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Comparison of Alfentanil and Ketamine Infusions in Combination with Midazolam for Outpatient Lithotripsy

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Sixty unpremedicated outpatients undergoing elective extracorporeal shock wave lithotripsy using an unmodified Dornier HM-3 lithotriptor were randomly assigned to receive an intravenous infusion of either alfentanil or ketamine as an adjuvant to midazolam for sedation and analgesia. Although both drug regimens allowed the maximal number of shock waves and energy level, the alfentanil group had significantly better calculi fragmentation (78% *vs.* 50% of patients with fragments < 2 mm). Ketamine infusion provided superior intraoperative cardiorespiratory stability; however, it was associated with more disruptive movements (22 *vs.* 5) and dreaming (35% *vs.* 5%) during the procedure ($P < 0.05$). Postoperatively, confusion also occurred more frequently in the ketamine-treated patients (31% *vs.* 5%, $P < 0.05$). Alfentanil infusion was associated with more episodes of hemoglobin oxygen desaturation to < 90% (12 *vs.* 2, $P < 0.05$), itching (23% *vs.* 4%, $P < 0.05$), and ability to recall intraoperative events (45% *vs.* 12%, $P < 0.05$). The incidence of postoperative nausea was decreased (not significantly) in the alfentanil group (32% *vs.* 54%). The mean anesthesia time was similar in both groups; however, discharge times (means ± standard deviations) were shorter in the alfentanil group (142 ± 42 min *vs.* 161 ± 31 min, $P = 0.05$). These data suggest that although both techniques proved effective for anesthesia in outpatients undergoing immersion lithotripsy, alfentanil is superior to ketamine as part of a sedative–analgesic technique because of the improved recovery profile and calculi fragmentation. (Key words: Anesthesia, outpatient: lithotripsy. Anesthesia techniques, intravenous sedation: midazolam–alfentanil; midazolam–ketamine. Intravenous sedation. Monitored anesthesia care: extracorporeal shock wave lithotripsy.)

FOLLOWING ITS INTRODUCTION in 1980, extracorporeal shock wave lithotripsy (ESWL) has become the preferred treatment for calculi in the upper urinary tract.[1,2] Although ESWL is considered a noninvasive procedure, the impact of the shock waves at the entry site causes a sharp stinging pain.[3] While single shock waves are easily tolerated, administration of multiple shocks requires anesthetic drugs.[4]

Most anesthesiologists use continuous epidural anesthesia for procedures involving the Dornier HM-3 immersion lithotriptor.[5] This regional anesthetic technique provides excellent analgesia for outpatient ESWL; however, it is associated with prolonged recovery times (269–284 min) and a higher-than-expected hospital admission rate (9.9%) despite the use of short-acting local anesthetics.[6] For less painful lithotripsy procedures performed under monitored anesthesia care,[7–9] use of intravenous (iv) sedative–analgesic techniques (*e.g.*, alfentanil infusion) can provide adequate analgesia with shorter recovery times when used as an alternative to epidural anesthesia. While the use of an alfentanil infusion provided for adequate analgesia during the more painful immersion ESWL procedures,[10] the technique was associated with occasional episodes of profound respiratory depression.

Ketamine is a safe, rapid-acting iv anesthetic that has become more widely used to supplement benzodiazepine sedation for brief diagnostic and therapeutic procedures.[11–15] Ketamine's ability to produce sedation–analgesia without clinically significant ventilatory depression might offer an advantage over techniques involving the use of opioid analgesic infusions.[7–10] Furthermore, immersion in the warm-water bath can be associated with significant decreases in blood pressure, and ketamine's cardiostimulatory properties might be advantageous in maintaining cardiovascular stability during the procedure. Finally, since shock wave production with the HM-3 lithotriptor is synchronized with the patient's QRS complex, the increase in heart rate (HR) associated with ketamine might decrease the ESWL procedure time.

We designed a randomized, double-blind study to compare the clinical efficacy and safety of ketamine and alfentanil when infused in combination with midazolam during immersion lithotripsy. In addition, we assessed recovery times, postoperative side effect profiles, and therapeutic outcomes when these two iv sedative–analgesic techniques were used for outpatient lithotripsy.

