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Research article

Evaluation of dexmedetomidine as a sole agent in sedation of cancer patients undergoing radiological interventional procedures

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ABSTRACT

Background: Previous studies have shown that dexmedetomidine has proven effectiveness as sedative in many outpatient settings and several reports are now available documenting its success for sedation of both non-invasive and invasive procedures.
Objective/purpose: This investigation aimed at evaluation of dexmedetomidine efficacy when used alone for sedation of patients undergoing radiological interventional procedures and measuring its different outcome variables.
Methods: A total of sixty patients who underwent interventional procedures requiring sedation in radiology department were enrolled. Only ages from 18 to 65 years and ASA physical status of I–II were allowed into the study. A loading infusion of one μg/kg over 10 min was started to be followed by a maintenance infusion of 0.2–1 (0.6) μg/kg/h. HR, blood pressure and Spo2 were continuously monitored while pain and sedation were assessed every 10 min by using visual analogue scale (VAS) and Ramsay sedation score (RSS) respectively. cortisol and blood glucose levels were measured pre and post interventionally in addition to the recording of the previously mentioned hemodynamics.
Results: Compared to the pre-sedation values, we observed an acceptable reduction; 11% for blood pressure and 10% for heart rate. Fentanyl was required as a rescue analgesia in 61% of patients enrolled in the study the levels of cortisol and blood glucose in the post intervention period showed statistically significant increase in the post-intervention samples as compared with pre-intervention ones ($P < 0.001$)
Conclusion: Dexmedetomidine can be used alone for sedation of interventional procedures when minimal to mild pain is in prospect thus provides an alternative for anesthesiologists for high risk patients but cannot be used alone when intense pain is anticipated.
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1. Introduction

Conscious sedation is the gold standard for a wide range of outpatient interventions like endoscopy, dental procedures and interventional radiological procedures. The combination of an opiate and a benzodiazepine is known to provide excellent analgesia and sedation during such procedures [1]. However, they carry the risk of respiratory depression among other adverse effects. Local anesthesia alone has been advocated for many interventional radiological procedures in order to avoid risks as well as cost and of conscious sedation. But this approach is likely to be less acceptable to patients and reduce their willingness to undergo repeated procedures e.g. chemoembolization. On the other hand moderate sedation is a logical way to avoid hypoxia in the more susceptible patients.

The research for an ideal sedative is being carried out constantly [2]. Dexmedetomidine is a potent and highly selective α-2 adrenoceptor agonist with sympatholytic, sedative, amnestic and analgesic properties. It has continuously expanding uses, as the FDA approved its use as a sedative in non-intubated patients in late 2008, it received a special consideration to be used in many outpatient settings [3]. It also has the privilege of having a minimal depressant effect on the respiratory system.

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The objective of this study was evaluating dexmedetomidine when used as a sole IV drug for sedation during interventional radiological procedures for cancer patients, and eventually gaining insight about the feasibility and efficacy of dexmedetomidine use in interventional radiology settings. Primary outcome was measuring dexmedetomidine different outcome variables in terms of Ramsy sedation score, VAS score, blood pressure and pulse. Secondary outcome was the determination of dexmedetomidine effect on serum cortisol as a stress hormone and subsequently blood glucose.

2. Patients and methods

The current study enrolled sixty patients scheduled for interventional procedures requiring sedation in radiology department of National Cancer Institute. This clinical trial is registered in clinical trials website as (NCT02180737). Interventions included nephrostomy, radiofrequency ablation, arterial and venous chemoembolization under radiographic imaging. Only ages from 18 to 65 years and ASA physical status of I–II were allowed into the study. Patients suffering from bradycardia or heart block were not included in the study. Patient who received an alpha2-agonist or antagonist within 14 days, IV opioid within 1 h, or an oral or IM opioid within 4 h of the start of study drug administration were excluded. Patients who are allergic to dexmedetomidine were also excluded.

In the pre-procedural holding area; patients were instructed in how to report their pain using VAS pain score, where 0, "no pain" and 100, "Worst pain imaginable". We asked the patients to describe their pain with standardized adjectives that corresponded to numerical scores as follows: 0, none; 10–20, mild; 30–40, discomforting; 50–60, distressing; 70–80, horrible; and 90–10, excruciating Fentanyl was given incrementally by a dose of (0.5–2 μg/kg) as a rescue analgesia when VAS score exceeded 40 mm.

