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Dexmedetomidine vs propofol as sedation for implantation of neurostimulators: A single-center single-blinded randomized controlled trial

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Background: During the lead implantation of most spinal cord neurostimulators, the patient has to be comfortable and without pain. However, the patient is expected to provide feedback during electrical mapping. Titrating sedatives and analgesics for this double goal can be challenging. In comparison with our standard sedative agent propofol, the pharmacological profile of dexmedetomidine is more conducive to produce arousable sedation. The latter, however, is associated with hemodynamic side effects. We investigated whether dexmedetomidine is preferable over propofol during neurostimulator implantation.

Methods: This single-center single-blinded randomized controlled trial included 72 patients with an indication for a neurostimulator, randomized to sedation with either propofol (0.5 mg/kg for 10 minutes, followed by 2.0 mg/kg/h) or dexmedetomidine (1 μg/kg for 10 minutes, followed by 0.6 μg/kg/h). The primary outcome was patient satisfaction with the sedation. The secondary outcomes were patient's and operator's comfort, number of titration adjustments, standard intraoperative hemodynamic and respiratory parameters and side effects.

Results: Data of 69 patients (dexmedetomidine n = 35; propofol n = 34) were analyzed. Those receiving dexmedetomidine were more satisfied with the sedation than those receiving propofol; i.e. with sedation delivery (median 100.0 vs 83.3, $P < .01$), procedural recall (median 95.8 vs 83.3, $P = .03$), and sedation side effects (median 90.0 vs 83.3, $P = .01$). Fewer changes in the dexmedetomidine titration were necessary to maintain arousable sedation. Over time, mean arterial pressure and heart rate were significantly lower in the dexmedetomidine group. Hemodynamic side effects were comparable across groups.

Conclusions: Dexmedetomidine sedation resulted in higher patient satisfaction and allowed for better arousable sedation than sedation with propofol. Although differences in hemodynamic parameters were found between the groups, these differences were not regarded as clinically relevant.

1 | INTRODUCTION

For correct lead placement of most spinal cord neurostimulators, the patient's feedback on the overlap between the area of neurostimulation-induced paresthesia and the pain area is essential.[1] Being awake in prone position during a lead implant procedure can be uncomfortable and possibilities for local anesthesia are limited because the deeper structures should preferably not be anesthetized. Because the patient is expected to give immediate and adequate feedback, a superficial local anesthesia combined with arousable sedation analgesia is often used in these interventions.[2,3]

Our standard sedative agent so far has been propofol, which acts on $GABA_A$ receptors. An alternative to this is the use of dexmedetomidine, a highly selective, long-lasting presynaptic α2-adrenoreceptor agonist with sedative, anxiolytic, and analgesic characteristics. It induces a state mimicking natural sleep with easy arousability and no decline in cognitive skills or cooperation. A return to sedated state after arousal by external stimulation is achieved within a few minutes.[4-7] The use of dexmedetomidine does not result in respiratory depression, and is associated with a lower incidence of delirium, as well as lower opioids consumption. On the other hand, side effects such as hypotension and bradycardia have been reported.[8-11] Recently, the use of dexmedetomidine was found beneficial during other procedures requiring arousable sedation, such as an awake craniotomy.[12-14]

We hypothesized that sedation with dexmedetomidine could provide a more stable situation for the patient than sedation with propofol. The primary aim of this study was to determine patient satisfaction with each of these methods of sedation. Secondary aims included determining patient's and operator's comfort, ease of arousable sedation, standard intraoperative hemodynamic and respiratory parameters, and side effects associated with the use of dexmedetomidine and that of propofol during the implantation of a neurostimulator.

Editorial Comments

Both propofol and dexmedetomidine can be suitable agents for sedation in various clinical settings. This study shows that in this single centre cohort who underwent neurostimulator implantation, patients sedated with dexmedetomidine reported higher levels of satisfaction, though those sedated with propofol were generally also satisfied.

2 | MATERIALS & METHODS

Trial registration ISRCTN registry: ISRCTN46302353, ISRCTN registry URL: http://www.isrctn.com/ISRCTN46302353. Clinical trial number: NL52755.078.15.

