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Clinical Effect of Fospropofol Disodium for Injection on Maintenance of General Anesthesia

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Abstract

Objective: To observe the application of fospropofol disodium for injection in the maintenance of general anesthesia in adult surgery, and to evaluate its safety and effectiveness. METHODS Patients aged 18-65 years old, ASAI-III, who were scheduled for elective surgery under general anesthesia, were treated with 10-20 mg/(kg·h) of fospropofol disodium combined with remifentanil 0.1-1.0 μ g/(kg.h) and dexmedetomidine 0.2-0.7 μ g/(kg.h) by continuous intravenous pump. Anesthesia was maintained by intermittent administration of sufentanil and cis-atracurium, and the bispectral index (BIS) was maintained at 40-60. The medication was adjusted according to the changes of vital signs and BIS monitoring results. When the sedation depth was insufficient, the dose of fospropofol disodium was adjusted. BIS, blood pressure, heart rate and related indicators of recovery period were recorded. Results The total of 73 patients were observed, continuous intravenous pumping of 10-20 mg/(kg.h) of fospropofol disodium combined with remifentanil 0.1-1.0 μ g/(kg.h) and dexmedetomidine 0.2-0.7 μ g/(kg.h) resulted in a BIS value of 40-60 in all patients. The average maintenance dose of fospropofol disodium was 16.2±4.2 mg/(kg.h). The most common adverse events observed in this study were delayed awakening (49.3%) and hypotension (9.6%). Conclusion Continuous intravenous infusion of fospropofol disodium for injection 10-20 mg/(kg.h) can provide a more suitable sedation depth for the maintenance of general anesthesia, with less effect on blood pressure and higher quality of postoperative recovery. Early discontinuation of the drug before the end of surgery may be considered in view of the observed high incidence of delayed awakening.

Keywords: Fospropofol disodium; Maintenance of anesthesia; Clinical observation; Effectiveness; Security

Introduction

Anesthesia maintenance refers to the anesthesia management during the period from the completion of general anesthesia induction to the end of surgery. At present, propofol is the most commonly used intravenous anesthesia maintenance drug, which has the advantages of rapid onset of anesthesia, short maintenance time,

perfect recovery, low incidence of postoperative nausea and vomiting [1,2]. However, propofol has adverse reactions and potential risks such as inhibition of cardiopulmonary function, pain at the injection site and microbial contamination [3]. Fospropofol disodium for injection is a new type of intravenous general anaesthetic, which is a newly marketed chemical. Fospropofol disodium is the first water-soluble precursor of propofol in China. It is metabolized into the active substance propofol in the body and has anesthetic effect. It is one of the most advanced general intravenous anesthetics currently studied in China [4,5]. Compared with fat emulsion propofol, early clinical trials showed that fospropofol disodium has many advantages. For example, fospropofol disodium does not need lipid emulsion as a drug carrier, which can relieve injection pain, avoid hyperlipidemia after long-term injection, and reduce the growth rate of bacteria [6,7]. At present, there is a limited amount of clinical literature available for reference when fospropofol disodium is used for intravenous anesthesia. This study will observe the effect of fospropofol disodium for injection on the maintenance of general anesthesia in adult surgery, evaluate its safety and effectiveness in the maintenance of anesthesia, and further enrich and optimize the maintenance of general anesthesia program.

Data and Methods

General information

73 patients undergoing elective surgery under general anesthesia in the First Affiliated Hospital of Anhui Medical University were selected as the study subjects. The types of surgery included urological surgery, gynecological surgery, and general surgery. Inclusive criteria: (1) Patients aged 18-65 years; (2) Body mass index (BMI) is unlimited; (3) The American Association of Anesthesiologists (ASA) is classified as Grade I-III. Exclusion criteria: (1) Patients with severe heart, brain, lung, liver, kidney and metabolic diseases; (2) People with neuromuscular system diseases and mental diseases.

