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Original Article

Safety, feasibility, and acceptability of patient-controlled anxiolysis with dexmedetomidine for burn-care dressing changes: an open-label, single-arm, pilot study

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Abstract: Anxiety is common among patients with burn injury, occurring frequently surrounding wound care. Few pharmacologic interventions targeting anxiety in burn injury have been evaluated. This study aimed to evaluate patient-controlled anxiolysis using dexmedetomidine (PCA-DEX) in patients undergoing burn dressing changes. This was a prospective, open-label, single-arm pilot study to determine the feasibility, safety, and acceptability of PCA-DEX. PCA-DEX included a loading dose, continuous infusion, and patient-administered boluses during dressing changes for up to 5 days. Vital signs were monitored throughout PCA-DEX. Procedural pain and anxiety were evaluated before and after each dressing change. Nursing and patient satisfaction were evaluated after each dressing change. Twenty patients were included; 9 (45%) males and 11 females (55%) with a mean age of 45.1 ± 16.9 years and median total body surface area burn injury of 7 [IQR 4-9.5]%. Median heart rate and systolic blood pressure prior to PCA-DEX on day 1 were 82 [75-97] bpm and 147 [128-170] mmHg. Overall PCA-DEX was tolerated well with a median heart rate of 72 [66-82] bpm and systolic blood pressure 115 [99-141] mmHg after PCA-DEX. One patient was withdrawn due to severe bradycardia (heart rate < 45 bpm) not attributed to PCA-DEX; 4 patients experienced mild hypotension (systolic blood pressure 85-89/diastolic blood pressure 45-49 mmHg), all of which resolved without intervention. The majority of both nurses and patients were either satisfied or highly satisfied with PCA-DEX overall (78.1% for nursing, 86.5% for patients). PCA-DEX is a novel, safe and feasible method of anxiolysis during burn dressing changes with high patient and nurse satisfaction rates. A randomized, controlled trial is warranted to confirm the efficacy of PCA-DEX.

Keywords: Dexmedetomidine, anxiety, pain, wound care, burn injury

Introduction

It is well known that patients with burn injury experience significant amounts of anxiety throughout hospitalization, although there are challenges with regards to accurate assessment and management of anxiety in this population [1-6]. There is an intimate relationship between anxiety and pain in patients with burn injury, with the level of anxiety being directly related to level of pain during dressing changes [6]. The psychological response of sustained anxiety is associated with an increase in sympathetic activation resulting in the release of catecholamines and changes in local blood flow which lower the nociceptive threshold and sensitize the wound [7, 8]. Additionally, muscle tension in the area of burn injury can occur with anxiety to an extent that local nociceptors are activated. Anxiety can also potentiate the perception of pain through triggering of higher brain centers and memories of the previous trauma [9]. These psychological and physiological factors associated with sustained and significant anxiety intensify in a positive feedback phenomenon known as the "wind-up phenom-

enon", contributing to the immense challenges of providing adequate pain management and ultimately decreasing quality of life in patients experiencing burn care interventions [7]. Multiple dressing changes and treatments over the course of the burn patients' recovery can increase fear and anxiety and ultimately patients report feelings of helplessness and loss of control [10]. Finally, inadequate control of procedural pain has been associated with psychological complications including increases in anxiety, background pain, and future procedural pain, which further demonstrates the intimate, cyclical relationship between anxiety and pain [11].

