Thyroidectomy case study

32-year-old female 5'3", 52.2 kg (115 lb) BMI 20.4 kg/m²

Comorbidities
• Mild hepatic impairment (Child-Pugh grade A)
• Persistent depressive disorder (diagnosed 6 years ago)

Prior history of alcoholism, 5 years abstinent
No known drug allergies
No family history of adverse reactions to anesthetic agents
Medication: SSRI

The concomitant use of Ultiva with other drugs that affect the serotonergic neurotransmitter system has resulted in serotonin syndrome. Carefully observe the patient, particularly during treatment initiation and dose adjustment. Discontinue ULTIVA if serotonin syndrome is suspected.

Intraoperative awareness has been reported in patients under 55 years of age when ULTIVA has been administered with propofol infusion rates of ≤ 75 mcg/kg.

This case study is for illustrative and educational purposes only. The dosing regimen is specific to this case study and other regimens may vary depending on patient and procedure. Any use of this product is subject to the judgment of the practitioner in each case. Please consult the full Prescribing Information, including the boxed warning, for use of this product.

**WARNING: ADDICTION, ABUSE, AND MISUSE**
ULTIVA exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing ULTIVA.

**INDICATION**
ULTIVA is indicated for IV administration:

• As an analgesic agent for use during the induction and maintenance of general anesthesia for inpatient and outpatient procedures.

• For continuation as an analgesic into the immediate postoperative period in adult patients under the direct supervision of an anesthesia practitioner in a postoperative anesthesia care unit or intensive care setting.

• As an analgesic component of monitored anesthesia care in adult patients.

Please see Important Safety Information, including Boxed Warning. Please see the full Prescribing Information for all precautions, warnings, contraindications, and adverse events.
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**Hypothetical total intravenous anesthesia (TIVA) plan**

<table>
<thead>
<tr>
<th>Stage of procedure</th>
<th>Action</th>
<th>Notes and safety considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Induction</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remi produces adverse events that are characteristic of μ-opioids, such as respiratory depression, apnea, tachycardia, bradycardia, hypotension, hypertension, and skeletal muscle (including chest wall) rigidity. Due to the presence of glycine in the formulation, Remi is contraindicated for epidural or intrathecal administration. Remi is also contraindicated in patients with known hypersensitivity to fentanyl analogs.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remi has a synergistic effect with other anesthesia drugs and may reduce the dosage of propofol and other agents.</td>
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<tr>
<td></td>
<td></td>
<td>Administer Remi in port closest to patient to avoid accumulation in IV tubing. Titrate slowly in small increments until patient response is adequate to help minimize side effects, such as muscle rigidity or respiratory depression.</td>
</tr>
<tr>
<td></td>
<td>Lidocaine 50 mg IV</td>
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<tr>
<td></td>
<td>Propofol 140 mg IV</td>
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<tr>
<td></td>
<td>Rocuronium 31 mg IV</td>
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<tr>
<td></td>
<td>Remi* 1 mcg/kg IV over 30-60 seconds</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dexamethasone 8-10 mg IV</td>
<td></td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
<td>Propofol 100 mcg/kg/min</td>
<td>Increase dose of Remi for painful or stimulating parts of procedure. Rapid response within 5-10 minutes of dose adjustment.</td>
</tr>
<tr>
<td></td>
<td>Remi 0.2-0.3 mcg/kg/min</td>
<td>Maintain adequate amount of analgesic to prevent increase in blood pressure. Adjust dose of Remi to help provide hemodynamic stability.</td>
</tr>
<tr>
<td><strong>Emergence and postoperative</strong></td>
<td>Ondansetron 4 mg 30 minutes prior to end of case</td>
<td>Prepare for postoperative pain. Rapid offset of Remi results in rapid dissipation of analgesic effect within 5-10 minutes of discontinuation. Other analgesics may be administered prior to discontinuation where postoperative pain is anticipated.</td>
</tr>
<tr>
<td></td>
<td>Hydromorphone 1 mg IV for postoperative pain</td>
<td>Rapid offset and rapid recovery regardless of infusion duration.</td>
</tr>
<tr>
<td></td>
<td>At beginning of closure, turn off Remi and propofol and await spontaneous ventilation</td>
<td>Due to residual effects of concomitant anesthetics, respiratory depression may occur up to 30 minutes after discontinuation of Remi.</td>
</tr>
<tr>
<td></td>
<td>As spontaneous ventilation begins, titrate Remi to maintain ETCO2 in the low 50 mm Hg range</td>
<td>In adult general anesthesia studies, of 281 patients given Remi for postoperative analgesia, 61 (22%) experienced nausea, 22 (8%) experienced vomiting, 19 (7%) experienced respiratory depression, and 15 (5%) experienced shivering. After discontinuation in 929 patients, 339 (36%) experienced nausea, 150 (16%) experienced vomiting, 49 (5%) experienced shivering, and 44 (5%) experienced fever.</td>
</tr>
<tr>
<td></td>
<td>Discontinue Remi 2 minutes before dressing is applied</td>
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</tr>
</tbody>
</table>

*Remifentanil is commonly referred to as Remi by anesthesia providers.


**IMPORTANT SAFETY INFORMATION**

ULTIVA is contraindicated for epidural or intrathecal administration due to the presence of glycine in the formulation and in patients with hypersensitivity to remifentanil (e.g., anaphylaxis).

ULTIVA contains remifentanil, a Schedule II controlled substance. Because opioids are sought by drug abusers and people with addiction disorders, employ strategies to reduce the risks such as proper storage and control practices.