Methods

After the patient entered the operating room, the upper limb vein access was established, and ECG monitoring, non-invasive arterial blood pressure monitoring, blood oxygen saturation monitoring and Bispectral Index (BIS) monitoring were routinely performed. All patients were treated with etomidate emulsion injection (Jiangsu Enhua Pharmaceutical Co., Ltd., GYZZ H32022992, specification 10 mL: 20 mg) 0.15-0.30 mg/kg+sufentanil citrate injection (Yichang Humanwell Pharmaceutical Co., Ltd., GYZZ H20054171, specification 1 mL: 50 μ g) 0.2-0.3 μ G/kg+cisatracurium benzenesulfonate for injection (Jiangsu Hengrui Pharmaceutical Co., Ltd., GYZZ H20060869, specification 5 mL: 10 mg) 0.12-0.20 mg/kg for anesthesia induction. 3-5 minutes after the induction, the patient's muscle relaxes, and the laryngeal mask is placed or the trachea is intubated under the visual laryngoscope. During the operation, the BIS value was maintained between 40 and 60 by adjusting the dosage of fospropofol disodium for injection (Yichang Humanwell Pharmaceutical Co., Ltd., GYZZ H20210017, specification 0.5 g) to 10-20 mg/(kg.h), and remifentanil hydrochloride for injection (Yichang Humanwell Pharmaceutical Co., Ltd., GYZZ H20030197, specification 1 mg) to 0.1-1.0 μg/(kg.h), dexmedetomidine hydrochloride injection (Jiangsu Hengrui Pharmaceutical Co., Ltd., GYZZ H20090248, specification 2 mL: 200 μ g) 0.2～0.7 μg/(kg.h) micropump continuous intravenous injection, intermittent intravenous injection of sufentanil and cis atracurium. If BIS is higher than 60 and lasts for more than 1 min, increase the dosage of fospropofol disodium to maintain the pumping dosage. If the depth of sedation still cannot reach the target value, intravenous injection of fospropofol disodium is 5-10 mg/kg, and fospropofol

disodium is added for three times at most. If the above treatment still fails to reach the target sedation depth, substitute drugs such as propofol medium/long chain fat emulsion injection (Beijing Fesenyuskabi Pharmaceutical Co., Ltd., GYZZ J20110058, specification 50 ml: 1 g) Sevoflurane for inhalation (Jiangsu Hengrui Pharmaceutical Co., Ltd., GYZZ H20040772, specification 120 ml) or midazolam injection (Jiangsu Enhua Pharmaceutical Co., Ltd., GYZZ H19990027, specification 1 mL: 5 mg); If BIS is lower than 40 and lasts for more than 1 min, reduce the pump dosage of fospropofol disodium. Heart Rate (HR) is lower than 45 times/min, and atropine sulfate injection (Tianjin Jinyao Pharmaceutical Co., Ltd., GYZZ H12020382, specification 1 mL: 0.5 mg) is 0.01 mg/kg intravenously; When the Mean Arterial Pressure (MAP) is lower than 65 mmHg or the Systolic Blood Pressure (SBP) is reduced by more than 30% of the base value, ephedrine hydrochloride injection (Northeast Pharmaceutical Group Shenyang First Pharmaceutical Co., Ltd., National Pharmaceutical Standard H21022412, 1mL: 30mg) is given 0.5-1.0 mg/kg.

Observations

(1) The SBP, Diastolic Blood Pressure (DBP), HR, BIS, and MAP calculated according to SBP and DBP were recorded at admission (T0), 5 min (T1), 10 min (T2), 20 min (T3), 30 min (T4), and 40 min (T5). (2) Record the eye-opening time (i.e., the time from drug withdrawal to the patient's eye opening) and the awakening time (i.e., the time from drug withdrawal to the patient's modified observer's assessment of alert /sedation (MOAA/S) reaching 5 points). (4) The use of ephedrine, atropine and other drugs, the cumulative dose of fospropofol disodium and the duration of surgery were recorded. (5) The occurrence of adverse reactions during operation was recorded, such as bradycardia (HR<60 bpm), tachycardia, hypotension, hypertension, body movement, cough, hiccup, and awareness during operation. (6) The occurrence of adverse reactions after operation was recorded, such as delayed awakening (MOAA/S still could not reach 5 points 30 min after drug withdrawal), delirium, restlessness, dizziness, nausea and vomiting during awakening.

Statistical analysis

Sort out and summarize statistical data. For continuous or ordinal variables, data conforming to normal distribution shall be expressed as mean ± standard deviation, and non-normal distribution data shall be expressed as median (interquartile range). For classified variables, the number and proportion of each category shall be listed.

Results

Demographic and baseline characteristics

A total of 73 patients, with an average age of 46.7 years, were enrolled in this study; The average BMI is 25.3 kg/m2; ASA Class I-III. See **Table 1** for details.