2.1 | Study design

This was a single-blinded, randomized controlled study. The study protocol was approved by the Medical Ethics Review Board of Erasmus University Medical Center and registered with the Netherlands Clinical Trials Registry on 17 September 2015 (NL52755.078.15) and the ISRCTN registry on 03 December 2015 (ISRCTN46302353). All participants provided a written informed consent.

2.2 | Inclusion of patients

From October 2015 to April 2018, we included 72 consecutive patients (aged 18-65 years) with an indication for implantation of a neurostimulator. Exclusion criteria were hypersensitivity to either of the drugs investigated, atrioventricular block (II-III), acute cerebrovascular disease, HR ≤ 60 bpm, pregnancy, recent acute epilepsy or uncontrolled seizure, severe liver dysfunction, use of beta blocking agents, psychopathology, or a communication problem. The assignment of patients to either the experimental group (i.e. receiving dexmedetomidine) or the group receiving propofol was randomized by the hospital pharmacy using a randomization list compiled by a statistician. To ensure blinding, the hospital pharmacy provided white lines for infusion and covering material for the syringe.

2.3 | Blinding

Sedation was performed by an anesthesiologist who could not be blinded to the study group allocation because the sedation protocols for dexmedetomidine and propofol are different. The patient and the operator however were blinded to the study group allocation. In addition, a blinded observer, not involved in the sedation or the interventional procedure, enrolled the patients and performed all perioperative study measurements. If a medical emergency would have occurred during the intervention, the blinding would have been broken and the reason for it reported.

2.3.1 | Procedural details

Before the procedure, all patients received a standard explanation about the procedure from a specialized pain nurse. Intraoperative standard monitoring parameters, i.e. noninvasive mean arterial pressure (MAP) and heart rate (HR) via ECG, peripheral oxygen saturation (SpO_2), and end tidal CO_2 ($etCO_2$) were measured from the pre-operative moment till the post-operative moment.

Before the start of the procedure, the patient received 1 cc lidocaine (1%) iv to cover possible pain due to the administration of propofol. Both dexmedetomidine and propofol were infused through an iv cannula.

Standard care involved supplemental oxygen by nasal prongs.

To provide analgesia, 1% lidocaine in combination with adrenaline (1:200 000) was infiltrated to the skin prior to the skin incision by the operator. The level of the mid line incision (T5), dissected till the fascia of the paravertebral muscles, was determined by on the stimulation target on the spinal cord or concerned dorsal root(s).

In addition to lidocaine, a set dose of remifentanil (3 μg/kg/h) was administered 10 minutes after administration of the loading dose of dexmedetomidine or propofol. Any pain during the procedure that could not be locally treated with lidocaine, was treated with an additional bolus of remifentanil (25 μg).

The patient's pain problem determined the choice for spinal cord stimulation or dorsal root ganglion stimulation and the number of leads were to be implanted. The preferred location of the battery was the left buttock, unless the patient wished otherwise. The procedure was performed in the surgical day care unit.

2.4 | Sedation protocol

Patients in the dexmedetomidine group received a loading dose of dexmedetomidine of 1 μg/kg over 10 minutes to achieve the required level of sedation, followed by a maintenance dose of 0.6 μg/kg/h. Subjects in the propofol group received a loading infusion of 0.5 mg/kg propofol 1% over 10 minutes followed by a maintenance dose of 2.0 mg/kg/h. The level of sedation during procedure was measured by the Ramsey Sedation Scale immediately before the initiation of sedation and at 5-minute intervals until the end of the procedure. The required depth of sedation was equal to a Ramsey score of 3, corresponding to 'Awake, responds only to commands'.[15] If the level of sedation was inadequate, the dose of sedative was adjusted. Dexmedetomidine was increased or decreased with steps of 0.1 μg/kg/h with an acceptable range of 0.6-1.4 μg/kg/h. Propofol was increased or decreased with steps of 1 mg/kg/h with an acceptable range of 2.0-4.0 mg/kg/h. All such adjustments were recorded and used as an indicator for the production of arousable sedation. Sedation was not stopped during the procedure.