Materials and Methods

Sixty unpremedicated adult outpatients, ASA physical status 1–3, undergoing elective ESWL for upper urinary tract calculi with the unmodified Dornier HM-3 lithotriptor, were studied according to a protocol approved by the Institutional Review Board. After written informed consent was obtained, patients were randomly assigned to receive either alfentanil or ketamine for iv sedation–analgesia. Exclusion criteria included age less than 18 or greater than 70 yr, a history of drug or alcohol abuse, or allergy to any of the study medications. Ten patients (7 in the alfentanil group and 3 in the ketamine group) were subsequently eliminated from our data analysis because they had ureteral stents placed immediately prior to the lithotripsy procedure under monitored anesthesia care.

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All health care providers administering the study drugs and assessing the patients (as well as the patients themselves) were blinded as to the sedative–analgesic technique used during the procedure.

Preoperatively, baseline measurements of mean arterial pressure (MAP) and HR were obtained with a Dinamap® automatic blood pressure cuff and ECG, respectively, and of respiratory rate (RR) and room air oxygen saturation (Sp_{O_2}) with a Datex® capnograph–pulse oximeter. After placement of the iv catheter, midazolam 2 mg iv was administered in the preoperative holding area. Following transport to the operating room, patients positioned themselves in the lithotriptor chair and supplemental oxygen was administered using nasal prongs (4 l/min) containing a capnograph sampling port for monitoring the patient's RR.

After placement in the warm water bath (37° C), additional midazolam 2–6 mg iv was titrated until the patient achieved a sedation level of 3 (*i.e.*, eyes closed but arousable to verbal commands).[16] Patients were then administered one of the two maintenance analgesic drugs using the Baxter infusion pump (model AS20GH). Group 1 (alfentanil, n = 23) received a loading dose of alfentanil 10 $\mu g \cdot kg^{-1}$ iv, followed by maintenance infusion at an initial rate of 1.0 $\mu g \cdot kg^{-1} \cdot min^{-1}$. Group 2 (ketamine, n = 27) received a loading dose of ketamine, 0.4 $mg \cdot kg^{-1}$ iv, and maintenance infusion at an initial rate of 25 $\mu g \cdot kg^{-1} \cdot min^{-1}$. The alfentanil and ketamine infusion rates were varied by 50–100% to maintain an adequate level of analgesia (*i.e.*, absence of complaints of pain or grimaces in response to the stimulus). If the patient complained of pain, the infusion rate was increased by 50–100%. In the absence of signs of inadequate analgesia, the infusion rate was decreased by 25–50% at 15-min intervals to maintain cardiorespiratory stability. Additional midazolam in 0.5-mg iv bolus doses was given if the patient appeared restless or exhibited excessive movement (which interfered with the surgeon's ability to focus on the renal stone during fluoroscopy) *and* did not respond to increases in the maintenance infusion rate of the study medication. In response to bradypnea (RR less than 10 breaths per min) or $Sp_{O_2} < 90\%$, the maintenance infusion rate was decreased by 50% (or transiently discontinued). The infusion was restarted at the lower infusion rate when the Sp_{O_2}increased to greater than 90%.

Cardiorespiratory variables (MAP, HR, RR, and Sp_{O_2}) were recorded in the preoperative holding area, after the loading dose, 2 and 5 min after initiating the maintenance infusion, and then every 5 min until the end of the ESWL procedure. Intraoperative side effects, including patient movement, complaints of pain, and episodes of desaturation ($Sp_{O_2} \leq 90\%$) also were recorded. After the analgesic infusion was discontinued at the end of the operation, the urologist and anesthetist caring for the patient were asked to evaluate the adequacy of sedation and analgesia using a four-point scale (1 = excellent, 2 = good, 3 = fair, and 4 = unacceptable).

The patients remained in the postanesthesia care unit (PACU) until they returned to their baseline mental status and met the standardized discharge criteria (*i.e.*, awake and oriented, stable vital signs for 30–60 min, no active anesthetic problems, and able to ambulate without assistance). Immediately prior to discharge from the PACU, each patient was asked to assess his or her satisfaction with the iv sedative–analgesic technique as well as to evaluate his or her level of comfort using a 100-mm visual analog scale (0 = extremely uncomfortable to 100 = extremely comfortable), and to report any adverse effects (*e.g.*, pain, nausea, or confusion). In addition, requirements for analgesic, antiemetic, and/or sedative medications in the PACU, and discharge times were noted.