To date, there are limited studies addressing pharmacologic anxiolytic therapy during burn dressing changes. Three studies guide adjunctive benzodiazepine based anxiolysis during burn dressing changes with inconclusive evidence of effectiveness [12-14]. A limitation of this common practice is that medications are administered at the nurses' discretion based on subjective observations of a patient's anxiety. Numerous studies have demonstrated that patient-controlled analgesia in burn patients is beneficial given the patient can self-administer medication according to individual perceived needs that are not controlled by the clinician's judgement [15, 16]. Patient-controlled sedation (PCS) with propofol has been evaluated in a variety of settings without anesthesia-trained personnel including the emergency department and for lithotripsy, dental procedures, and colonoscopy [17-21]. Two pilot studies, in Canada and Sweden, have specifically evaluated the role of PCS with propofol in burn dressing changes [22, 23]. However, there are currently no published studies in the United States of America evaluating the methods for patients with burn injury to engage in anxiety self-management. Dexmedetomidine, an α_2-agonist FDA-approved medication for surgical sedation or procedures, has previously been evaluated as a method for PCS in mechanically ventilated patients and may be a safer option than propofol for self-administration in patients without a protected airway due to its lack of respiratory depressive effects [24, 25]. There is, however, limited examination of dexmedetomidine in the burn population, and it is not known if patient self-administration of dexmedetomidine for anxiety is safe or effective as adjunct therapy for burn patients during painful and distressful burn care treatments [26]. The primary aim of this pilot study was to establish the feasibility and safety of patient-controlled anxiolysis with dexmedetomidine (PCA-DEX) during burn care dressings for patients with burn injury.

Materials and methods

Study design, setting, sample

This was a prospective, open label, single arm, pilot study of adult burn patients requiring burn wound care in the inpatient setting. This study was performed at an American Burn Association verified, adult, comprehensive, 22-bed burn center that treats an average of 330 hospitalized burn patients a year and has over 1600 outpatient visits annually. This study was approved by the institutional review board and was conducted according to US and international standards of Good Clinical Practice (FDA Title 21 part 312 and International Conference on Harmonization guidelines), applicable government regulations and Institutional research policies and procedures. This study was conducted under IND#124973. An Independent Data and Safety Monitoring Board reviewed all patient data after every 5 patients were enrolled to ensure safety for the patients and integrity of the data.

For the purposes of this pilot study, a convenience sample of 20 patients was desired to address our aims. Any patient age 18-89 years admitted to the burn unit for initial management of thermal burn injury (flame, scald, contact) who presented to the burn center within 48 hours of burn injury, with an initial assessment of thermal burn size greater than 1% total body surface area (TBSA), who were expected to stay at least 3 days, and could read, write and speak English were evaluated for inclusion. All patients were required to provide their own informed consent. Patients were excluded if any of the following criteria were present: admission to the intensive care unit, positive pregnancy test or lactation, incarceration, active alcohol withdrawal, current hemodynamic instability (systolic blood pressure (SBP) < 100 mmHg, heart rate (HR) < 60 beats/min sustained for at least 10 minutes without a pacemaker, or symptomatic bradycardia), second or third degree heart block, paralysis or

Table 1. Severity grading for adverse events

Vital Signs	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Potentially Life Threatening (Grade 4)
Bradycardia-beats per minute	50-54	45-49	< 45	Requirement intervention (e.g. pacer or atropine), emergency rapid response activation or transfer to a higher level of care (e.g. intensive care unit or progressive care unit)
Hypertension (systolic)-mmHg	141-150	151-155	> 155	Requirement for medication for hypertension as assessed by burn physician or transfer to a higher level of care (e.g. intensive care unit or progressive care unit)
Hypertension (diastolic)-mmHg	91-95	96-100	> 100	Requirement for medication for hypertension as assessed by burn physician or transfer to a higher level of care (e.g. intensive care unit or progressive care unit)
Hypotension (systolic)-mmHg	85-89	80-84	< 80	Requirement for intravenous fluids, vasopressor agents rapid response activation or transfer to a higher level of care (e.g. intensive care unit or progressive care unit)
Hypotension (diastolic)-mmHg	45-49	40-44	< 40	Requirement for intravenous fluids, vasopressor agents emergency rapid response activation or transfer to a higher level of care (e.g. intensive care unit or progressive care unit)
Respiratory Rate-breaths per minute	12-17	8-12	< 8	Requirement for reversal agent (e.g. naloxone), rapid response activation or intubation
Oxygen saturation, %	85-91	80-85	< 80	Requirement for reversal agent (e.g. naloxone), emergency rapid response activation or intubation

other condition preventing ability to operate PCA device, acute hepatitis or liver failure, acute stroke or acute, uncontrolled seizures, acute myocardial infarction, severe cognition or communication difficulties (e.g., coma, deafness without signing literacy, dementia, non-English speaking), chemical or electrical burn. Based on the recommendation by the Independent Data and Safety Monitoring Board after review of the first 5 patients, the exclusion for second or third degree heart block was based on an electrocardiogram obtained during screening, rather than based on patient reported medical history alone. Patients were approached for study participation prior to their first burn wound dressing change.