2.5 | Measurements

The primary outcome parameter was patient satisfaction with the sedation, measured with the Patient Satisfaction with Sedation Index (PSSI), a valid and reliable instrument.[16] The PSSI consists of 4 subscales, i.e. sedation delivery (2 items), procedural recall (4 items), sedation side-effects (10 items), and global satisfaction (4 items). Subscale scores can range from 0 to 100, with higher scores indicating higher patient satisfaction. Since the study population was Dutch-speaking, 3 Dutch physicians (native speakers) who were fluent in English had translated the US version of the PSSI into Dutch. Differences between the 3 translations were discussed until consensus was reached, resulting in a single Dutch translation. Back translation into English resulted in hardly any difference with the original English version.[17]

The secondary outcomes were: (a) patient's comfort and operator's comfort throughout the procedure, measured as the response to the question "What score would you give to the comfort during the procedure?" — from 1 (bad) till 4 (excellent); (b) number of adjustments made during dexmedetomidine or propofol titration; (c) level of sedation measured with the Ramsey Sedation Scale; (4) sedation side effects[18] (i.e. desaturation, airway intervention, laryngospasm, hypotension, bradycardia, vomiting, and unwanted movement), and (5) intraoperative standard monitoring parameters — i.e. noninvasive MAP and HR via ECG, SpO_2, and $etCO_2$.

2.6 | Data collection

The measurements were performed every 5 minutes during the procedure.

Each procedure was divided into 9 predefined phases (pre-operative and T1-T8). Measurements were made at the following predefined moments: a pre-operative measurement baseline measurement in the outpatient clinic during pre-operative screening; (T1) at lidocaine infusion; (T2) at start of infusion of dexmedetomidine or propofol; (T3) at start of remifentanil; (T4) at start of the procedure; (T5) at midline incision (incision of the skin for anchoring the lead of the subcutaneous fascia and subcutaneous tunneling of the lead); (T6) at the end of the procedure; (T7) in the recovery room; and (T8) post-operatively on the ward.

The mean values of the measurements made during each predefined served as the outcomes of the phases. Mean values were calculated because the predefined phases varied in duration.

2.7 | Statistical analysis

The sample size calculation was based on the primary outcome parameter: patient satisfaction measured by the validated Patient Satisfaction with Sedation Index (PSSI). A statistically detectable and clinically relevant effect size (d) of 0.45 was chosen on the basis of Vargo et al[16] The power of the study ($1 - \beta$) was chosen to be 0.8, the allocation ratio to be 1:1, and the two-sided level of significance (α) to be .05. The required a priori total sample size computed by this method is 72.

Descriptive statistics were used to determine the frequencies of the demographic variables and the outcome parameters, and to describe measures of central tendency and variability, depending on the shape of the distribution.

All distributions were checked for normality using the Kolmogorov-Smirnov test. If a parameter appeared to be normally distributed, its features are presented as mean ± standard deviation (SD). When not normally distributed, data are presented as median and interquartile range (IQR).

Differences between the 2 groups in variables measured only once were tested with the independent-samples Mann-Whitney *U* test if the parameter was not normally distributed, or with the independent samples t test if the parameter was normally distributed.

Differences in relative frequencies between the 2 groups were tested with Fisher's Exact test.

TABLE 1 Patient characteristics by study group

	Dexmedetomidine group (n = 35)	Propofol group (n = 34)
Age (y), median [IQR]	46.9 [52.9-40.9]	46.4 [56.2-36.7]
Female gender, n (%)	23 (65.7)	25 (73.5)
BMI (kg/m^2), mean (SD)	27.2 (5.8)	27.2 (5.3)
Pre-operative NRS pain score, median [IQR]	7.9 [8.8-6.5]	7.7 [8.3-6.6]
Medications, n (%)		
None	6 (17)	3 (9)
Paracetamol	10 (29)	14 (41)
NSAID	8 (23)	8 (24)
Gabapentinoids	16 (46)	9 (27)
Weak opioids	1 (3)	3 (9)
Strong opioids	17 (49)	15 (44)
Antiepileptic's	1 (3)	2 (6)
Antidepressants	14 (40)	14 (41)
Benzodiazepines	7 (20)	9 (27)
Smoking, n (%)		
Non-smoker	22 (63)	22 (65)
Smoker	8 (23)	10 (29)
Unknown	5 (14)	4 (12)
Alcohol use, n (%)		
Yes	22 (63)	14 (41)
No	4 (11)	15 (44)
Unknown	9 (26)	5 (15)
Neurostimulator indication, n (%)		
CRPS I & II upper extremity	6 (17)	8 (24)
CRPS I & II lower extremity	14 (40)	11 (32)
Neuropathy	6 (17)	6 (18)
Failed back surgery syndrome	9 (26)	7 (21)
Other	0 (0)	2 (6)

Abbreviations: CRPS, complex regional pain syndrome; NRS pain score, numeric rating scale (11-point NRS 0-10); NSAIDs, non-steroidal anti-inflammatory drugs; weak opioids: codeine or tramadol; strong opioids: morphine, oxycodone, tapentadol, fentanyl, methadone, extended release morphine.