Table 1: Demographic and baseline characteristics.

project	Age Average value (SD)	Gender (M/F)	BMI (kg/m^2) Average value (SD)	ASA (Class I/II/III)
Number of patients (n=73)	46.7(12.7)	49/24	25.3(3.4)	4/56/13

Dosage of fospropofol disodium

The average total dose of fospropofol disodium administered during operation was 16.2±4.2 mg/(kg.h). Among them, 58 patients obtained an appropriate depth of anesthesia in the dose range of 10～20 mg/(kg.h) fospropofol disodium, and 15 patients (20.5%) received additional doses of fospropofol disodium of 5～10 mg/kg due to insufficient depth of sedation (4 patients received two additional doses, and 11 patients received one additional dose). See **Table 2** for the mean/Standard Deviation (SD) of specific dose of maintenance medication during operation. See **Table 3** for the average maintenance dose of fospropofol disodium, the total amount of fospropofol disodium, and the mean/Standard Deviation (SD) of operation duration in different dosage ranges of fospropofol disodium.

Table 2: Doses of fospropofol disodium, remifentanil and dexmedetomidine [Mean/SD].

Observations	Mean (SD)
Total dose of fospropofol disodium (mg)	1601.8 (851.7)
Average maintenance dose of fospropofol disodium [mg/ (kg.h)]	16.2 (4.2)
Total dose of remifentanil（μg)	591.5 (442.4)
Total dose of dexmedetomidine（μg)	53.1 (18.7)

Table 3: Relevant indicators of different doses of fospropofol disodium maintenance medication [Mean/SD].

Observations	<10 mg/(kg.h) fospropofol disodium (n=2)	10-20 mg/(kg.h) fospropofol disodium (n=58)	>20 mg/(kg.h) fospropofol disodium (n=13)
Average fospropofol disodium Maintenance dose [mg/ (kg.h)]	8.7(0.4)	14.9(2.7)	22.9(2.0)
Total dose of fospropofol disodium (mg)	792.5(407.5)	1659.4(863.8)	1469.6(728.3)
Operation duration (min)	92.0(52.0)	89.2(43.8)	55.5(21.8)

Sedation depth

The mean value of the lowest BIS of patients during surgery was 30.4 ± 5.3, of which 71 (97.3%) patients had a BIS lowest value less than 40 and 42 (57.5%) patients had a BIS lowest value less than 30. The mean value (Mean)/Standard Deviation (SD) of MAP, HR and BIS at different time points during the operation of fospropofol disodium are shown in **Table 4.**

Table 4: MAP, HR, BIS [Mean/SD] at different time points.

Observations	T_0	T_1	T_2	T_3	T_4	T_5
MAP (mmHg)	103(60)	91(15)	90(32)	87(15)	85(14)	83(13)
HR（bpm）	71(12)	61(12)	57(9)	57(8)	58(7)	58(8)

BIS	98(2)	57(60)	55(11)	50(10)	43(9)	42(7)

Safety

53 patients (72.6%) receiving fospropofol disodium had at least one estimated adverse event related to treatment during surgery, including bradycardia (n=42,57.5%), delayed awakening (n=35,47.9%) and hypotension (n=7,9.6%). No serious adverse reactions such as apnea and cardiac arrest were found in the patient, and no death was reported. Bradycardia and hypotension mainly occurred during the maintenance of anesthesia and recovery of anesthesia. See **Table 5** for specific parameters and results at each time point.

Table 5: Occurrence of hypotension and bradycardia in patients at different time points [n=73, cases (%)].

Adverse reactions	T_0	T_1	T_2	T_3	T_4	T_5
Hypotension	1(1.4)	3(4.1)	2(2.7)	4(5.5)	5(6.8)	6(8.2)
Bradycardia	10(13.7)	41(56.2)	53(72.6)	53(72.6)	49(67.1)	51(69.9)

