Comparison of Sufentanil and Fentanyl for Surgical Repair of Congenital Cardiac Defects

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Abstract

In the present study, the authors compared sufentanil to fentanyl in pediatric patients undergoing congenital cardiac repair. The purpose of the study was to evaluate the hemodynamic variables, time of awakening and successful extubation of the two groups.

A prospective, randomized study of 60 children scheduled for elective surgery of congenital cardiac defects was made. Patients were randomly divided into two groups:- Group I; sufentanil and Group II; fentanyl (mean body weight, 16.02 ± 6.67 kg; range 4 to 35 kg; mean age, 5.22 ± 3.55 years; range 4 months to 1 year). All were premedicated with oral chloralhydrate 50 mg/kg, one hour preoperatively. Anesthesia was induced with sufentanil 1 μg/kg (Group I) or fentanyl 2 μg/kg (Group II) and thiopenthal 2 mg/kg, followed by atracurium 0.6 mg/kg. All patients were intubated with atracurium 0.6 mg/kg. Anesthesia was maintained using isoflurane in oxygen, nitrous oxide (in non-cyanotic patients). In Group I, sufentanil 0.5 μg/kg was administered intravenously prior to skin incision, median sternotomy, cardiopulmonary bypass (CPB) and after coming off CPB. In Group II, fentanyl 1 mg/kg was administered at the same time periods. Hemodynamic parameters, heart rate (HR), systolic (SBP), diastolic (DBP) and mean arterial blood pressure (MAP), central venous pressure (CVP) were recorded. The administration of pain therapy was determined postoperatively.

There was no statistical difference in the demographic data between the patients in the two groups. Following induction of anesthesia, the systolic, diastolic and mean arterial pressures and heart rate decreased. Following tracheal intubation, all hemodynamic parameters in the sufentanil group remained below the baseline values, while the fentanyl group showed an increase above baseline values. An increase above control values of all hemodynamic variables was detected in both groups following skin incision and sternotomy, except that the mean systolic blood pressure and heart rate in the sufentanil group was less than the baseline values. No differences in hemodynamic variables were detected between the two groups following median sternotomy and skin closure. There were significant differences in mean arterial pressure at the time of intubation and skin incision between the two groups. No significant changes in CVP occurred. There were no significant differences in the average time of awakening from anesthesia. The average time before postoperative tracheal extubation was 171.38 ± 112.74 and 113.72 ± 67.83 minutes in the sufentanil group and fentanyl group respectively, which was statistically significant. There was no difference in the requirements for morphine (pain relief) and sedation with chlolorahydrate between the groups. Bradycardia was found

in 7 and 3 patients receiving sufentanil and fentanyl respectively which was not statistically significantly different. The bradycardia recovered in a few minutes, following intravenous injection of atropine. Slow injection of the anesthetic drugs can protect patients against serious bradycardia.

In conclusion, the safety and efficacy of sufentanil in patients undergoing repair of complex congenital heart defects was the same as fentanyl. There were no significant differences in times of awakening in the two groups. The patients in sufentanyl group had a longer time to extubate than the fentanyl group. The need of postoperative sedation and analgesia was the same in both groups.

Key word : Sufentanil, Fentanyl, Congenital Heart Defect, Anesthesia

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Anesthetic management for the correction of congenital cardiac defects should ideally provide rapid and potent analgesia, maximal hemodynamic stability, maintenance of the balance between pulmonary and systemic vascular resistance, and attenuation of the stress response.

Sufentanil is a thienyl analogue of fentanyl which is extremely lipophilic and is rapidly and extensively distributed to all body tissues. It is five to ten times as potent as fentanyl[1]. Compared to fentanyl, sufentanil has a more rapid onset and a more shorter duration of action[1]. But it has a higher threshold for producing convulsions[2]. Sufentanil has been shown to produce hemodynamic stability[3,4] and its' pharmacokinetics are like fentanyl[5]. High doses of sufentanil can be used safely as a primary anesthetic agent for infants and children undergoing corrective cardiac surgery[6]. Kay, et al have shown that sufentanil 1 μg/kg was effective in supressing the hemodynamic response to tracheal intubation[7]. The purpose of this study was to compare low-dose sufentanil with fentanyl anesthesia for infants and children undergoing elective surgical repair for congenital cardiac defects.