The repeated measured parameters (i.e. MAP, HR and SpO_2) were analyzed using a repeated measures MANOVA. The factor group (the dexmedetomidine group and the propofol group) and the factor time (i.e. all phases of the implantation procedure [Pre-operative and T1-T8]) served as independent parameters. Dependent variables were the repeated parameters mentioned above.

The MANOVA for repeated measurements within factors model requires that each dependent variable entered into the analysis be normally distributed. However, if the distribution of repeated measured parameters was non-normally distributed the MANOVAs were still used, because the Monte Carlo experiments have shown that, for sample sizes of 3 or 5, it is possible to analyze distributions quite dissimilar to normal ones. These latter experiments demonstrated that the empirically determined rejection region of the F-distribution would be no larger than $\alpha = 0.08$ when the usual 5% rejection is used (Keppel 1973).[19] For all statistics, α was set at the .05 level.

3 | RESULTS

3.1 | Patient characteristics

Three of the 72 included patients dropped out from the study: one because the patient's back anatomy necessitated lead placement guided by a MRI-scan (which was not available), and 2 patients for logistical reasons (study measurements performed by a non-blinded person). Table 1 presents the characteristics of the patients for both groups.

3.2 | Patient satisfaction

The scores of the patients in the dexmedetomidine group on 3 of the 4 subscales of the PSSI were significantly higher than those of the patients in the propofol group, which shows a greater satisfaction of the former (see Table 2). We excluded item 20 of the subscale 'Global satisfaction', which measures satisfaction with the current intervention compared to that of a previous one, from the analysis because three quarters of the patients did not have a previous one.

3.3 | Patient's and operator's comfort

In both groups, the median patient's comfort score was 3.00 [IQR 1.0] ($P = .75$). The operators' comfort score in the dexmedetomidine group was 3.00 [IQR 1.0] vs 3.00 [IQR 0.63] in the propofol group ($P = .50$).

3.3.1 | Hemodynamic variables

Mean arterial pressure

The MAP showed a bigger decrease over time in the dexmedetomidine group than in the propofol group (factor "Time × Group"

TABLE 2 Patient Satisfaction as assessed with the Patient Satisfaction Sedation Index (PSSI), patient satisfaction subscales and transformed scores: score 0 (= low satisfaction) to 100 (= high satisfaction) notated as median [IQR]

	Dexmedetomidine group (n = 35)	Propofol group (n = 34)	*P*-value
Sedation delivery	100.0 [100.0-91.7]	91.7 [93.8-83.3]	<.01
Procedural recall	91.7 [95.8-83.3]	83.3 [91.7-75.0]	.03
Sedation side-effects	90.0 [95.0-85.0]	83.3 [87.1-80.0]	.01
Global satisfaction (item 20 excluded)	94.4 [100.0-88.9]	88.9 [100.0-83.3]	.17

$F_{(4.0,\ 268.0)}$ = 3.5, P < .01). There was a difference regarding the factor time (factor "Time" $F_{(4.0,\ 268.0)}$ = 81.8, P < .01) and regarding the factor group (factor "Group" $F_{(1,\ 67)}$ = 4.8, P = .03). The post hoc test revealed only a significant difference at T8 (P = .005) (see Figure 1).

At some time during the procedure, 2 patients in the dexmedetomidine group had a MAP < 60 mm Hg, with a minimum perioperative pressure of 51 and 54 mm Hg respectively. Both were given a single ephedrine injection. In the propofol group one patient had a MAP < 60 mm Hg (minimum 58 mm Hg).

Heart rate

The HR course differed between the groups over time (factor "Time × Group" $F_{(3.6,\ 242.8)}$ = 9.6, P < .01). There was a difference regarding the factor time (factor "Time" $F_{(3.6,\ 242.8)}$ = 5.1, P < .01) and regarding the factor group (factor "Group" $F_{(1,\ 67)}$ = 8.4, P < .01). The post hoc test revealed a significant difference at the last 3 moments of measurements (T6-T8) (all P < .001) (see Figure 2).

