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Original Research Article

To Compare the Effects of Remimazolam and Dexmedetomidine with respect to the QoR-40 Score of Patients who have undergone FESS

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Abstract:

Background: Chronic Rhinosinusitis (CRS) is a common illness that reduces a patient's quality of life. When medication is inadequate, Functional Endoscopic Sinus Surgery (FESS) can improve quality of life and symptoms of sickness both temporarily and permanently. However, 65% of patients with FESS experienced mild to severe pain on postoperative Day 1 (POD1). Although Remimazolam is a new ultrashort-acting benzodiazepine with minimal side effects and hemodynamic stability, it is rapidly becoming a sedative-anesthetic in clinical practice. Remimazolam have anti-inflammatory, immunomodulatory and analgesic properties.

Aim: The current study aims to compare the effects of remimazolam and dexmedetomidine with respect to the QoR-40 score of patients who have undergone FESS

Method: GMERS Medical College in Junagadh, Gujarat, was the place to conduct a single-blind, randomized controlled clinical trial for this investigation. The university's ethical committee accepted the study, and regular procedures were followed to ensure the research's validity. A 1:1:1 random assignment was used to place the 120 eligible patients in Group R, Group D, or Group C. Age between 18 and 65 years, synchronous sinonasal symptoms that have persisted for more than 12 weeks, sinusitis as shown by a sinus computerized tomography (CT) scan, physical status I or II as defined by the American Society of Anesthesiologists (ASA), and a scheduled elective FESS were the criteria used to prospectively enroll CRS subjects.

Results: QoR-40 scores of Groups R (154.5, 152.0–159.0) and D (155.0, 154.8–159.3) had lower QoR-40 (median, IQR) scores overall at POD1 than Group C (139.0, 136.8–142.0) ($P < 0.001$). The overall QoR-40 score did not differ significantly between Groups R and D. Moreover, the emotional intelligence scores on POD1, Groups R and D had lower state, physical comfort, and pain dimensions than Group C ($P < 0.005$). Moreover, the maximal VAS pain score was lower in the PACU and ward in Groups R and D than in Group C ($P < 0.001$). The RASS score was lower upon PACU arrival in Groups R and D than in Group C ($P < 0.001$).

Conclusion: From the analysis of study, it has been concluded that after FESS, remimazolam and dexmedetomidine may lower the intensity of pain and enhance the quality of recovery. Remimazolam's efficacy and safety are on par with dexmedetomidine.

Keywords: Remimazolam, Dexmedetomidine, Quality of recovery, chronic rhinosinusitis, Functional endoscopic sinus surgery.

Introduction

A prevalent condition that lowers a patient's quality of life is Chronic Rhinosinusitis (CRS). Functional Endo-scopic Sinus Surgery (FESS), which can enhance quality of life and illness symptoms both temporarily and permanently that is indicate when medicine is ineffective [1,2].

On postoperative Day 1 (POD1), however, mild to severe pain was reported by 65% of patients who had FESS [3]. After surgery and anaesthesia, the Quali-ty of Recovery (QoR) score is currently an objective indicator of the patient's overall health [4]. The QoR-40 questionnaire has been verified in patients having a variety of surgical procedures and is known for its high completion and response rates as well as its time efficiency [5].

Due to its calming, analgesic, and sympathetic effects, dexmedetomidine, a highly selective α-2 adrenergic agonist, was used to enhance the quality of life [6]. Prior research had demonstrated that intravenous dexmedetomidine could improve adult

patients' quality of life following elective surgery [7]. Remimazolam is quickly becoming a sedative-aesthetic in clinical practice, even though it is a novel ultrashort-acting benzodiazepine with haemodynamic stability and little adverse effects [8,9]. However, may have analgesic, immunomodulatory, and anti-inflammatory effects [10]. Interestingly, a prior study found that remimazolam could increase the synaptic inhibitory cytokines and lessen injection pain caused by propofol [11,12].

Thus, the purpose of this study was to assess how the QoR of patients who had undergone FESS was affected by the intravenous administration of dexmedetomidine and remimazolam. We postulated that remimazolam administered intravenously is a viable choice for enhancing quality of life.

Aim

The current study aims to compare the effects of remimazolam and dexmedetomidine with respect to the QoR-40 score of patients who have undergone FESS

Method

This study was single-blind, randomized controlled clinical trial completed at GMERS Medical College, Juna-gadh, and Gujarat. The study was approved by ethical committee of university and standard protocols were fol-lowed to maintain the authenticity of the research. 120 patients who qualified for the trial were randomly as-signed 1:1:1 to Group R, Group D, or Group C. A computer-generated random table was used to carry out block randomization.

