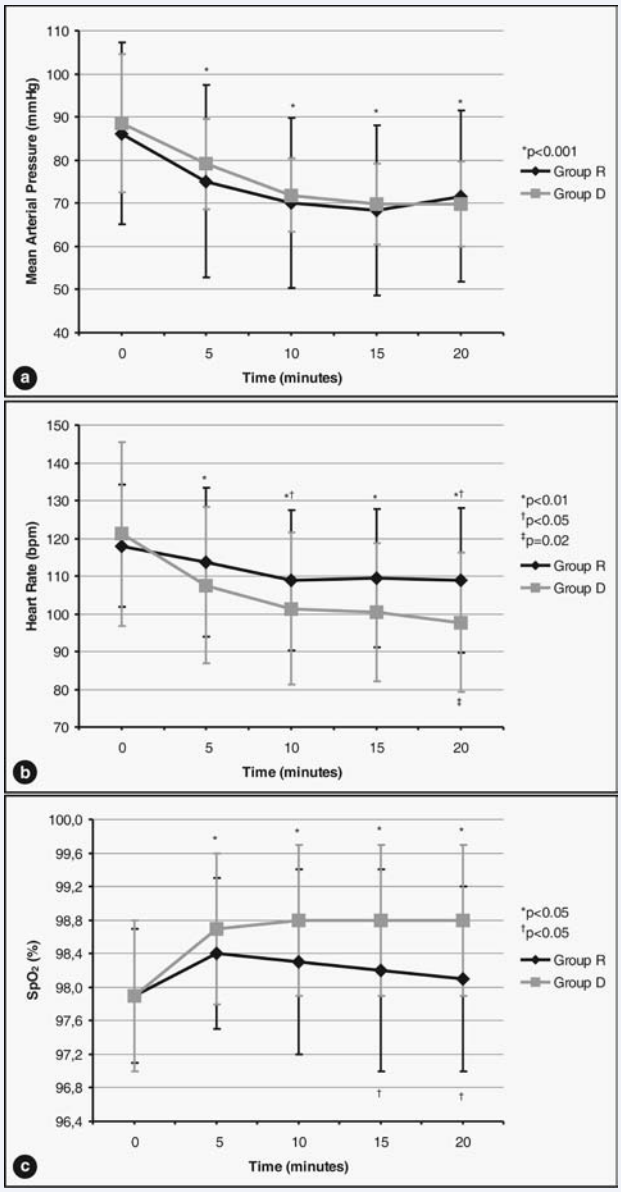

Figure 2 Hemodynamic parameters during ESWL. (a) Mean Arterial Pressure (MAP); the decrease of MAP by time were statistically significant in both groups during the procedure (*p<0.001*). (b) Heart Rate (HR); HR in Group D was lower than the baseline in time after sedation (*p<0.001*). It was also decreased in Group R but was significant only at 10 and 20 minutes post sedation (*p<0.05*) compared to preoperative baseline values. When D and R groups were compared, lower HR was significant in Group Data 20 minutes (*p=0.02*). (c) Peripheral Oxygen Saturation (SpO2); SpO2 values were lower in-group R at 15 and 20 minutes when compared with Group D (*p<0.05*).

patients [13]. In this study, conscious sedoanalgesia was used for immobility and analgesia for patients aged between 2 and 16. None of the patients required general or regional anesthesia, and all the ESWL transactions were completed without failure.

Remifentanil has a fast onset time and rapidly metabolized, hence causes a reduction in sympathetic nervous system tone, respiratory depression and analgesia [4,5]; its effects include adose-dependent decrease in HR, arterial pressure, respiratory rate, and tidal volume [5].

Dexmedetomidine modulates the release of catecholamine in the sympathetic ganglia, resulting in a sympatholytic effect, causes bradycardia and hypotension [6,14]. However, aninitial high peak concentration with a loading infusion may lead to transient hypertension due to stimulation of peripheral α 2b-receptors. Its actions are not mediated by the GABA-mimetic system; therefore it does not depress the respiratory tract [6].