MATERIAL AND METHOD

Following protocol approval by the Ethical Review of Research Committee, the Ministry of Public Health, and the Institutional Human Rights Committee, informed consent was obtained from each parent of 60 pediatric patients scheduled for elective repair of congenital heart defects. The children were randomly allocated to one of the study groups. All patients were premedicated with oral chloralhydrate 50 mg/kg one hour before anesthesia.

Arriving at the operating theater, electrocardiogram (ECG), digital pulse oximeter and noninvasive blood pressure were monitored. Under local anesthesia, an intravenous catheter was inserted. Anesthetic induction was achieved using thiopental 2-3 mg/kg and sufentanil 1 μg/kg (Group 1) or fentanyl 2 μg/kg (Group 2). In both groups atracurium was used to facilitate tracheal intubation and to provide neuromuscular relaxation. Anesthesia was maintaned with isoflurane, oxygen, nitrous oxide (except for those with cyanotic heart disease), sufentanil 0.5 μg/kg (Group 1) or fentanyl 1 μg/kg (Group 2) intravenously prior to skin incision, median sternotomy, during cardiopulmonary bypass (CPB) and after weaning from bypass. The heart rate (HR), systolic (SBP), diastolic (DBP), mean (MBP) arterial blood pressure and central venous pressure (CVP) were obtained at the following times: prior to anesthetic induction (baseline values), 60 seconds after induction, tracheal intubation, skin incision, sternotomy, cardiopulmonary bypass, and skin closure. Heparin 300 units/kg was given to achieve an activated clotting time (ACT)>400 seconds prior to and during cardiopulmonary bypass. A standard cardiopulmonary bypass composed of roller pump and membrane oxygenator

was used. At the termination of CPB, nitroglycerin and inotropic agents were administered if necessary. All patients were sent to continue ventilatory support in the surgical cardiac care unit. The time taken for the patient to respond to voice and verbal command along with the time of tracheal extubation were recorded. Perioperative complications were observed. Postoperative analgesic and sedative administration were recorded.

Statistical analysis was carried out using the SPSS software package, version 10.0. Values were presented as mean ± standard deviation (SD). Demographic and operative data were compared between the groups by independent sample *t*-test. Heart rate, systolic, diastolic, mean arterial blood pressure and central venous pressure were tested by repeat-measures ANOVA test with intergroup differences and with grouping effect. Differences in narcotic requirements in the postoperative period were tested by a Chi-square test. A p-value of less than 0.05 was considered significant.

RESULTS

Sixty patients with various types of congenital cardiac diseases were included in the study (Table 1). The demographic and operative characteristics are shown in Table 2 (all results mean ± SD). The two groups did not differ with respect to age, body weight, surgical course and duration of anesthesia. Perioperative hemodynamic data are shown in Table 3. Following induction of anesthesia, systolic, diastolic and mean arterial pressures as well as heart rate decreased compared with baseline values (Table 3). Following tracheal intubation, all hemodynamic parameters in the sufentanil group remained below baseline values, while those in the fentanyl group increased above baseline values. Response of the hemodynamic variables above baseline values was detected in both groups following skin incision and sternotomy, except that the systolic pressure and heart rate in the sufentanil group was lower than the baseline value. No differences were detected between the two groups in the hemodynamic variables following median sternotomy and skin closure. There were significant differences in mean arterial pressure at the time of intubation and skin incision between the two groups (Fig. 1). The central venous pressure did not change significantly at any time during the study.

Bradycardia occurred in 23.33 per cent and 10 per cent in the sufentanil and fentanyl groups

Table 1. Cardiac diagnoses of the patients.