The primary endpoints included the feasibility of subject recruitment and adherence to the PCA-DEX for burn care dressing changes protocol. Feasibility was defined by the number and proportion of patients who consented to enrollment, the number of days on protocol that patients successfully used the PCA device, and protocol adherence defined as the proportion of treatment days without protocol violations related to the drug, pump, or both. The primary safety endpoints included the proportion of patients who experienced an adverse effect. Adverse events associated with PCA-DEX including hypotension, bradycardia, and protocol deviations related to drug, pump or both were collected. Each adverse event was assessed for severity (**Table 1**). In addition, all adverse events were assessed for causality using the World Health Organization-Uppsala Monitoring Center standardized case causality assessment system. The secondary endpoints included patient reported pain and anxiety, and patient and nursing acceptability of the PCA-DEX protocol.

Study intervention and measurements

All patients enrolled in the study received burn care dressing changes within the designated treatment room by a trained burn nurse and a patient care assistant. Wound care occurs once daily and the daily dressing change process standardly consists of bathing (either in the shower if the patient is able to stand or in a stainless steel trolley bed if non-ambulatory), mechanical debridement as necessary, assessment of burn wound and/or graft site, and application of topical agent and/or dressing per provider order.

All patients received opioid therapy plus patient controlled anxiolysis with PCA-DEX for burn care dressing changes for up to five days, or until the patient was no longer receiving dressing changes, was discharged from the burn center or until the patient exited the study. After the study period, the anxiolytic medication regimen for burn care dressing changes reverted to usual care (midazolam 1-3 mg IV per nurse driven protocol) if deemed necessary by the attending physician. Opioid therapy was prescribed at the discretion of the attending physician per usual care protocol, which

includes oral oxycodone 5 mg or oxycodone/acetaminophen 5/325 mg administered 30 minutes prior to burn wound care, buccal fentanyl 400 mcg as needed during burn wound care, and IV morphine 4-12 mg or hydromorphone IV 0.5-1.5 mg as needed for breakthrough pain during burn wound care.

PCA-DEX consisted of a dexmedetomidine loading dose, continuous infusion and patient controlled dosing administered via the Alaris®PCA Module. Ten minutes prior to the start of burn wound care, a loading dose of dexmedetomidine (0.25 mcg/kg) was administered intravenously over 10 minutes, followed by a continuous basal infusion of 0.4 mcg/kg/hr with 6 allowable patient-controlled self-boluses per hour (0.1 mcg/kg) each with a 10-minute lockout. This regimen was developed with the aim to balance adequate sedative effect while minimizing risks of hypotension and bradycardia based on a review of the pharmacokinetics of dexmedetomidine and the literature [27, 28]. Prior to the initiation of the first dressing change, patients were educated on the use of the PCA device and instructed to press the button when they felt anxious.

Patients were monitored by the treatment room nurse, patient care assistant, and a non-physician research personnel (CVM, RC, KM) starting 10 minutes prior to the initiation of PCA-DEX, and every 10 minutes throughout the burn wound care. Monitoring continued for 60 minutes after discontinuation of study drug to ensure heart rate and blood pressure returned to baseline. Based on the recommendation by the Independent Data and Safety Monitoring Board after review of the first 5 patients, patients were subsequently screened using standardized criteria on each study day to ensure they were appropriate to receive PCA-DEX based on pre-procedural vital signs. If the study subject had evidence of sustained hemodynamic instability (HR < 60 bpm, SBP < 90 mmHg or DBP < 50 mmHg for at least 10 minutes) during the daily pre-procedure assessment, the patient was not eligible to receive PCA-DEX and received standard of care as appropriate. Alert parameters to notify the physician and the Independent Data and Safety Monitoring Board during burn wound care included: HR < 55 bpm sustained for at least 10 min; SBP < 90 mmHg or > 140 mmHg sustained for at least 10 minutes; DBP < 50 mmHg or > 90 mmHg sustained for at least 10 minutes, respiratory rate < 10 breaths per minute sustained for at least 10 minutes or oxygen saturation < 92% sustained for at least 10 minutes; or persistent inability to understand rationale for triggering the PCA device despite education and demonstration. Subjects exited from the study if any of the following occurred: death or a serious persistent adverse event such as unexplained rash or sustained adverse event, such as SBP < 90 mmHg, diastolic blood pressure (DBP) < 50 mmHg, HR < 50 beats/min or respiratory rate < 10 breaths/minute, for at least 10 minutes.