The recovery room nurse also was asked to evaluate the patient in the PACU using a four-point scale (1 = excellent, 2 = good, 3 = fair, and 4 = unacceptable), and variables relating to the urologic procedure itself were recorded (*i.e.*, stone size, density and location, number of shocks delivered, maximal voltage (kilovolts) and degree of fragmentation). Finally, 24 h following completion of the ESWL procedure, the patients were telephoned and questioned regarding their recall of the procedure (*e.g.*, entering the water bath and the sound of the shock waves), their level of satisfaction with the sedative–analgesic technique (*e.g.*, highly satisfied, acceptable, or unacceptable), and the incidence of side effects following discharge from the outpatient facility (*e.g.*, pain, nausea, or confusion).

Data Analysis

Data were analyzed with the Stata® statistical program using one-way analysis of variance (ANOVA) with the

TABLE 1. Demographic Characteristics of the Patients

	Alfentanil Group	Ketamine Group
Number (n)	23	27
Age (yr)*	47 ± 12	50 ± 16
Weight (kg)*	85 ± 31	83 ± 20
Height (cm)*	169 ± 19	171 ± 11
Sex (M:F)	15:8	17:10
Stone size (mm^2)*	75 ± 47	77 ± 56
Stone location (%)		
Caliceal	39	59
Pelvis	26	11
Ureter	35	30
Stone density (%)†		
1	0	0
2	4	7
3	35	37
4	61	56

* Mean values ± SD.
† 1 = radiolucent to 4 = very opaque.

TABLE 2. ESWL Variables and Fragmentation as Functions of the Type of Sedative–Analgesic Medication

	Alfentanil	Ketamine
Number of shocks*	2078 ± 515	1937 ± 542
Voltage (kV)*	20 ± 1	20 ± 1
Fragmentation (%)		
<2 mm	78	50†
2–5 mm	17	42†
>5 mm	4	8

* Mean values ± SD.
† Significantly different from the alfentanil group, $P < 0.05$.

Bonferroni option to compare continuous demographic data, cardiorespiratory variables, anesthesia time, lithotripsy room stay, ESWL procedure time, PACU stay (*i.e.*, phase 1 [lying on a gurney] and phase 2 [sitting up in chair] recovery times), pain scores, and stone-related outcome data for the two sedative–analgesic treatment groups. Nominal data were analyzed using chi-squared analysis. Differences were considered to be statistically significant when the P value was < 0.05. Values are expressed as means ± standard deviation (unless otherwise specified).

Results

The two sedative–analgesic treatment groups were comparable with respect to demographic data and stone characteristics (table 1). There were no differences in the number and voltage (kilovolts) of the shock waves given to each group. However, following the procedure, stone fragmentation was found to be significantly better in the alfentanil group (table 2). In addition, phase 1 recovery time and the hospital discharge time (combined phase 1 and 2 recovery) were shorter for the alfentanil group ($P = 0.05$) (table 3).

Preoperatively, both groups received similar doses of midazolam (5.8 ± 1.7 mg *vs.* 6.6 ± 1.9 mg for alfentanil and ketamine groups, respectively). The total sedative and analgesic dose requirements (and ranges) for the alfentanil group were midazolam 6.4 ± 1.6 mg (4–9 mg) and alfentanil 4.0 ± 1.7 mg (0.6–8.1 mg). The median alfentanil infusion rate was 1.2 $\mu g \cdot kg^{-1} \cdot min^{-1}$ with a range of 0.5–2.0 $\mu g \cdot kg^{-1} \cdot min^{-1}$. The total drug doses in the ketamine group were midazolam 8.5 ± 2.7 mg (4–14 mg) and ketamine 118 ± 43 mg (56–240 mg). The median ketamine infusion rate was 30 $\mu g \cdot kg^{-1} \cdot min^{-1}$, with a range of 20–50 $\mu g \cdot kg^{-1} \cdot min^{-1}$. Intraoperatively, the ketamine group required significantly more midazolam to control restlessness and agitation than did the alfentanil group (ketamine 1.9 ± 2.3 mg *vs.* alfentanil 0.6 ± 0.9 mg, $P < 0.05$).

The perioperative hemodynamic variables are summarized in figures 1A and 1B. As expected, the ketamine group had significantly higher MAP values throughout the ESWL procedure; however, HR was significantly

TABLE 3. Duration (min) of Perioperative Events

	Alfentanil Group	Ketamine Group
Anesthesia	49 ± 12	51 ± 13
ESWL procedure	32 ± 10	30 ± 11
Lithotripsy room	57 ± 11	58 ± 14
Phase I recovery (PACU)	49 ± 21	60 ± 22*
Discharge (phases 1 and 2)	142 ± 42	161 ± 31*

Mean values ± SD.
* Significantly different from the alfentanil group, $P \leq 0.05$.