Diagnosis	Sufentanil	Fentanyl
Ventricular septal defect	11	8
Atrial septal defect	2	5
Tetralogy of Fallot	15	10
Atrioventricular canal	-	2
Transposition of the great arteries	-	1
Situs ambiguus	-	1
Ebstein's anomaly	-	2
Total anomalous pulmonary venous return	1	-
Pulmonary atresia, intact ventricular septum, PDA	1	-
Right atrial fibroma, PFO	-	1

PDA = patent ductus arteriosus, PFO = patent foramen ovale.

Table 2. Patient characteristics and clinical data.

	Sufentanil	Fentanyl
Age (yr)	5.46 ± 3.62	4.99 ± 3.52
Body weight (kg)	16.31 ± 7.31	15.73 ± 6.08
Duration of anesthesia (min)	208.47 ± 50.33	205.17 ± 57.42
Duration of surgery (min)	175.60 ± 49.89	169.57 ± 52.90
Cardiopulmonary bypass (min)	92.63 ± 35.92	100.67 ± 58.21
Aortic cross clamp time (min)	64.24 ± 27.37	56.41 ± 27.96

Table 3. Hemodynamic changes during induction, intubation and surgery in patients undergoing cardiac surgery. received sufentanil and fentanyl. Values expressed as mean ± SD.

Variable	Baseline	After induction	After intubation	After skin incision	After sternotomy	Skin closure
Sufentanil						
SAP	105.10 ± 16.37	88.80 ± 5.52*	97.67 ± 16.73§	100.60 ± 13.15*§	108.43 ± 2.23*	106.37 ± 13.37
DAP	54.30 ± 12.08	43.40 ± 11.27*	50.87 ± 13.10§	63.50 ± 3.27*§	69.40 ± 1.81*	58.50 ± 9.96
MAP	73.43 ± 12.77	58.74 ± 1.27*	65.26 ± 12.60§	77.83 ± 10.50*§	86.96 ± 9.86*	76.96 ± 19.17
HR	108.31 ± 26.33	100.48 ± 26.21	99.34 ± 8.95*	87.79 ± 26.34*	92.34 ± 28.21*	136.17 ± 3.88*
CVP	-	-	8.27 ± 2.51	8.69 ± 2.18	8.23 ± 1.83	9.62 ± 2.69
Fentanyl						
SAP	106.43 ± 18.04	95.21 ± 17.83*	115.07 ± 16.73§	123.21 ± 17.90*§	119.79 ± 13.63*	102.89 ± 15.08
DAP	58.04 ± 15.87	48.64 ± 14.31*	65.25 ± 17.64§	76.79 ± 17.97*§	73.39 ± 14.44*	58.43 ± 10.21
MAP	74.96 ± 15.52	67.96 ± 14.80*	82.83 ± 16.34§	94.08 ± 18.08*§	92.21 ± 13.60*	74.38 ± 7.85
HR	102.67 ± 25.27	100.67 ± 24.10*	109.48 ± 23.61*	107.41 ± 27.25*	105.33 ± 29.00*	139.33 ± 19.00*
CVP	-	-	10.10 ± 3.31	10.20 ± 3.31	10.30 ± 3.20	9.51 ± 1.58

SAP = systolic blood pressure, DAP = diastolic blood pressure, MAP = mean blood pressure (mmHg), HR = heart rate (beats/minute), CVP = central venous pressure (mmHg)
* $p<0.01$ within group compared with baseline, § $p<0.01$ between groups.

respectively, but the difference was not significant. All of them responded to atropine administration. Two patients who received sufentanil had hypotension along with bradycardia. There was no evidence of any other serious complications (Table 4). Analysis of variance showed no significant difference in the complication rate between the two groups.

Recovery from anesthesia was uneventful. No significant difference in the mean time of awakefulness between the two groups was detected (Table 5). The time taken for response to verbal command was 93.28 ± 47.98 min in the sufentanil group *vs* 67.00 ± 43.02 min in the fentanyl group. The mean time interval from the end of anesthesia to tracheal extubation in the sufentanil group was longer than in the fentanyl group (Table 5).