In the dexmedetomidine group, 2 patients had, once or more, a perioperative HR < 50 bpm (minimum 38 and 49 bpm, respectively) for which one patient was given a single ephedrine injection. In the propofol group none of the patients had a HR < 50 bpm.

Peripheral oxygen saturation

No interaction of time and group was found regarding SpO_2 (factor "Time × Group" $F_{(5.0,\ 333.6)}$ = 1.8, P = .12). The course of SpO_2 differed regarding the factor time (Factor "Time" $F_{(5.0,\ 333.6)}$ = 12.5, P < .01), however, no difference was found regarding the factor group (factor "Group" $F_{(1,67)}$ = 0.1, P = .74). No significant differences were found at any moment of measurement as a result of the post hoc test (see Figure 3).

In the dexmedetomidine group, desaturation (SpO_2 < 90%) was found in 2 patients on one or more moments during the procedure (89% and 88% minimum, respectively) compared with 4 patients in the propofol group (86%, 84%, 89%, and 86% minimum respectively).

Study and rescue medication

The mean amount of dexmedetomidine consumption was 74.79 (SD 36.0) µg. The median of propofol consumption was 186.0 [IQR 240.0] mg.

A rescue bolus of remifentanil 25 µg was given if a patient reported a high level of pain. In the dexmedetomidine group, 18 patients received 1-5 rescue boluses and 1 patient received > 5 rescue boluses. In the propofol group, 18 patients received 1-5 rescue boluses and 3 received > 5 rescue boluses. In total, there were 50 in the dexmedetomidine and 61 in the propofol group (P = .523).

The median total amount of remifentanil administered, continuous and bolus infusion combined, was 342.80 [IQR 238.8] µg in the dexmedetomidine group vs 336.90 [IQR 317.0] mg in the propofol group (P = .75).

A remifentanil bolus can cause a respiratory depression. In the dexmedetomidine group, 2 patients showed a desaturation of SpO_2 < 90% during the procedure, which in one patient occurred after a bolus administration. In the propofol group, 4 patients experienced desaturation; 1 patient experienced 2 desaturations; and 3 patients experienced 1 desaturation. Four of these 5 desaturations occurred after a bolus administration.

Local anesthetic

The anesthetic solution used to provide local anesthesia contained 1% lidocaine plus adrenaline (1:200 000). The mean total volume of