Prospective enrolment of CRS subjects was based on the following criteria: age between 18 and 65 years, syn-chronous sinonasal symptoms present for more than 12 weeks, sinusitis demonstrated by a sinus computerized tomography (CT) scan, physical status I or II according to the American Society of Anesthesiologists (ASA), and scheduled for elective FESS.

The following conditions were excluded: hypovolemia, bradycardia (heart rate < 50 beats per minute or less), second- or third-degree atrioventricular blockage, BMI > 30 kg/m2, a re-cent history of acute upper respiratory tract infection, and systemic diseases (including neuropsychiatric, respiratory, circulatory, etc.).

Statistical analysis

SPSS version 23.0 was used to analyze the data. The data's normal distribution was assessed using the Shapiro-Wilk test. The mean (standard deviation or SD) is used to represent continuous variables. The Student's t test was used to compare variables that were normally distributed. The Kruskal–Wallis H test was used to compare nonnormally distributed variables, which are shown as the Median and Interquartile Range [M (IQR)].

Results

Table 1:

Variables	Group R (n = 40)	Group D (n = 40)	Group C (n = 40)	P-value
Age (years)	41.8 ± 13.7	43.3 ± 12.9	43.7 ± 13.7	0.734
Height(cm)	170.9 ± 9.1	169.9 ± 7.9	169.1 ± 11.2	0.548
Weight (kg)	65.9 ± 11.8	65.1 ± 11.1	66.1 ± 12.2	0.915
Gender (male/female)	10/30	15/25	11/29	0.662
ASA physical status (I/II)	24/16	29/11	25/15	0.637
Duration of surgery(min)	99.2 ± 7.7	101.3 ± 11.7	124.4 ± 15.6	< 0.001
Duration of anesthesia (min)	120.6 ± 13.5	118.4 ± 12.9	138.4 ± 19.5	0.001
Time to return of conscious-ness (min)	21.6 ± 6.4	27.9 ± 3.3	21.2 ± 3.1	< 0.001
Length of PACU stay (min)	49.8 ± 8.9	52.2 ± 4.8	38.2 ± 8.8	< 0.001
Cumulative consumption of propofol (mg)	470.5 ± 97.3	521.4 ± 50.9	610.3 ± 137.9	< 0.001
Cumulative consumption of remifentanil (μg)	1190.9 ± 210.9	1080.0 ± 169.5*	1312.5 ± 236.5	< 0.001

Table 1 demonstrates that Groups R and C had considerably shorter times to return to awareness and longer stays in the PACU than Group D (P = 0.001 and P < 0.001, respectively).

Table 2:

	Group R (n = 40)	Group D (n = 40)	Group C (n = 40)	P-value
Preoperative				
Total QoR-40 Score	162.0 (158.0 -164.0)	161.0 (159.0 -163.0)	162.0 (158.3 -163.8)	0.931
POD1 Emotional state	34.0 (33.8 -36.3)	35.5 (33.8—36.0)	28.5 (28.8—31.0)	< 0.001
Physical comfort	42.5 (42.0—44.3)*	42.0 (40.0—43.3)	40.0 (38.0—41.3)	0.004
Physical independence	22.0 (21.0—22.0)	22.0 (20.8—22.0)	20.5 (20.0—22.0)	0.219
Psychological support	28.0 (26.8—29.0)	28.0 (26.0—29.0)	27.0 (26.0—28.0)	0.475
Pain	29.0 (28.0—30.3)	30.0 (28.0—30.3)	25.5 (24.8—27.0)	< 0.001
Total QoR-40 Score	154.5 (152.0 -159.0)	155.0 (154.8 -159.3)	139.0 (136.8 -142.0)	< 0.001

Table 2 analyzed the QoR-40 scores. Groups R (154.5, 152.0–159.0) and D (155.0, 154.8–159.3) had lower QoR-40 (median, IQR) scores overall at POD1 than Group C (139.0, 136.8–142.0) (P < 0.001). The overall QoR-40 score did not differ significantly between Groups R and D. Moreover, the emotional intelligence scores on POD1, Groups R and D had lower state, physical comfort, and pain dimensions than Group C (P < 0.005).