After recording a baseline measurements of heart rate (HR), mean arterial blood pressure (MAP) and Spo2, a peripheral IV access was obtained. We inserted a 18- or 20-gauge intravenous catheter to facilitate fluid and drug administration. Dexmedetomidine diluted in 0.9% saline (4 μg/ml) was prepared in a syringe infusion pump. A loading infusion of one μg/kg over 10 min was started to be followed by a maintenance infusion of 0.2–1 (0.6) μg/kg/h to be given through a separate intravenous line. The rates were adjusted to reach Ramsay Sedation Score (RSS) [4] of 3–4. The RSS 1–6 were recorded at 10 min intervals for conscious sedation [4]. We have chosen the RSS score of 3 as our target level of sedation as it meets the conditions of conscious sedation, that is a minimally decreased level of consciousness, preserving the patients' ability to maintain their airway and to respond appropriately to verbal command.

Venous blood samples were collected before starting dexmedetomidine and immediately after the procedure for serum cortisol and blood glucose measurements and was conducted as follows:

2.1. Sample collection

Blood samples were collected from all patients on clot activator vacutainer tubes for serum cortisol assessment and sodium fluoride containing vacutainer tubes for plasma glucose assessment, before and after procedure. Specimens were centrifuged immediately for serum and plasma separation.

2.2. Methods for assessment

The quantitative measurement of cortisol was done using the IMMULITE® 2000 system analyzer which is a solid-phase competitive chemiluminescent enzyme immunoassay, and enzymatic UV test (hexokinase method) for the quantitative determination of plasma glucose level was done using the Beckman Coulter AU 680 analyzers.

Patients were transferred to the procedure room fully monitored. Patients received oxygen through nasal cannula 4 L/min, followed by a local skin anesthetic of 5–15 mL of 2% lidocaine with a 22 Gauge needle to decrease the initial patient discomfort and to eliminate pain associated with needle placement by the interventionist.

HR, MAP, SaO_2, drugs administered, RSS and time to achieve desired level of Sedation, VAS pain scores were recorded in a flow chart against time. Also adverse events including air way obstruction, apnea, bradycardia, failed sedation and total time of sedation were treated and documented.

Hypotension was defined as systolic blood pressure below 90 mmHg which was managed by IV fluid administration of 10 ml/kg initially and/or ephedrine (0.25–1 mg/kg). Bradycardia was defined as pulse rate below 55 bpm where atropine was given in a dose of 0.01 mg/kg. Desaturation was defined as SpO_2 below 90%. If the oxygen saturation decreased to between 90% and 95%, the patient was asked to take deep breaths if responding to commands while chin left and jaw thrust were applied in case of deep sedation. If the saturation decreased to 90% or less, supplemental oxygen was administered at a rate of 6 L/min via oxygen mask instead of supplying it through nasal cannula. Dexmedetomidine infusion was stopped once the intervention was terminated. Patients were discharged in two stages: first to the recovery room were again HR, MAP and Spo2 recorded and finally home discharge, the discharge criteria required that the patients be awake and alert with stable vital signs, able to ambulate without assistance, pain scores as pre-procedure level, and free of side effects.

3. Statistical methods

Data management and statistical analysis were performed using the Statistical Package for Social Sciences (SPSS) vs. 21. Numerical data were summarized using means and standard deviations or medians and ranges. Categorical data were summarized as numbers and percentages.

Comparisons pre and post procedure were done by paired *t* test while comparisons overtime intraoperative were done by repeated measure analysis of variance.

All p-values are two-sided. P-values < 0.05 were considered significant.

4. Results

4.1. Demographic data

48 males (80%) and 12 females (20%) with age range of 24–68 years old were included in this study. Patients underwent 63 procedures Table 1, least duration of the procedure was 20 min and maximal was 60 min.

4.2. Clinical parameters

Compared to the pre-sedation values, both mean systolic as well as diastolic blood pressures showed a clear and statistically significant post-procedural decline by 11% and 13% respectively ($P < 0.001$), Table 2. The 95% confidence interval for the difference in mean systolic blood pressure was −23.8 to −14 and that for mean diastolic blood pressure was −13.5 to −7.5. Blood pressure decreased steadily on repeated measurements over time during the intraoperative period ($P < 0.001$), Table 3. Intra procedural

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