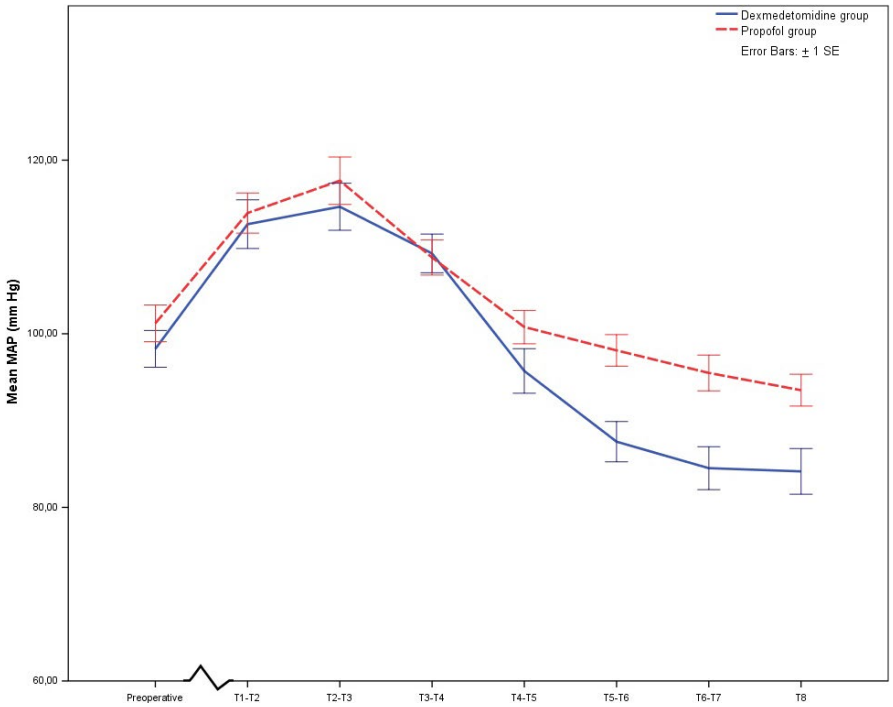

FIGURE 1 Data on MAP during the procedure. Predefined moments are a pre-operative measurement; (T1) at lidocaine infusion; (T2) at start of infusion of dexmedetomidine or propofol; (T3) at start of remifentanil; (T4) at start of the procedure; (T5) at midline incision; (T6) at the end of the procedure; (T7) in recovery; and (T8) post-operatively on the ward

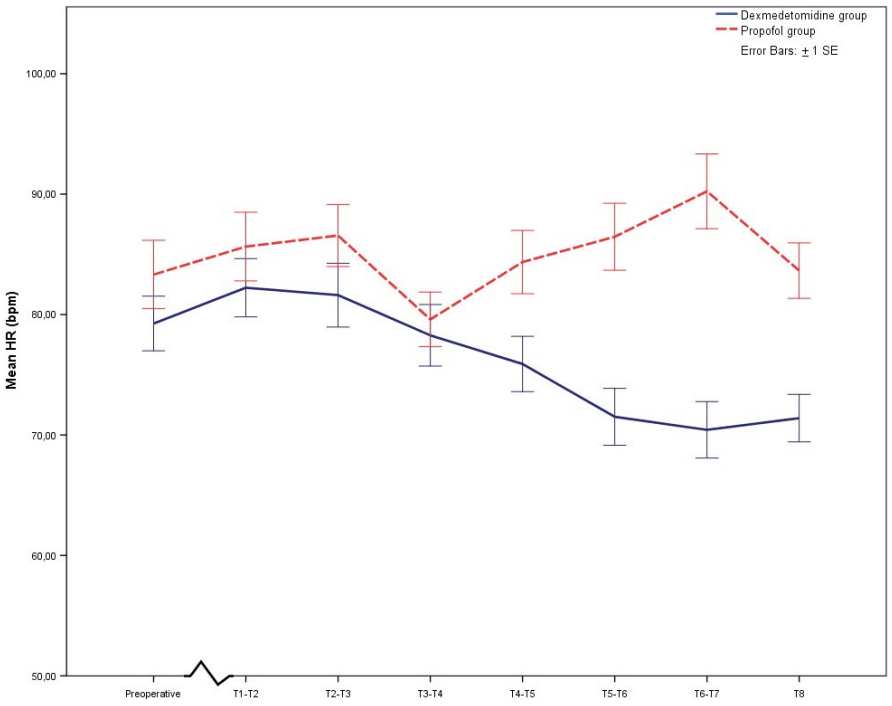

FIGURE 2 Data on HR during the procedure. Predefined moments are a pre-operative measurement; (T1) at lidocaine infusion; (T2) at start of infusion of dexmedetomidine or propofol; (T3) at start of remifentanil; (T4) at start of the procedure; (T5) at midline incision; (T6) at the end of the procedure; (T7) in recovery; and (T8) post-operatively on the ward