On each study day with PCA-DEX, patients' anxiety and pain were assessed using the abbreviated Burn Specific Anxiety and Pain Scale (BSAPS). A 100-mm Visual Analogue Scale-Anxiety (VAS-A) and a 100-mm Visual Analogue Scale-Pain (VAS-P) were completed by the patient before and after burn wound care on days they received the PCA-DEX intervention [29-31]. Upon completion of the PCA-DEX protocol on days 1-5, both patients and nurses completed an investigator-developed survey about their satisfaction with self-administration of medication to manage anxiety, ease of medication administration, and the overall satisfaction.

Statistical analysis

Summary statistics are reported as mean ± standard deviation or median [inter-quartile range] and categorical variables are reported as frequencies (%) where relevant. Box plots were created to provide graphical representations of the summary statistics over time for the relevant outcomes. SAS version 9.4 (SAS Institute, Cary, NC) was used for all statistical analyses.

Results

Patient population and feasibility

Twenty patients who met all criteria for inclusion were approached for consent. All twenty patients consented, were enrolled and successfully received PCA-DEX for their first burn wound dressing change. Patients had a median TBSA of 7 [IQR 4-9.5]%. Substance abuse history included 6 (30%) patients with drug abuse, 7 (35%) with tobacco use, and 1 (5%) with alcohol abuse. One (5%) patient had a docu-

Table 2. Baseline and burn injury related characteristics

	PCA-DEX (n=20)
Age, years (mean ± SD)	45.1 ± 16.9
Male sex, n (%)	9 (45)
Race, n (%)	
Caucasian	13 (65)
African America	4 (20)
Hispanic	3 (15)
CAD, n (%)	1 (5)
COPD, n (%)	1 (5)
PUD, n (%)	1 (5)
Liver disease, n (%)	1 (5)
Diabetes mellitus, n (%)	4 (20)
CKD, n (%)	1 (5)
Solid tumor, n (%)	3 (15)
Anxiety, n (%)	1 (5)
Other mental health disorder, n (%)	1 (5)
Tobacco use, n (%)	7 (35)
Alcohol abuse, n (%)	1 (5)
Drug abuse, n (%)	6 (30)
Drugs abused, n (%)	
Marijuana	4 (20)
Opioids	3 (15)
Cocaine	2 (10)
Amphetamines	1 (5)
Burn etiology, n (%)	
Scald	10 (50)
Flame	7 (35)
Contact	3 (15)
Percent TBSA burn (median [IQR])	7 [4-9.25]
Percent TBSA full thickness burn (median [IQR])	2.38 [1.8-2.8]
Percent TBSA partial thickness burn (median [IQR])	7.75 [4.5-8.75]

CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; PUD, peptic ulcer disease; CKD, chronic kidney disease; TBSA, total body surface area.

mented history of anxiety. Patient baseline characteristics are summarized in **Table 2**. No patients had a medical history of heart failure, peripheral vascular disease, stroke, dementia, or hematologic malignancy. Median hospital length of stay was 2 [IQR 1-6.5] days. The majority of patients (85%) were discharged home with only 3 (15%) discharged to a skill nursing facility.