The mean time of eye opening (SD) was 31.3 ± 14.6 min, 52.1% of patients opened their eyes within 30 min, and the time range of eye opening was 3-92 min after stopping the administration of fospropofol disodium; The mean value of postoperative recovery time (SD) was 32.6 ± 15.0 minutes. 50.7% of the patients woke up within 30 minutes. The range of recovery time was 3-93 minutes after stopping the administration of fospropofol disodium. The incidence of hypertension and tachycardia during operation was low. Two of them had hypertension and tachycardia at the same time, which may be related to hypertension or stimulation after intubation, but not to fospropofol disodium. The incidence of other intraoperative adverse reactions (body movement, cough, hiccup, intraoperative awareness) and postoperative adverse reactions (delirium, restlessness, dizziness, nausea and vomiting during awakening) was 0 (0%). The adverse reactions of fospropofol disodium during and after operation are shown in **Table 6** and **Table 7.**

Table 6: Incidence of adverse reactions of fospropofol disodium during operation

Intraoperative adverse reactions	[n=73, cases (%)]
Kinesis	0 (0)
Cough	0 (0)
Hiccup	0 (0)
Hypotension	7 (9.6)
Hypertension	3 (4.0)
Tachycardia	3 (4.0)
Bradycardia	42 (58.0)
Intraoperative awareness	0 (0)

Table 7: Incidence of adverse reactions of fospropofol disodium after operation.

Postoperative adverse reactions	[n=73, cases (%)]
Eye opening delay	35(47.9)
Delayed awakening	36(49.3)
Emergence delirium	0(0)
Restlessness	0(0)
Vertigo	0(0)
Nausea	0(0)
Vomit	0(0)

Discussion

The results of this study showed that 10～20 mg/(kg.h) fospropofol disodium was safe and effective for the maintenance of general anesthesia in adult surgery. In the 73 patients observed, 10-20 mg/(kg.h) fospropofol disodium was used in combination with 0.1-1.0 remifentanil μg/(kg.h), dexmedetomidine 0.2～0.7 μg/(kg.h) continuous intravenous pumping for anesthesia maintenance. BIS value of all patients was maintained at 40-60. The actual average maintenance dose of fospropofol disodium was 16.2±4.2 mg/(kg.h). Most patients (82%) used fospropofol disodium 10-20 mg/(kg.h) for sedation maintenance without additional dose. All patients could obtain appropriate depth of anesthesia after two additional doses at most. No patient needed to use alternative sedatives. Bradycardia (58%), delayed awakening (49.3%) and hypotension (9.6%) were the most common adverse reactions observed. All adverse reactions improved after fluid infusion, adjustment of maintenance drug dosage or application of vasoactive drugs. The average recovery time after drug withdrawal was 32.6 minutes. The incidence of other adverse reactions was low.

Propofol is the most commonly used general anesthetic and sedative drug, which has the characteristics of rapid onset, short duration, etc. It is highly controllable when used for the depth control of anesthesia and sedation. The motor and nerve functions of patients under propofol anesthesia recovered well after awakening. Studies have shown that propofol has an anti-serotonin 3 effect, and can inhibit postoperative nausea, vomiting and other adverse symptoms, but it also has an adverse reaction. For example, propofol is a fat emulsion. Long term infusion may cause hyperlipidemia, infusion syndrome, bacterial infection during infusion, etc. Propofol has obvious inhibition on circulation, and the incidence of hypotension during induction and maintenance of anesthesia is relatively high. In addition, after a single injection of propofol in some outpatient examinations, the duration of the effect is too short, so it needs to be added repeatedly **[1,8].** The preliminary clinical research results found that, as a substitute for sedative drugs currently used for general anesthesia, fospropofol disodium has the following advantages compared with fat emulsion propofol: first, the incidence of pain caused by fospropofol disodium injection is significantly reduced, which increases the comfort and compliance of patients; Secondly, the problems of hyperlipidemia, transfusion syndrome and bacterial infection in the process of transfusion associated with fat emulsion were avoided; Third, the active metabolite propofol is gradually released into the blood to play its role. The concentration of propofol in the blood is relatively stable, the blood

concentration is more stable, the respiratory and circulatory inhibition is slighter, and the action time is longer, reducing the number of additional anesthetics and dosage after induction **[1-3,9].**

Some studies have shown that after intravenous administration, fospropofol disodium is metabolized into propofol, formaldehyde and phosphate by alkaline phosphatase **[1,10].** Studies have shown that the peak time of plasma drug concentration of fospropofol disodium is about 8 min, and the elimination half-life is about 2 hours **[4,11].** The existing clinical data show that the average maintenance doses of fospropofol disodium and propofol during anesthesia are 11.3±2.5 mg/(kg.h) and 4.4±1.0 mg/(kg.h), respectively, and can achieve the same sedative effect. In this study, it was found that 10～20 mg/(kg.h) fospropofol disodium was used for anesthesia maintenance, BIS of all patients was maintained at 40～60, and the actual average maintenance dose of fospropofol disodium was 16.2±4.2 mg/(kg.h). Therefore, fospropofol disodium is effective and reliable for the maintenance of general anesthesia in adult surgery.