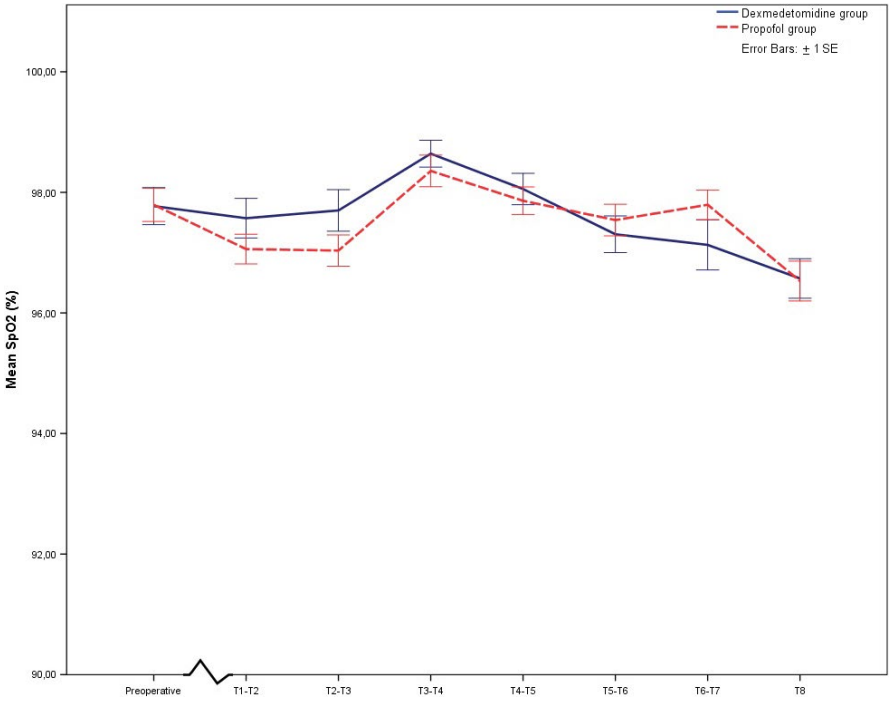

FIGURE 3 Data on SpO_2 during the procedure. Predefined moments are a pre-operative measurement; (T1) at lidocaine infusion; (T2) at start of infusion of dexmedetomidine or propofol; (T3) at start of remifentanil; (T4) at start of the procedure; (T5) at midline incision; (T6) at the end of the procedure; (T7) in recovery; and (T8) post-operatively on the ward

lidocaine administered in the dexmedetomidine group was 37.3 cc (equals 373 mg lidocaine and 186.5 μg adrenaline) vs 38.2 cc (equals 382 mg lidocaine and 191 μg adrenaline) in the propofol group (P = .74).

Side effects

One patient in the propofol group was subjected to a head tilt/chin lift after the sedation has suddenly deepened (up to Ramsey score 4) and the patient had lost consciousness. Three patients in the dexmedetomidine group were given a single ephedrine injection after MAP had decreased and/or HR decreased. One patient in the propofol group showed a vagal reaction at the start of the procedure, for which a single ephedrine injection was administered. The number of administered ephedrine injections did not differ between the groups (P = .61).

Production of arousable sedation

Regarding the production of arousable sedation, sedative titration was adjusted for 11 patients in the propofol group vs 2 patients in the dexmedetomidine group (P < .01) (see Table 3).

TABLE 3 No. of patients requiring titration adjustments and no. of patients experiencing side effects

	Dexmedetomidine group (n = 35)	Propofol group (n = 34)	*P*-value
Number of titration adjustments			
Patients, n (%)	2 (5.7)	11 (32.4)	<.01
No. of titration increasement	2	17	
No. of titration decreasement	1	16	
Side effects, no. of patients (%)			
Desaturation	2 (5.7)	4 (11.8)	.43
Airway intervention	0 (0)	1 (2.9)	
Laryngospasm	0 (0)	0 (0)	
Hypotension (MAP < 60 mm Hg)	2 (5.7)	1 (2.9)	1.00
Bradycardia (HR < 50 bpm)	2 (5.7)	0 (0)	.49
Vomiting	0 (0)	1 (2.9)	
Unwanted movement	0 (0)	2 (5.9)	

Duration

The median duration from the start of procedure until median incision was 40.00 [IQR 26.0] minutes in the dexmedetomidine group and 36.00 [IQR 17.0] minutes in the propofol group (*P* = .81). The duration of the entire procedure was 71.00 [IQR 28.0] minutes in the dexmedetomidine group and 70.50 [IQR 34.3] minutes in the propofol group (*P* = .82). The median time elapsed from start of sedation till reaching a Ramsay score of 3 was 20.00 [IQR 6.0] minutes in dexmedetomidine group vs 20.00 [IQR 12.3] minutes in the propofol group (*P* = .41).

4 | DISCUSSION

In this study, we compared the degree of the satisfaction with the sedative of patients undergoing implantation of a neurostimulator between those who received dexmedetomidine and those who received propofol as a sedative agent.

4.1 | Satisfaction

Patients who had received dexmedetomidine were more satisfied with the sedation than those who had received propofol. This higher level of satisfaction was related to the sedation delivery, the procedural recall, and to the sedation side effects. Although patient satisfaction is important in its own right, it has also become increasingly important as an indicator of the quality of health care. Inevitably, it will also have an effect on reimbursements.[20-22] However, the relative importance of aspects regarding sedation from the patient's perspective and from the clinical perspective can be questioned considering that patient safety cannot be deduced from the patient's experience and needs to be based on clinical parameters.

