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**The effect of individualized analgesia
on respiratory adverse events after
adenotonsillectomy in Children
—randomized double-blind controlled trial**

2016-11-15

Study protocol

Study background

Adenotonsillectomy in children is a common operation in Department of ENT, and it is also the main method for treatment of obstructive sleep apnea syndrome (OSAS). Clinically, there are a considerable number of children with OSAS who underwent adenotonsillectomy, some of which are severe OSAS.

Recurrent nocturnal hypoxemia occurred in children with severe OSAS.

Their susceptibility to opioids increased and the quantity of opioid needed for no pain after operation was less than that of mild children .

Therefore, the dosage of opioids for postoperative analgesia in children with different severity is different. If all children are treated with a small dose of opioid analgesics, the analgesic efficacy of mild or non OSAS children is not sufficient; if a large dose is used, then severe children are prone to respiratory adverse events . Studies have shown that the incidence of respiratory adverse events in children with severe OSAS is as high as 29.6%, which is about 10 times that of children with mild OSAS. Therefore, it is very important to differentiate the patients with severe and mild OSAS for targeted individualized use of analgesics in children with adenotonsillectomy .

Since children with severe OSAS have an increased susceptibility to opioids, we hypothesized that the sensitivity of children to opioids could

be judged by the response of respiratory rate to small doses of opioids, which can guide the use of long-acting opioids after surgery to reduce the incidence of respiratory adverse events. Based on our previous studies, we found that the fentanyl test results were correlated with the postoperative morphine requirement. Children with positive fentanyl test need less morphine requirement (median morphine use was 30 μ g/kg), and negative children need less postoperative morphine requirement (median morphine use was 50 μ g/kg) [13]. It shows that the conventional analgesic dose (25 μ g/kg) is larger for some of the children with positive fentanyl, which may increase the incidence of postoperative respiratory adverse events . It is small for the children with negative fentanyl test, there is a lack of pain relief, which extends the duration of pain in children. Fentanyl test cannot identify the severity of OSAS, but it can be used to identify children with different morphine requirements. Therefore, we hypothesized that individual analgesia should be performed according to the results of fentanyl test. More amount of morphine in children with positive fentanyl test and less amount of morphine in children with negative fentanyl test can reduce the incidence of postoperative adverse events in children, and improve the analgesic efficacy of children.

Materials and Methods

The study received approval from the Institutional Review Board of the Children's Hospital Fudan university (Human Research Review Committee Approval No.2016189) and written parental informed consent. Since November 2016, Children between the ages of 3 and 10 years with ASA classification of I or II and scheduled for adenotonsillectomy were eligible for inclusion in the study. Exclusion criteria were cognitive dysfunction, asthma, and obesity (BMI > 30 kg/m squared), a facial deformity, neuromuscular joint disease, drug allergy, preoperative analgesic drugs, etc.