A total of 39 patient days of PCA-DEX were administered, with the majority of patients receiving 1 or 2 days of PCA-DEX. One patient received 3 days and 3 patients received 4 days of PCA-DEX. No patients had PCA-DEX for all 5 allowable days. One patient who received 3 days of PCA-DEX on days 1, 4 and 5 as no dressing changes were required on days 2 or 3. One patient who received 4 days of PCA-DEX failed to receive PCA-DEX on day 3 for a qualifying dressing change. Median duration of dressing change with PCA-DEX was 50 [31-58.5] minutes. On all study days, the median number of PCA-DEX demands exceeded the number of boluses delivered. Data regarding opioids and dexmedetomidine administration for PCA-DEX dressing changes are summarized in **Table 3**.

The overall adherence rate to the PCA-DEX protocol was 92.3%. Lack of adherence to the DEX-PCA protocol occurred on 3 of the 39 total treatment days as follows: PCA-DEX was not administered for an eligible dressing change, PCA infusion pump failed to administer one loading dose, PCA infusion pump lost data and failure to obtain vital sign data due to water interference with the monitor. The last two protocol violations occurred in the same patient on the same treatment day.

Safety

A total of 5 (20%) patients experienced an adverse event. For all patients, the intervention was discontinued and patients were monitored per protocol. No medical interventions beyond discontinuation of PCA-DEX were required for any of the adverse events. Two of the 5 patients with adverse events received PCA-DEX on subsequent qualifying days, two did not receive PCA-DEX as no further qualifying days occurred, and one patient was withdrawn from the study. One patient was withdrawn due to severe bradycardia (HR < 45 bpm); 4 patients experienced mild hypotension (2 systolic and 2 diastolic hypotension). The patient with severe bradycardia met exit criteria at 70 minutes, PCA-DEX was discontinued at 76 minutes, and the

Table 3. Dexmedetomidine and opioids administered for dressing changes on study days 1 through 5

	Study Day 1	Study Day 2	Study Day 3	Study Day 4	Study Day 5
Number of patients receiving PCA-DEX, n (%)	20 (100)	11 (55)	2 (10)	4 (20)	2 (10)
Duration of dressing change (minutes)	55 [41.8-10.8]	45 [24.5-49]	45.5 (41-50)	53.5 [44.5-60.3]	26 (20-32)
Patients with pre-dressing opioids, n (%)	15 (75)	8 (66.7)	1 (50)	2 (50)	1 (50)
Pre-dressing change opioids (OME)	15 [15-15]	15 [15-15]	30	22.5 [18.8-26.3]	30
Patient with opioids during dressing change, n (%)	16 (80)	6 (50)	2 (100)	3 (75)	1 (50)
During dressing change opioids (OME)	135 [120-157.5]	136 [123-155]	140 (120-160)	140 [130-150]	120
Total PCA-DEX dose (mcg)	57 [44.1-82.3]	40.2 [30.5-64.1]	83.8 [44-123.6]	59.6 [54.2-98.4]	43.6 [35.5-51.8]
Number of PCA-DEX demands	10 [4-17]	12 [2-15]	7.5 (3-12)	33 [19-42]	14.5 (5-24)
Number of PCA-DEX boluses delivered	2 [1.5-3]	2 [1-2]	2 (1-3)	3 [2.8-3.3]	1.5 (1-2)

Data presented as median [IQR], or median (minimum-maximum) for data sets ≤ 2, unless otherwise noted PCA-DEX, patient-controlled anxiolysis with dexmedetomidine; OME, oral morphine equivalents.