We selected the doses of remifentanil and dexmedetomidine based on previous clinical trials [1,4-6,8,15]; by calculation of similar flow rates [mL/h] using a per fuser. When we compared the hemodynamic parameters, MAP values diminished gradually in both, and there was no difference between the two groups. The HR was also decreased in both groups, but it was lower in Group D at 20 minutes when compared with Group R. Regardless of statistical significance, these changes were clinically negligible, none of the patients required further medication. Richa et al., used the same drug combination for obtaining controlled hypotension and found lower MAP and HR in remifentanil group [16]. In contrast to our study, both BP and HR levels were lower with remifentanil; this could be either due to the adult age of their patients, the type of anesthesia being general anesthesia; or the difference in dosages. However, similar findings on BP and HR values as in our study were reported previously in various clinical scenarios for sedation purposes, using same medications [8,15,17].

Although there were no hemodynamic side–effects requiring further treatment in our study, previous reports warn that these abnormalities could be higher when dexmedetomidine administered with other medications with negative chronotropic effects; in situations that might exaggerate negative chronotropic effect in patients with co-morbid cardiovascular disorders; and after initial large or rapid bolus doses [7].

In this study, RSS was increased throughout the procedure in both groups while this rise was faster in the remifentanil group. Dexmedetomidine was efficient and safe for sedation during ESWL in adults, producing successful cooperative sedation in both children and adult patients in the literature [6,18]. Kaygusuz et al., demonstrated comparable sedation by dexmedetomidine or propofol during ESWL in adults [8]. Koroglu et al., compared dexmedetomidine with midazolam and propofol for sedation of pediatric patients during magnetic resonance imaging [MRI] in two separate studies. Midazolam group was more likely to experience inadequate sedation resulting difficulty in completing the procedure with higher mean time to onset of sedation, but their next study did not show statistical significance regarding inadequate sedation, the inadequate sedation rated requiring propofol was 17%, and compatible with the literature [15]. Of note, none of the above studies including ours have used an electro physiological monitoring like bispectral index [BIS], a processed electro encephalo graphic parameter that provides a measure of sedation depth [19]. BIS has been described a useful objective tool to guide physicians for children undergoing painful procedures in outpatient settings for adequately identifying the level of sedation [20]. It appears that the absence of neurophysiological monitoring might better describe the higher incidence of propofol requirement for inadequate sedation, both in our study and in the literature [15,21].

The addition of a dexmedetomidine infusion before propofol MRI sedation results in fewer sedation-related adverse events, particularly upper airway obstruction in children under going MRI [22]. Both infusions and intermittent bolus injections of remifentanil provided adequate sedation and analgesia for the adult patients during ESWL, yet large and rapid loading doses and when combined with other sedatives may result in increased respiratory depression and serious cardiovascular adverse effects [4,23]. Significant respiratory depression and hypoventilation after bolus administration in spontaneously breathing patients were also reported [24]. In the current study, decreased SpO2 values [<90%] and apnea were seen in 20% of patients in Group R; verbal and painful stimuli were enough to deal with this terrible adverse effect, none of these patients require further medical intervention. However, apnea was not seen, and SpO2 values were significantly higher in group D. The effect of dexmedetomidine on respiratory rate is controversial, some authors did not observe any respiratory side effect [1,15,18], others have reported respiratory complications, especially with large and rapid loading doses [25].

We preferred evaluating the pain intensity by WBPFAS, due to the age group of the study population. Pain scores were significantly higher through the procedure in Group R where as they were the same at the end. However, both drugs were sufficient enough to control the pain and did not affect the success of the intervention or necessitated any rescue medication or additional analgesia during the treatment. Lower visual analog scale pain scores with dexmedetomidine during ESWL were reported, previously [8,18]. Lower infusion doses of remifentanil plus intermittent demands were as effective as higher infusion doses plus the same amount of intermittent demands for remifentanil, smaller doses being associated with significantly fewer side effects [4]. Analgesic responses comparison of healthy volunteers during step wise target-controlled infusions of dexmedetomidine and remifentanil in adult's revealed dexmedetomidine not as effective an analgesic as remifentanil [26]. Apparently further studies are needed to assess the analgesic properties of dexmedetomidine particularly at the pediatricage; however, one should not to forget its benefits concerning analgesic and sedative features and also its effects on reducing the need for opioid agents in both major and minor painful interventions at the pediatric age [7,27].