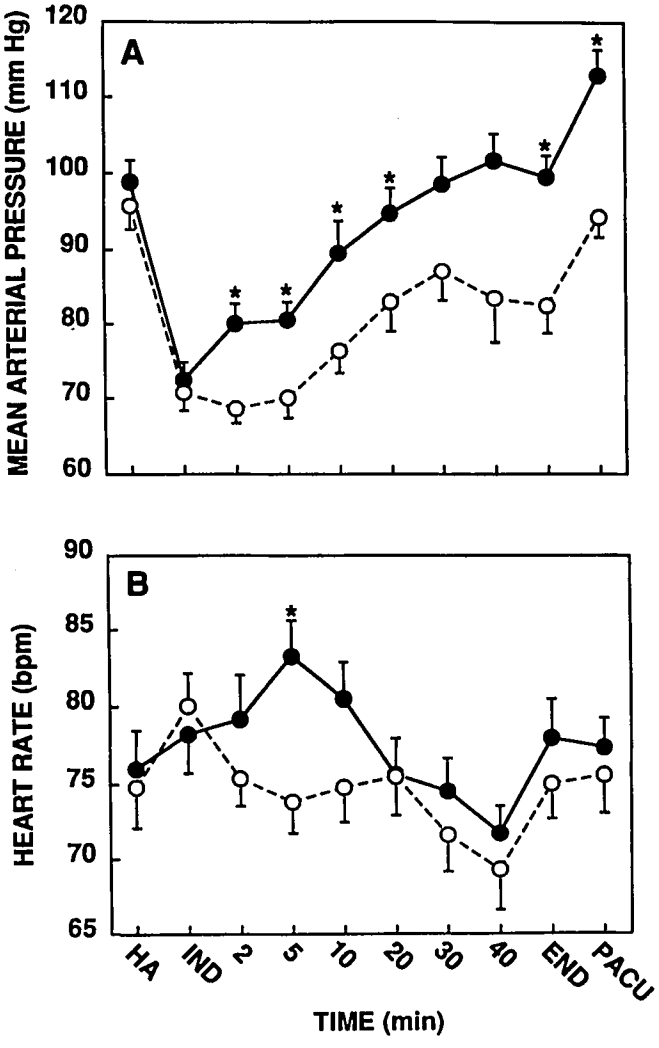

FIG. 1. Perioperative mean arterial blood pressure (*A*) and heart rate (*B*) values in patients receiving either ketamine, n = 27 (filled circles) or alfentanil, n = 23 (open circles). Measurements were performed in the preoperative holding area (HA), after the loading dose (IND), at the end of the procedure (END), and immediately after arrival in the recovery room (PACU). Mean values ± SEM. *$P < 0.05$ was considered to be statistically significant.