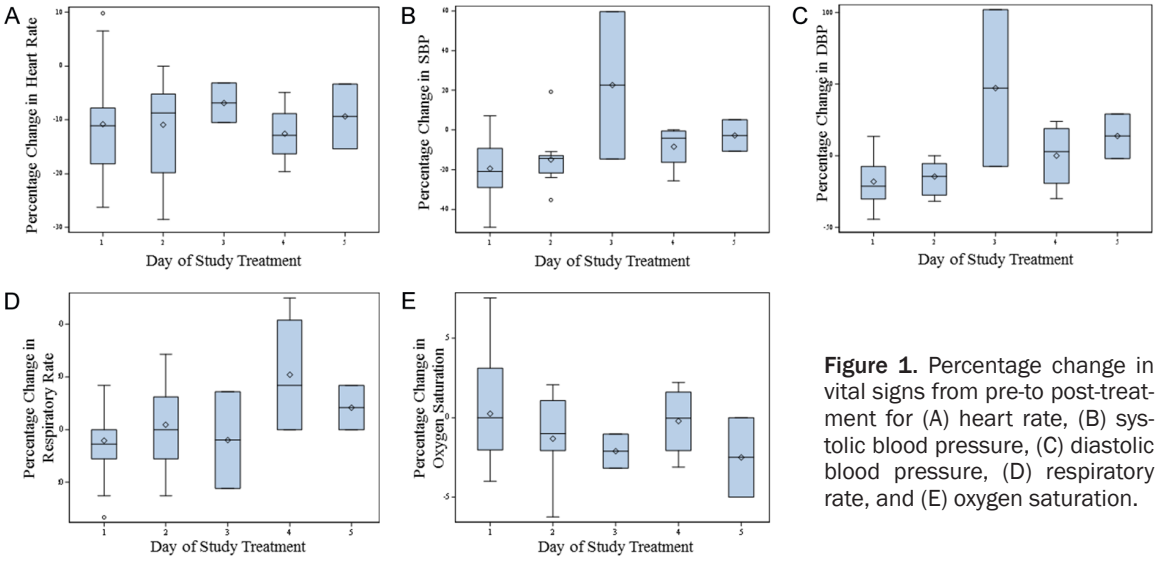

Figure 1. Percentage change in vital signs from pre-to post-treatment for (A) heart rate, (B) systolic blood pressure, (C) diastolic blood pressure, (D) respiratory rate, and (E) oxygen saturation.

patient met criteria for severe bradycardia at 90 minutes. This patient went on to develop tachycardia on day 1, followed by bradycardia day 2, unrelated to PCA-DEX. Cardiology was consulted and they noted dehydration due to home diuretic therapy rather than dexmedetomidine was the most likely etiology.

Pain and anxiety

Median pre-treatment HR and SBP on day 1 were 82 [75-97] bpm and 147 [128-170] mmHg. Overall PCA-DEX was tolerated well with a median post-treatment HR of 72 [66-82] bpm and SBP 115 [99-141] mmHg. Percentage change in vital signs for all patients from pre- to post-treatment are shown in **Figure 1A-E**.

Daily BSPAS scores are reported in **Figure 2**. Pain decreaesd from pre-procedure (49.6 [30.5-80]) to post-procedure (33 [13-67]), while median anxiety also decreased (from 34.5 [13-70] to 15.5 [5-43]). The daily pain and anxiety scores decreased each day from pre- to post-procedure with the exception of day 5 when pain increase slightly (**Figure 3A** and **3B**).

Nurse and patient satisfaction

A total of 41 nursing surveys and 37 patient surveys were completed. Two patients did not complete a survey on one of the study treatment days. Overall, the majority of both nurses and patients were either satisfied or very satisfied with PCA-DEX (78.1% for nursing, 86.5% for patients). Nurses were satisfied or very satisfied (85%) with PCA-DEX as an anti-anxiety medication during burn dressing changes. Nursing satisfaction (satisfied and very satisfied) increased from 62.5% with the nurse's first exposure to 88% with the nurse's second exposure to the PCA-DEX protocol. Looking at future use of PCA-DEX, 80.8% of the nurses

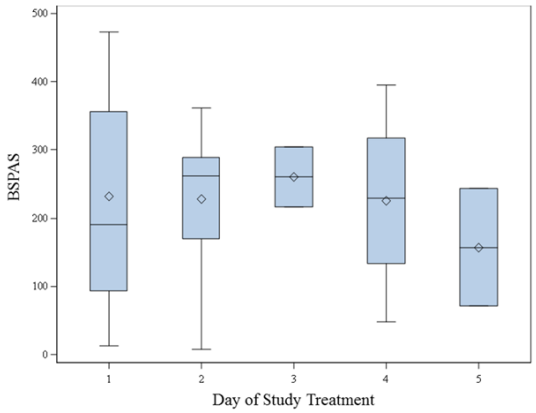

Figure 2. Burn specific pain and anxiety score by study day of treatment.

indicated they would be likely or very likely to select PCA-DEX as a future anti-anxiety medication option if available implying that incorporation into standard practice would be supported by the nursing staff. Patients were satisfied or very satisfied with the ability to self-administer the medication (86.49%), the ability to control their anxiety themselves (86.49%), and the overall level of anxiety control (86.49%).