There was no significant difference in the requirement of morphine for postoperative analgesia or chloralhydrate for postoperative sedation between the two groups.

DISCUSSION

Narcotic agents have been long used in cardiac anesthesia because in high doses they provide hemodynamic stability and attenuate stress responses to surgical stimuli[8-12]. But high-doses of narcotic agents do not allow early extubation in the postoperative period, which has become popular nowadays, even in pediatric cardiac surgery[13-15]. Therefore the use of low-doses narcotic agents in combination with an inhalational agent may promote early extubation[16]. Isoflurane and sevoflurane have been shown to produce less myocardial depression than halothane[17]. So they can be safely used for cardiac anesthesia. In our practice, we give intermittent low-dose fentanyl in combination with isoflurane during anesthesia for infants and children undergoing cardiac surgery. Administration of high-dose fentanyl before surgery may require fluid resuscitation to maintain adequate blood pressure[18]. Otherwise high-dose fentanyl cannot produce enough depth of anesthesia to suppress the hemodynamic responses to surgery[19,20]. In this study, we demonstrated that fentanyl 2 μg/kg and sufentanil 1 μg/kg significantly decreased blood pressure after induction without an intergroup difference. However, only sufentanil could successfully attenuate the hemodynamic responses to intubation. The results of using sufentanil for intubation were the same as in the study of Kay B and colleagues[7]. After skin incision and sternotomy, the mean arterial pressure increased significantly in

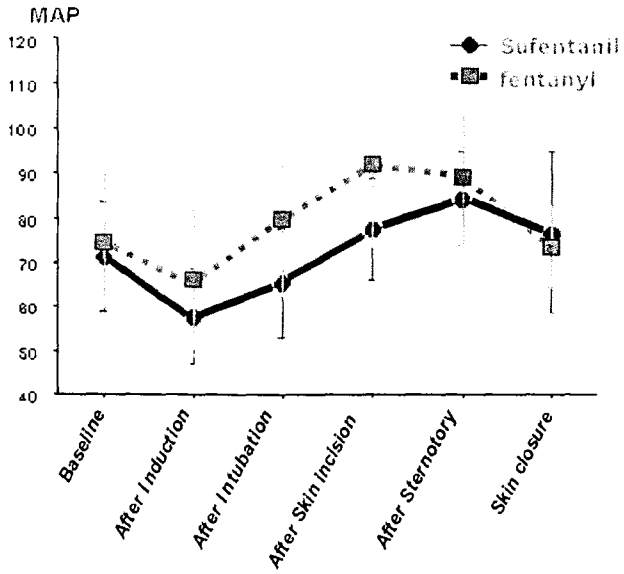

Fig. 1. Differences in mean arterial pressure (MAP) (mm Hg) between sufentanil and fentanyl groups during tracheal intubation and skin incision.

Table 4. Number of patients who experienced side effects and complications.

	Sufentanil	Fentanyl
Bradycardia	7	3
Hypertension	-	1
Hypotension	2	-
Coughing	2	-
Nausea	1	1
Vomiting	1	1

both groups. Patients in the fentanyl group showed a significantly higher increase in mean arterial pressure than the others. This might be due to the fact that there was a difference in dosage of the two drugs that were not equipotential in effect. In this study, the total dose of fentanyl was 6 μg/kg, while sufentanil was 3 μg/kg. Duncan HP and colleagues showed that fentanyl 2 μg/kg did not provide hemodynamic stability during cardiac anesthesia in infants and small children[19]. Their recommended doses were between 25-50 μg/kg. Besides cardiovascular stability, the neurohormonal response to cardiac surgery should also be attenuated. This may cause significant myocardial dysfunction in the postoperative period[21]. Sufentanil has been demonstrated to produce a non-significant increase in catecholamine levels during surgery[19]. Fentanyl 2 μg/kg could not obtund the stress responses to the pre-bypass phase of cardiac surgery either[18].