First, in terms of hemodynamics, Fechner J **[12]** found that compared with propofol, fospropofol disodium had less impact on the hemodynamics of patients. In this study, it was observed that the incidence of hypotension caused by the use of fospropofol disodium was low, and it was improved by the administration of vasoactive drugs, fluid infusion or without any treatment. Therefore, it can be considered that the effect of fospropofol disodium on the circulatory system was mild, transient and self-limited. Secondly, in terms of awakening time, Han Yuan **[13]** found that the patients who used propofol had a shorter time of eye opening, extubation and recovery of orientation. The research of Fechner J and Cohen LB **[12,14]** shows that fospropofol disodium may cause delayed awakening of patients. The recovery delay is defined as that the patient still cannot wake up and shake hands after the recovery time exceeds 30 minutes, and has no response to pain stimulation **[15].** In this study, the infusion of disodium phosphate propofol was stopped immediately after the operation, and it was observed that many patients had delayed awakening, which suggested that early drug withdrawal before the end of the operation could be considered in the clinical use process. Thirdly, in terms of the quality of recovery, Chen Nannan **[16]** found that propofol can play a role of stable sedation and hypnosis, reduce postoperative nausea and vomiting, and thus inhibit postoperative restlessness. In this study, the incidence of other postoperative adverse reactions such as delirium, agitation, dizziness, nausea and vomiting in the wake-up period of patients using fospropofol disodium to maintain anesthesia was 0%, which can be considered that the quality of postoperative recovery of patients using fospropofol disodium was high. In addition, the incidence of other intraoperative adverse reactions in this study, such as body movement, cough, hiccup and intraoperative awareness, was 0%. It can be considered that the incidence of intraoperative adverse reactions of fospropofol disodium was low. In this study, the dosage range of 10-20 mg/(kg.h) of fospropofol disodium combined with remifentanil 0.1-1.0 was used μg/(kg.h), dexmedetomidine 0.2～0.7 μg/(kg.h) continuous intravenous pumping for anesthesia maintenance, more patients (58%) have bradycardia, while previous studies showed that the incidence of bradycardia in patients using dexmedetomidine was significantly higher than midazolam and propofol **[17,18].** Therefore, the correlation between the high incidence of bradykinesia in this study center and the continuous infusion of dexmedetomidine during operation cannot be determined. In addition, many previous studies have shown that the most common adverse reactions related to fospropofol disodium are abnormal sensation and itching in the perineum and perianal area **[1,12,13,19],** but this study did not observe the above adverse reactions in patients, which may be related to the use of other sedatives to induce or pump dexmedetomidine to reduce the incidence of itching **[20].**

This study is an open study on safety and effectiveness. There is no control group for comparison. Data collection is not a blind method. The interpretation of research results is limited by the study design. Secondly, this study did not set up a control to exclude the interference of dexmedetomidine, which could not prove whether bradycardia was related to the adverse effects of fospropofol disodium, and the correlation between the two needs further study. However, dexmedetomidine is a commonly used intravenous sedative in clinical anesthesia. Therefore, our clinical design and results also have relatively broad clinical reference value. To sum up, the anesthesia was maintained by intravenous infusion of 10-20 mg/(kg.h) of fopropofol disodium combined with remifentanil 0.1-1.0 μg/(kg.h) and dexmedetomidine 0.2-0.7 μg/(kg.h), the results showed that 10-20 mg/(kg.h) fospropofol disodium for injection for general anesthesia maintenance in adult surgery can achieve the appropriate depth of sedation, is safe and effective, the incidence of adverse reactions related to patient treatment is low, and the quality of postoperative recovery is high. In view of the observed high incidence of delayed awakening, early drug withdrawal before the end of surgery can be considered. The predictable pharmacokinetic and pharmacodynamic characteristics of fospropofol disodium can further enrich and optimize the general anesthesia maintenance program.

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