Discussion

Management of procedural pain and anxiety in patients with burn injury remains a significant challenge to clinicians. There are limited interventions specifically aimed at anxiolytic therapy in this setting. This is the first study to evaluate the feasibility, safety and acceptability of patient administered dexmedetomidine during burn wound dressing care. PCA-DEX was shown to be feasible based on 100% of eligible patients consenting for enrollment, although the majority of patients only received 1-2 days of treatment with PCA-DEX. Compliance with the PCA-DEX protocol was high at 92.3%. Overall, PCA-DEX was well tolerated and adverse events predominantly consisted of mild hypotension (SBP 85-89 mmHg; DBP 45-49 mmHg) and resolved without intervention.

Current practice guidelines recommend early analgesic intervention with a standardized approach for the management of pain associated with burn-care treatments [32]. However, it has been demonstrated that anxiety is a strong independent predictor of pain during dressing changes [6]. Despite high levels of anxiety among burn patients and the known connection to pain, there is currently no standard of care relating to anxiety management for burn dressing changes. A survey of American Burn Association burn centers found that the primary anxiolytic used for burn dressing changes was benzodiazepines (43% of responders), and that 15% of responders reported not using any anxiolytic agent for burn dressing changes [33]. Two studies utilizing oral lorazepam for wound care indicated that early administration within 24-72 hours of burn injury resulted in improvements in both pain and anxiety control [13, 14]. However, Bidwell et al noted no improvement in pain control with the use of intravenous midazolam for wound care when initiated later during burn care [12]. Although there may be benefits associated with benzodiazepines for anxiety associated with wound care, included limited reporting of adverse events. Patterson et al reported that no patients were excluded due to concerns of lorazepam side effects; however, no data regarding hemodynamic or respiratory response after lorazepam treatment were reported. Bidwell et al similarly did not report hemodynamic or respiratory response after midazolam treatment, but did describe one patient who experienced a significant oxygen desaturation to 88%. The current study demonstrated that PCA-DEX was well tolerated with mild reductions in SBP, DBP and HR and essentially no impact on respiratory rate or oxygenation. With limited data to support the efficacy of benzodiazepines, it is important to recognize that this drug class carries risks of both over and under treatment of anxiety, as well as respiratory depression and delirium. Additionally, the existing data for benzodiazepines does not address the potential benefits with self-administered anxiolytic therapy.

There is limited data for patient self-management of sedation or anxiolysis in patients undergoing burn wound care. PCS with propofol has previously been shown to have similar effectiveness to physician-controlled sedation in various procedural settings [17-21]. Two small studies have evaluated the role of PCS with propofol in patients with burn injury [22, 23]. A small dosing finding study in 20 patients receiving their first dressing change 5 days after skin grafting evaluated propofol for PCS [22]. An effective dose of 0.47 ± 0.09 mg/kg with no lockout period was identified to achieve