In our study, we extubated the patients in the fentanyl group significantly earlier than the sufentanil group, even though sufentanil has a shorter half-life than fentanyl[1]. A larger equipotent dose of sufentanil may be the cause of a longer period of intubation compared to the fentanyl group. This can be supported by results from the study of Moore RA, et al in which patients who received sufantanil 5 μg/kg could be extubated earlier when compared to those who received 10 and 20 μg/kg[19]. Using an anesthetic technique that combines short acting narcotics together with new inhalational agents, earlier extubation can be achieved as in our study[15,22]. We did not extubate our patients in the operating theater in order to save time. However 82.2 per cent and 96.6 per cent of our patients in the sufentanil and fentanyl groups respectively could be extubated within the first four hours. Vricella LA, et al reported that they could extubate 87.1 per cent of their patients

Table 5. Postoperative data.

	Sufentanil	Fentanyl
Awakening time (min)	50.00 ± 30.97	44.83 ± 32.87
Time of response to verbal command (min)	93.28 ± 47.98	67.00 ± 43.02*
Time to extubation (min)	171.38 ± 112.74	113.72 ± 67.83*

* $p<0.05$

in the operating theater and another 6.5 per cent in the first four hours[15]. While Marianeschi SM, et al could extubate 58 per cent of their patients in the theater, and 22 per cent in the first two hours[13]. There were no incidences of reintubation in our study or the other studies. The main benefits of early extubation include patient comfort, cost saving and reduction in the workload of nursing staff. This study demonstrates adequate and safe anesthesia can be obtained with a low dose of sufentanil in children undergoing surgical repair of complex congenital heart defects.

We concluded that anesthesia with low-dose sufentanil or fentanyl provided satisfactory anesthesia and a reasonable time to extubation for children undergoing surgical repair of congenital heart defects. Even though the patients in the sufentanil group had a statistically significant longer time to extubation than the fentanyl group, it was not clinically significant. However, the requirements for postoperative pain and sedative medication were not significantly different between the two groups. No serious complications occurred in this study.

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การใช้ยาซูเฟนตานิลและเฟนตานิลสำหรับการดมยาสลบในการการผ่าตัดหัวใจพิการแต่กำเนิด

อังกาบ ปราการรัตน์, พ.บ., ศิริลักษณ์ สุขสมปอง, พ.บ.**

การศึกษาครั้งนี้เพื่อเปรียบเทียบผลของยาซูเฟนตานิลและยาเฟนตานิลต่อหัวใจและระบบไหลเวียนเลือดของเด็กที่มารับการผ่าตัดหัวใจ รวมทั้งเปรียบเทียบระยะเวลาที่ผู้ป่วยตื่นจากการสลบและระยะเวลาที่สามารถถอดท่อช่วยหายใจภายหลังผ่าตัด

ทำการศึกษาผู้ป่วยเด็กจำนวน 60 ราย ที่มารับการผ่าตัดรักษาโรคหัวใจพิการแต่กำเนิด โดยการสุ่มผู้ป่วยแบ่งเป็น 2 กลุ่ม ๆ ละ 30 ราย กลุ่มที่ 1 ได้รับยาซูเฟนตานิล 1 ไมโครกรัม/กก และกลุ่มที่ 2 ได้รับยาเฟนตานิล 2 ไมโครกรัม/กก เมื่อเริ่มนำสลบ หลังจากนั้นผู้ป่วยกลุ่มที่ 1 จะได้รับยาซูเฟนตานิล 0.5 ไมโครกรัม/กก และกลุ่มที่ 2 ได้รับยาเฟนตานิล 1 ไมโครกรัม/กก อีก 4 ครั้ง คือก่อนเริ่มการผ่าตัด ก่อนการเลื่อยกระดูกอก รวมทั้งก่อนและหลังการใช้เครื่องหัวใจและปอดเทียม จะทำการบันทึกความดันเลือด คลื่นไฟฟ้าหัวใจ ความดันเลือดดำส่วนกลาง ระยะเวลาที่เริ่มตื่น ระยะเวลาที่ทำตามคำสั่ง ระยะเวลาที่ถอดท่อหายใจได้สำเร็จ รวมทั้งการใช้ยาระงับปวดหลังผ่าตัด