Table 3:

Variables	Group R (n = 40)	Group D (n = 40)	Group C (n = 40)	P - value
Time to first require rescue analgesia (h)	8.3 (8.9–10.5)	9.1 (8.5–11.0)	6.1(5.1–6.4)	< 0.001
Number of patients requiring analgesia (n, %)	8 (20%)	8 (20%)	20 (50.0%)	0.003
Bradycardia (n, %)	0 (0.0)	20 (50)	0 (0.0)	< 0.001
Number of patients occurring PONV (n) (0/1/2/3)	37/2/1/0*	36/2/2/0*	29/8/2/1	0.024

The analysis of table 3 indicates that Groups R (8.3, 8.9–10.5) and D (9.1, 8.5–11.0) had longer times to first rescue analgesia (median, IQR) than Group C (6.1, 5.1–6.4) (P < 0.001). Compared to Group C (20/40, 50.0%), fewer patients in Groups R (8/40, 20%) and D (8/40, 20%) needed rescue analgesia (P = 0.003). Moreover, Bradycardia occurred during surgery in 20 patients (20/40, 50%) in Group D.

Table 4:

Variables	Group R (n = 40)	Group D (n = 40)	Group C(n = 40)	P -value
Maximal VAS score (PACU)	2.9 0 (2.0—3.0)	2.8 (2.0—3.0)	3.0 (3.0—4.0)	< 0.001
Maximal VAS score (ward)	4.0 (3.8—4.3)	4.0 (3.0—4.0)	4.5 (4.0—5.0)	< 0.001
RASS score(upon PACU arrival)	-2.0 (-2.0—-1.0)	-2.0 (-3.0—-2.0)	1.0 (0.0—1.0)	< 0.001

Table 4, the maximal VAS pain score was lower in the PACU and ward in Groups R and D than in Group C (P < 0.001). The RASS score was lower upon PACU arrival in Groups R and D than in Group C (P < 0.001).

Discussion

The QoR-40 questionnaire is renowned for its excellent completion and response rates, as well as its time efficiency, and has been validated in patients undergoing a range of surgical operations. Dexmedetomidine, a highly selective α-2 adrenergic agonist, was utilized to improve quality of life because of its analgesic, sympathetic, and relaxing properties. Intravenous dexmedetomidine has been shown in previous studies to enhance the quality of life for adult patients after elective surgery.

According to analysis outcomes of current study, Group C (139.0, 136.8–142.0) exhibited higher QoR-40 (median, IQR) scores overall at POD1 than Groups R (154.5, 152.0–159.0) and D (155.0, 154.8–159.3) (P < 0.001).

There was no discernible difference in the ag-gregate QoR-40 score between Groups R and D. In addition, Groups R and D scored lower on POD1 for emo-tional intelligence than Group C in terms of status, physical comfort, and pain aspects (P < 0.005). Moreover, analysis has suggested that group C (6.1, 5.1–6.4) had shorter durations to first rescue analgesia (median, IQR) than Groups R (8.3, 8.9–10.5) and D (9.1, 8.5–11.0) (P < 0.001). Patients in Groups R (8/40, 20%) and D (8/40, 20%) required less rescue analgesia than those in Group C (20/40, 50.0%) (P = 0.003).

Moreover, 20 patients (20/40, 50%) in Group D experienced bradycardia during operation. As per the study of Li et al. (2024) [13], Groups R (9.3,8.9–10.5) and D (10.1,8.5–11.0) had longer median times to first rescue analgesia (IQR) than Group C (5.5,5.1–6.4) (P < 0.001). Compared to Group C (18/40, 45.0%), fewer patients in Groups R (7/40, 17.5%) and D (6/40, 15.0%) needed rescue analgesia (P = 0.003). Bradycardia occurred during surgery in 15 patients (15/40, 37.5%) in Group D.

Apart from this, the current analysis has identified that the maximal VAS pain score was lower in the PACU and ward in Groups R and D than in Group C ($P < 0.001$). The RASS score was lower upon PACU arrival in Groups R and D than in Group C ($P < 0.001$). Additionally, study of Li et al., (2023) [14] has a half-life of 1-2 hours, while dexmedetomidine has a half-life of 2-3 hours. Additionally, remimazolam has an antagonist called flumazenil. Thus, compared to Group D, Group R's time to return to awareness and length of stay in the PACU were considerably shorter. High doses of these drugs infused intravenously may cause side effects such respiratory or cardiovascular depression and delayed recovery [7].

Conclusion

Remimazolam and dexmedetomi-dine may improve the quality of recovery and lessen the severity of pain following FESS. Remimazolam's safety and effectiveness are not less than those of dexmedetomidine.

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