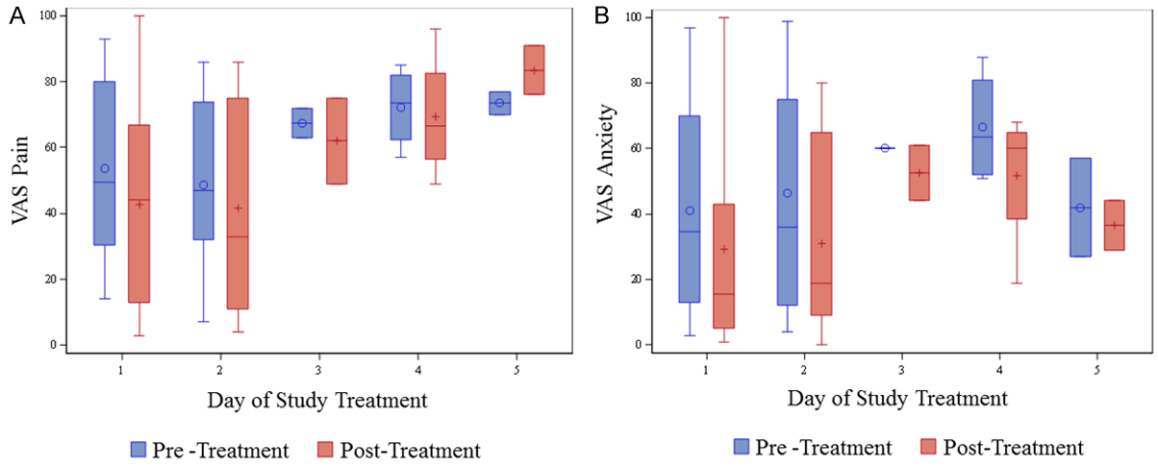

Figure 3. Daily pre- and post-treatment patient reported (A) pain and (B) anxiety using visual analogue scale.

adequate sedation based on a decrease in bispectral index (BIS) by at least 15% or spontaneous eye closure. With this dose patient and nurse satisfaction were high, arterial blood pressure was no more than 25% lower than baseline, but 50% of patients required supplemental oxygen to maintain an oxygen saturation > 94%. Nilsson et al performed a single center, crossover study to evaluate PCS with propofol and alfentanil in 11 patients with > 10% TBSA or > 5% TBSA full thickness burn [23]. Each patient administered bolus consisted of 4.44 mg propofol and 0.039 mg alfentanil and no lockout period was used. Patients first received a dressing change with anesthesiologist-controlled sedation (ACS), followed by the next dressing change with PCS. Sedation method, either ACS or PCS, for the third dressing change was chosen by the patient. Ultimately all 11 patients chose PCS for the third dressing change. PCS lead to lighter level of sedation based on BIS monitoring, and no patients during PCS experienced an oxygen saturation < 94% or respiratory rate < 10 bpm. However, the authors did not report requirements for supplemental oxygen. Both ACS and PCS were associated with significant drops in blood pressure with a MAP range from 60 to 96% of baseline. While these two studies demonstrate patient satisfaction with self-administered sedation, there may be significant limitations relating to both hemodynamic and respiratory stability with the selection of propofol for PCS. Although dexmedetomidine also has a known risk of blood pressure and HR reduction, the lack of respiratory depression may make it a more appealing option for PCS. The current study found reduction in HR, SBP and DBP associated with PCA-DEX similar to what was observed with PCS with propofol, although no patients required supplemental oxygen and no patients experienced a respiratory rate < 12 breaths per minute. Similar to PCS with propofol, PCA-DEX was associated with high nurse and patient satisfaction. With adequate pre-intervention criteria for HR, SBP and DBP, PCA-DEX may be a safer option than propofol for self-administration during burn dressing changes in settings without physician monitoring.

There are several limitations associated with this study. Based on the small sample size, lack of assessment of level of sedation, and no comparator, it is not possible to draw conclusions regarding the efficacy of PCA-DEX. However, the study did note high patient satisfaction levels with regards to anxiety control, which would imply that PCA-DEX would able to achieve patient specific goals. Additionally, correlation between anxiety and pain control were not assessed. Patients included in the current study had relatively small burn wounds and were limited to the adult population, which may limit application to all burn populations. Finally, patients with hemodynamic instability or intensive care unit admission were excluded for safety considerations, but this would limit application to more severe burn injuries.

Conclusions

Results from this pilot study indicate that PCA-DEX is a novel option for anxiolysis in patients with burn injury who are hemodynamically sta-

ble and have the physical and cognitive capacity to operate the device. While patient-controlled dexmedetomidine administration has previously been reported in a mechanically ventilated critically ill population, this is the first report in patients without a protected airway for procedural anxiety management. A randomized, controlled trial is warranted to confirm the efficacy of PCA-DEX for procedural anxiety in patients with burn injury.

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Disclosure of conflict of interest

None.

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