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Please see the full Prescribing Information for all precautions, warnings, contraindications, and adverse events.
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### Hypothetical IV and inhalational (balanced) plan

<table>
<thead>
<tr>
<th>Stage of procedure</th>
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<th>Notes and safety considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preoperative</strong></td>
<td>Midazolam 2-5 mg IV in incremental doses</td>
<td></td>
</tr>
</tbody>
</table>
| **Induction**      | Fentanyl 100 mcg IV  
                    Lidocaine 50 mg IV  
                    Propofol 140 mg IV  
                    Succinylcholine 60 mg IV  
                    Remi \(^*\) 0.5 mcg/kg/min  
                    Dexamethasone 4-8 mg IV |  
|  | • Remi has a synergistic effect with other anesthesia drugs and may reduce the dosage of propofol and other agents\(^1\)  
|  | • Administer Remi in port closest to patient to avoid accumulation in IV tubing.  
|  | • Titrate slowly in small increments until patient response is adequate to help minimize side effects, such as muscle rigidity or respiratory depression\(^1\) |  |
| **Maintenance**    | Desflurane at 4%-6% ET  
                    Remi 0.2-0.5 mcg/kg/min |  
|  | • Increase dose of Remi for painful or stimulating parts of procedure.  
|  | • Rapid response within 5-10 minutes of dose adjustment\(^1\)  
|  | • Maintain adequate amount of analgesic to prevent increase in blood pressure.  
|  | • Adjust dose of Remi to help provide hemodynamic stability\(^1\) |  |
| **Emergence and postoperative** | Ondansetron 4 mg 30 minutes prior to end of case  
At beginning of closure, decrease Remi to 0.08 mcg/kg/min and decrease desflurane to 3%  
At skin closure, decrease Remi to 0.02-0.03 mcg/kg/min, discontinue desflurane, keep flow at 2 L/min or less, spontaneous ventilation  
Titrate hydromorphone at 0.2 mg increments to maintain spontaneous ventilation between 10-14 bpm for postoperative pain  
Extubate with Remi 0.02-0.04 mcg/kg/min  
Discontinue Remi after extubation |  
|  | • Prepare for postoperative pain. Rapid offset of Remi results in rapid dissipation of analgesic effect within 5-10 minutes of discontinuation. Other analgesics should be administered prior to discontinuation where postoperative pain is anticipated\(^1\)  
|  | • Rapid offset and rapid recovery regardless of infusion duration\(^1\)  
|  | • Due to residual effects of concomitant anesthetics, respiratory depression may occur up to 30 minutes after discontinuation of Remi\(^1\)  
|  | • In adult general anesthesia studies, of 281 patients given Remi for postoperative analgesia, 61 (22%) experienced nausea, 22 (8%) experienced vomiting, 19 (7%) experienced respiratory depression, and 15 (5%) experienced shivering. After discontinuation in 929 patients, 339 (36%) experienced nausea, 150 (16%) experienced vomiting, 49 (5%) experienced shivering, and 44 (5%) experienced fever\(^1\) |  |

\(^*\)Remifentanil is commonly referred to as Remi by anesthesia providers.  

### IMPORTANT SAFETY INFORMATION, continued

Serious, life-threatening, or fatal respiratory depression has been reported with opioids. ULTVNA should be administered only by persons specifically trained in the use of anesthetic drugs and the management of the respiratory effects of potent opioids. Monitor patients closely, particularly during initiation and titration. Resuscitative and intubation equipment, oxygen, and opioid antagonists must be readily available. Respiratory depression in spontaneously breathing patients is generally managed by decreasing the rate of the infusion of ULTVNA by 50% or by temporarily discontinuing the infusion.

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IMPORTANT SAFETY INFORMATION, continued

Hypotension, profound sedation, respiratory depression, coma, and death may result from the concomitant use of ULTIVA with benzodiazepines or other CNS depressants. Patients should be advised to avoid alcohol for 24 hours after surgery. A potentially life-threatening condition could result from concomitant serotonergic drug administration. Discontinue ULTIVA if serotonin syndrome is suspected.

Continuous infusions of ULTIVA should be administered only by an infusion device. Interruption of an infusion of ULTIVA will result in rapid offset of effect. Discontinuation of ULTIVA should be preceded by the establishment of adequate postoperative analgesia.

IV tubing must be cleared to remove residual ULTIVA, which has been associated with respiratory depression, apnea, and muscle rigidity upon the administration of additional fluids or medications through the same IV tubing.

Skeletal muscle rigidity can be caused by ULTIVA and is related to the dose and speed of administration. ULTIVA may cause chest wall rigidity after single doses of >1 mcg/kg administered over 30 to 60 seconds, or after infusion rates >0.1 mcg/kg/min.

ULTIVA should not be administered into the same IV tubing with blood due to potential inactivation by nonspecific esterases in blood products.

Bradycardia has been reported with ULTIVA and is responsive to ephedrine or anticholinergic drugs. Monitor heart rate during dosage initiation and titration.

Hypotension has been reported with ULTIVA and is responsive to decreases in administration, or to IV fluid or catecholamine (epinephrine, ephedrine, norepinephrine, etc.) administration. Monitor blood pressure during dosage initiation and titration.

Intraoperative awareness has been reported in patients under 55 years of age when ULTIVA has been administered with propofol infusion rates of ≤75 mcg/kg/min.

Monitor for sedation and respiratory depression in patients susceptible to the intracranial effects of carbon dioxide retention.

Standard monitoring of patients should be maintained in the postoperative period to ensure adequate recovery without stimulation.

Most common adverse reactions (incidence ≥1%) were respiratory depression, bradycardia, hypotension, and skeletal muscle rigidity.

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