ผลการศึกษาความดันเลือดเฉลี่ยของผู้ป่วยทั้ง 2 กลุ่ม ภายหลังการนำสลบ จะมีค่าลดลงอย่างมีนัยสำคัญทางสถิติ แม้ว่าความดันเลือดเฉลี่ยของผู้ป่วยทั้ง 2 กลุ่ม จะเพิ่มอย่างมีนัยสำคัญทางสถิติเมื่อเริ่มผ่าตัดและเมื่อมีการเลื่อยกระดูกอก แต่จะพบความแตกต่างอย่างมีนัยสำคัญทางสถิติระหว่างผู้ป่วยทั้ง 2 กลุ่ม เฉพาะเวลาเมื่อเริ่มผ่าตัดเท่านั้น สำหรับอัตราเร็วของหัวใจเต้นของผู้ป่วยทั้ง 2 กลุ่มภายหลังการใส่ท่อหายใจ การเริ่มผ่าตัด การเลื่อยกระดูกและการปิดบาดแผลมีความแตกต่างจากค่าก่อนนำสลบอย่างมีนัยสำคัญทางสถิติ แต่ไม่พบความแตกต่างระหว่างยาทั้ง 2 กลุ่ม เป็นที่สังเกตว่าอัตราเร็วของหัวใจเต้นของผู้ป่วยจะลดลงภายหลังการนำสลบ และไม่เปลี่ยนแปลงในกลุ่มที่ได้รับยาซูเฟนตานิล ส่วนผู้ป่วยในกลุ่มเฟนตานิลมีอัตราเร็วของหัวใจเต้นเพิ่มขึ้นภายหลังการใส่ท่อหายใจ แต่ก็ไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติ ค่าเฉลี่ยของความดันเลือดดำส่วนกลางไม่แตกต่างอย่างมีนัยสำคัญทางสถิติ สำหรับระยะเวลาที่ผู้ป่วยเริ่มตื่นก็ไม่แตกต่างกันทั้ง 2 กลุ่มอย่างมีนัยสำคัญทางสถิติ แต่ระยะเวลาที่สามารถถอดท่อหายใจได้สำเร็จของผู้ป่วยกลุ่มซูเฟนตานิลนานกว่ากลุ่มเฟนตานิลอย่างมีนัยสำคัญทางสถิติ การใช้ยาระงับปวดและสงบผู้ป่วยก็ไม่แตกต่างอย่างมีนัยสำคัญ และไม่พบภาวะแทรกซ้อนร้ายแรงใด ๆ จากการศึกษาครั้งนี้

สรุป สามารถใช้ซูเฟนตานิลขนาดทั้งหมด 3 ไมโครกรัม/กก สำหรับการระงับความรู้สึกผู้ป่วยเด็กที่มารับการผ่าตัดโรคหัวใจพิการแต่กำเนิดภายใต้เทคนิคการใช้หัวใจและปอดเทียมได้อย่างปลอดภัย ไม่มีภาวะแทรกซ้อนร้ายแรง มีการเปลี่ยนแปลงของระบบไหลเวียนเลือดค่อนข้างน้อยกว่าเด็กที่ได้รับเฟนตานิล 6 ไมโครกรัม/กก ระยะเวลาตื่นจากยาสลบก็ไม่แตกต่างกันอย่างมีนัยสำคัญ แต่ระยะเวลาถอดท่อหายใจหลังผ่าตัดของกลุ่มเฟนตานิลสั้นกว่ากลุ่มซูเฟนตานิลอย่างมีนัยสำคัญ สำหรับความต้องการยาแก้ปวดหลังผ่าตัดของผู้ป่วยทั้ง 2 กลุ่ม ไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ

คำสำคัญ : ซูเฟนตานิล, เฟนตานิล, โรคหัวใจพิการแต่กำเนิด, การดมยาสลบ

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