4.2 | Comfort

A cooperative and calm patient is important for the operator, but deeper sedation and being pain-free provides more comfort for the patient. Ideally, a patient and the operators are both highly satisfied with the situation, and a balance has been reached between each party's requirements.[21] The results of this study show that this was achieved with each of the sedatives.

Although patients receiving dexmedetomidine were more satisfied than patients receiving propofol, they did not report a higher comfort. In hindsight, the operationalization of the concept of 'comfort' might have been capacious and ambiguous.

4.3 | Production of arousable sedation

A Ramsey Sedation Score not equal to 3 after an auditory or painful stimulus, was an indication to adjust the infusion rate. Because the anesthesiologist was guided by the Ramsey score, we presume that the decisions of the anesthesiologist, although not blinded, have not biased our results. More infusion rate adjustments had been made in the propofol group. The lesser need for adjustment in the dexmedetomidine group indicates that dexmedetomidine permits easier arousable sedation.

A recently introduced alternative approach for the implantation of 10-kHz high-frequency Spinal Cord Stimulation therapy requires no intraoperative paresthesia testing because it is based on anatomical lead placement.[23-25] The value of this approach for other neurostimulators using different frequencies is still being discussed. Obviously, arousable sedation need not be produced when an anatomical approach is used. Nonetheless, Tuohy needle placement on levels above L2 in sedated and or anesthetized patients is heavily disputed. It has been argued that arousable sedation is required in anatomical placement as well.

4.4 | Hemodynamic variables

Consensus on the safe ranges of MAP and HR during moderate sedation has not yet been reached, probably because patient populations, patient positioning, and procedures differ. Brady and colleagues express this as follows: "... *one size does not fit all*".[26] In the

present study, although more hemodynamic side-effects were found in the dexmedetomidine group compared to the propofol group, only few emergency interventions were needed in either group. Hence we conclude that both the use of dexmedetomidine and that of propofol can provide a safe situation during sedation.

Theoretically, the differences the experimental groups found in hemodynamic variables could have been the result of the adrenaline contained in the local anesthetic solution. However, given the small amount of lidocaine administered, we consider this unlikely.

4.5 | Pharmacokinetics

An alpha-2 agonist can cause a biphasic hemodynamic effect. This effect consists of a short-term hypertensive response via vasoconstriction through the alpha-2B receptors (peripheral smooth muscle cells), followed by a hypotensive response mediated through the alpha-2A receptors by inhibition of the firing of the locus coeruleus and the norepinephrine release at the neuroeffector junction.[7,27,28] Although this phenomenon has been described in relation to clonidine, Gerlach et al[29] reported that this is not common after dexmedetomidine infusion. In the present study, we found no evidence of a biphasic hemodynamic effect, possibly because dexmedetomidine was administered as a loading dose followed by a maintenance dose instead of a bolus.

4.6 | Limitations

A limitation of the present study is that it was performed in a single center, which restricts the generalizability of our results. Furthermore, the primary outcome 'patient satisfaction' was measured using a back and forward translated (Dutch language) version of the PSSI, which has not been specifically validated for the Dutch population. In addition, the Ramsey score is a subjective measure of depth of sedation. Instead of this measurement, a more continuous and objective measurement by BIS monitoring could be recommendable. Also, two relevant parameters — i.e. (a) the time elapsed between a stimulus and a coherent response from the patient and (b) the time course at the recovery — were not measured.

4.7 | Conclusion

As patients receiving dexmedetomidine were more satisfied with the provided sedation than were patients receiving propofol, dexmedetomidine might be preferable over propofol for the implantation of a neurostimulator. Moreover, the use of dexmedetomidine achieved an easier production of arousable sedation — with lesser need for a change in titration. Regarding the hemodynamic outcomes, the MAP and HR values in the dexmedetomidine group were lower than the values in the propofol group. A difference in SpO_2 was found between the groups, without a consistent pattern. Although differences in hemodynamic parameters were found between the groups, these are regarded as clinically irrelevant.

CONFLICT OF INTEREST

The authors have no competing interests to declare.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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