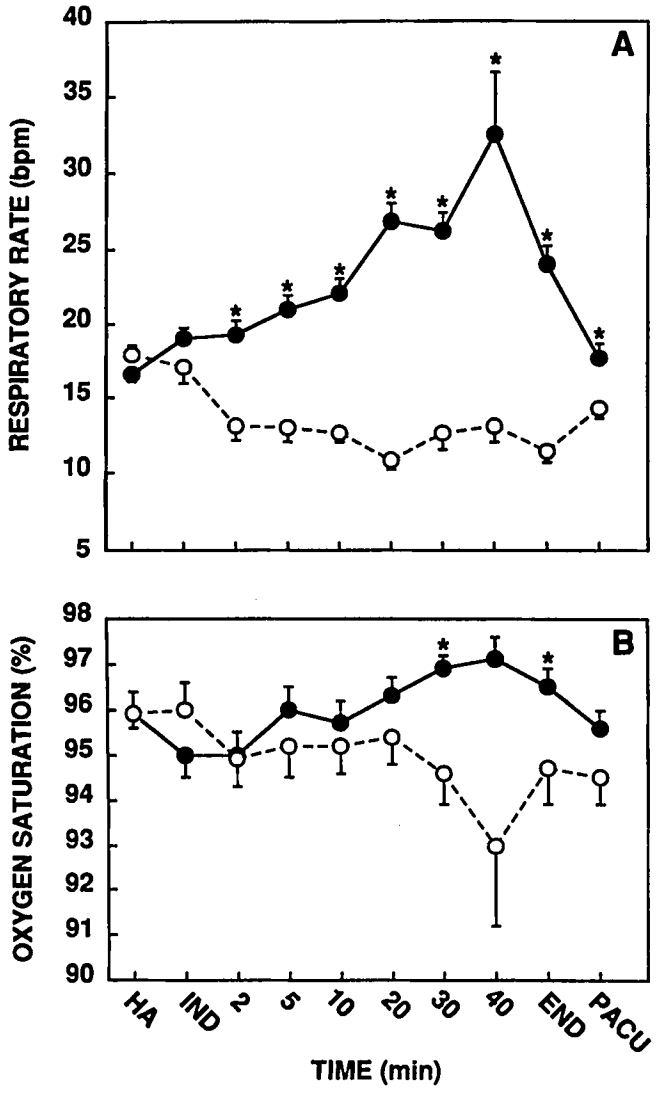

FIG. 2. Perioperative respiratory rate (*A*) and oxygen saturation (*B*) values in patients receiving either ketamine, n = 27 (filled circles) or alfentanil, n = 23 (open circles). Measurements were performed in the preoperative holding area (HA), after the loading dose (IND), at the end of the procedure (END), and immediately after arrival in the recovery room (PACU). Mean values ± SEM. *$P < 0.05$ was considered to be statistically significant.

higher in the ketamine group only at 5 min after the induction bolus. The ketamine group also had significantly higher RRs throughout the procedure (fig. 2A). Sp_{O_2} values were consistently higher in the ketamine group but achieved statistical significance only near the end of the procedure (fig. 2B). The number of episodes of $Sp_{O_2} < 90\%$ was significantly greater in the alfentanil group (table 4).

TABLE 5. Postoperative Patient Assessment on the First Postoperative Day

	Alfentanil Group	Ketamine Group
Comfort (analog scale: 0 = minimal to 100 = maximum)*	94 ± 9	97 ± 5
Recall of events during the procedure (%)	45	12†
Dreaming during the procedure (%)	5	35†
Itching during and after the procedure	23	4†
Confusion during the first 24 h after surgery (%)	5	31†
Patients feeling nauseated during the first 24 h after surgery (%)	32	54
Patients would feel less worried about future ESWL (%)	64	63
Patients without any postoperative anesthetic complaints	95	92
Patients desiring the same analgesic technique	95	100

* Mean values ± SD.
† Significantly different from the alfentanil group, $P < 0.05$.

Although patients in both groups reported being comfortable during the procedure, there were significantly more disruptive movements in the ketamine group (table 4). The postoperative requirements for analgesic (alfentanil 0% and ketamine 11%) and antiemetic (alfentanil 9% and ketamine 4%) medications were similar in both treatment groups. However, the incidence of nausea was greater (not significantly) in the ketamine group (54% *vs.* 32%). Sedative–anxiolytic medication was not required in either group in the PACU. On the postoperative questionnaire, the ketamine group reported a higher incidence of intraoperative dreaming and postprocedural confusion or transient disorientation with respect to person, place, or time (table 5). Recall of specific intraoperative events and itching were significantly less frequent in the ketamine group. The postprocedural patient assessment questionnaire revealed that both techniques were highly acceptable to the patients, and greater than 60% of patients in each

TABLE 4. Number of Intraoperative Side Effects

	Alfentanil Group		Ketamine Group	
	Patients	Episodes	Patients	Episodes
Disruptive movements (n)	3	5	11*	22*
Spontaneous complaints of pain (n)	17	23	14	22
Episodes of desaturation ($Sp_{O_2} < 90\%$)	8	12	2*	2*

* Significantly different from alfentanil group, $P < 0.05$.

TABLE 6. Assessment of Adequacy of the Alfentanil and Ketamine Techniques by the Patient and Professional Staff (%)

	Patient		Urologist		PACU Nurse	
Scale	ALF	KET	ALF	KET	ALF	KET
Excellent	96	70*	74	74	65	46
Good	0	26	26	22	26	42
Fair	4	4	0	0	9	12
Unacceptable	0	0	0	4	0	0

ALF = alfentanil; KET = ketamine.
* Significantly different from the alfentanil group, $P < 0.05$.

group reported that they would feel less worried if they had to have another ESWL procedure in the future.