Regarding anesthesia recovery time, dexmedetomidine is superior to standard barbiturates and hypnotics because of its short half-life of about 1.5 – 3h after IV injection [1], which makes the drug easier to titrate and faster to recover. In separate studies by Koruk et al., shorter recovery times with dexmedetomidine compared with midazolam and propofol was found [1,28]. In contrast to our study, greater recovery times were measured with dexmedetomidine by Ryuet al., and Park et al., in two different studies, compared with remifentanil; both for adult patients [29,30]. Remifentanil has been known as an ultra-short acting synthetic opioid, the elimination half-life of 3–10min and a short context sensitive half-life of 3–5min [4,5,29]. The shorter recovery times with remifentanil in the literature is probably due to the absence of its cumulative effect. In the current study, the authors suggest that the shorter recovery times with dexmedetomidine could be due to its sedative action resulting in the ordinary sleep-like effect that has been known as cooperative sedation, as was described above.

Nausea and vomiting are common side effects of opioid use, yet α-2 agonists have anti-emetic properties. Postoperative nausea and vomiting can be decreased by clonidine premedication. Dexmedetomidine is even utilized in the treatment of cyclic vomiting at the pediatric age which also reduces the incidence of postoperative nausea and vomiting [27]. The potential emetic effect of remifentanil is dose related [23]; along with its other dose-related complications such as dizziness and pruritus [4]. In the current study, nausea and vomiting were not seen in any of these two groups. This might be because of the anti-emetic feature of propofol used at anesthesia induction [22] and, the small dose of remifentanil which was not administered large bolus doses.

The initial results of this study are encouraging; however still needs to be improved. Due to the absence of a standard sedation and analgesia in the pediatric age group, we preferred to compare mostly used remifentanil and recently popular but not approved dexmedetomidine in a variety of dose range; obviously different dosages and comparison with other sedating analgesics in a number of clinical scenarios would be beneficial.

CONCLUSION

In conclusion, infusion of 0.2-0.7 μg/kg/h IV dexmedetomidine was satisfactory and safe enough in providing intended levels of sedation and analgesia in pediatric age patients for ESWL, the effects on hemodynamic parameters were clinically negligible and respiratory depression was not seen. Almost the same sedo-analgesic effects were obtained for dexmedetomidine and remifentanil, but respiratory problems occurred in 20% of the patients with an infusion of 0.25-0.5 μg/kg/min remifentanil. We suggest dexmedetomidine and remifentanil are safe, comfortable and suitable agents, supplying both cooperative sedation and adequate pain management without associated hemodynamic instability and respiratory depression for ESWL procedures at the pediatric age.

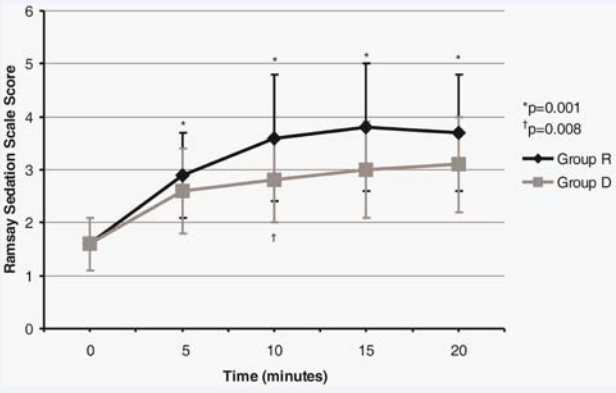

Figure 3 Ramsay Sedation Score during ESWL. RSS were increased gradually throughout the procedure in both groups (*p=0.001*), there was also a difference between the group comparison (*p=0.024*).

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