Patient, urologist, and PACU nurse satisfaction with the two techniques is summarized in table 6. Both techniques were judged to be good or excellent in over 90% of the cases by the patient and the health care personnel. However, significantly more patients in the alfentanil group rated the technique as excellent (96% alfentanil *vs.* 70% ketamine, $P < 0.05$). One patient in the ketamine group required general anesthesia because of excessive restlessness during the ESWL procedure.

Discussion

The development of sedative–analgesic techniques as alternatives to epidural analgesia for immersion lithotripsy has shortened the preparation time as well as the recovery time following ESWL procedures.[10] However, simplified anesthetic techniques are acceptable only if they do not require modification of the surgical technique or contribute to a suboptimal surgical outcome. Both of the iv sedative–analgesic techniques we evaluated allowed the maximal number of shock waves and energy levels during these elective ESWL procedures. However, patients in the ketamine group had less adequate fragmentation of their renal calculi. The poorer surgical outcome in the ketamine group was presumably related to the increased movements noted in response to the painful stimuli and/or to the effects of ketamine on the patients' ventilatory pattern. In contrast, the alfentanil group achieved fragmentation results similar to those seen with epidural anesthesia at our institution.§

Our preliminary study evaluating sedative–analgesic techniques for immersion lithotripsy found that the use of benzodiazepine–opioid combinations resulted in transient respiratory depression and hemoglobin oxygen desaturation (< 90%).[10] The use of ketamine as an alternative to alfentanil for maintenance of analgesia was associated with significantly fewer episodes of intraoperative hemoglobin oxygen desaturation and higher RRs throughout the procedure. The sympathomimetic actions associated with ketamine administration also maintained intraoperative blood pressure closer to the preimmersion (baseline) values. Thus, ketamine was superior to alfentanil with respect to intraoperative cardiorespiratory stability.

Although neither sedative–analgesic technique prolonged the anesthesia or procedure times,[6,10],§ ketamine analgesia resulted in a longer phase 1 recovery time and delayed discharge from our hospital-based outpatient facility compared to the alfentanil technique. In addition, more patients experienced confusion following ketamine administration (31% *versus* 5% with alfentanil). As expected, the midazolam–ketamine technique resulted in more dreaming and less recall of intraoperative events, whereas the midazolam–opioid technique was associated with greater respiratory depression[17] and a higher incidence of postoperative pruritus.

Despite these differences, the majority (greater than 90%) of patients in both groups stated that they were comfortable during the procedure and would choose the same analgesic technique for a future ESWL procedure. Our findings regarding side effects associated with ketamine are similar to those reported when a continuous infusion of ketamine was used for maintenance of anesthesia during brief outpatient procedures.[18] However, the use of clinical (*i.e.*, subjectively defined) endpoints in titrating the maintenance infusions may have contributed to a subconscious bias against ketamine that resulted in less than optimal titration of the ketamine infusion.

Other alternative approaches to general or regional anesthetic techniques during ESWL procedures have been studied. However, simplified techniques using application of a topical cream containing a eutectic mixture of local anesthetics (EMLA®) or local anesthetic infiltration have necessitated longer anesthesia preparation times and reduced shock wave energy (14–16 kV).[19–21],¶ Further studies are needed to compare the patient acceptance, safety, outcome, and cost efficiency of combining local anesthetic techniques with iv sedative–analgesic techniques for outpatient lithotripsy.

In conclusion, both iv sedative–analgesic techniques we studied proved effective for anesthesia in outpatients undergoing immersion lithotripsy. Ketamine analgesia provided superior intraoperative cardiorespiratory stability. However, the higher incidence of disruptive movements during the procedure and postoperative confusion resulted in inadequate stone fragmentation and longer recovery times, respectively. The use of alfentanil analgesia

§ McDougall EM, Denstedt JD, Brown RD, Clayman RV, Preminger GM, McClennan BL: Comparison of extracorporeal shock wave lithotripsy and percutaneous nephrolithotomy for the treatment of renal calculi in lower pale calices. Journal of Endourology 3:265–271, 1989.

¶ Fair WR, Malhotra V: Extracorporeal shock wave lithotripsy (ESWL) using local infiltration anesthesia (abstract). Journal of Urology 135:181A, 1986.

during ESWL procedures yielded stone fragmentation results comparable to those obtained with epidural anesthesia.§ In addition, the alfentanil iv sedative–analgesic technique appears to offer advantages over conventional epidural techniques with respect to anesthesia preparation and recovery times.[6,10]

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