Computer-aided Anesthesia and Oxygen Delivery System

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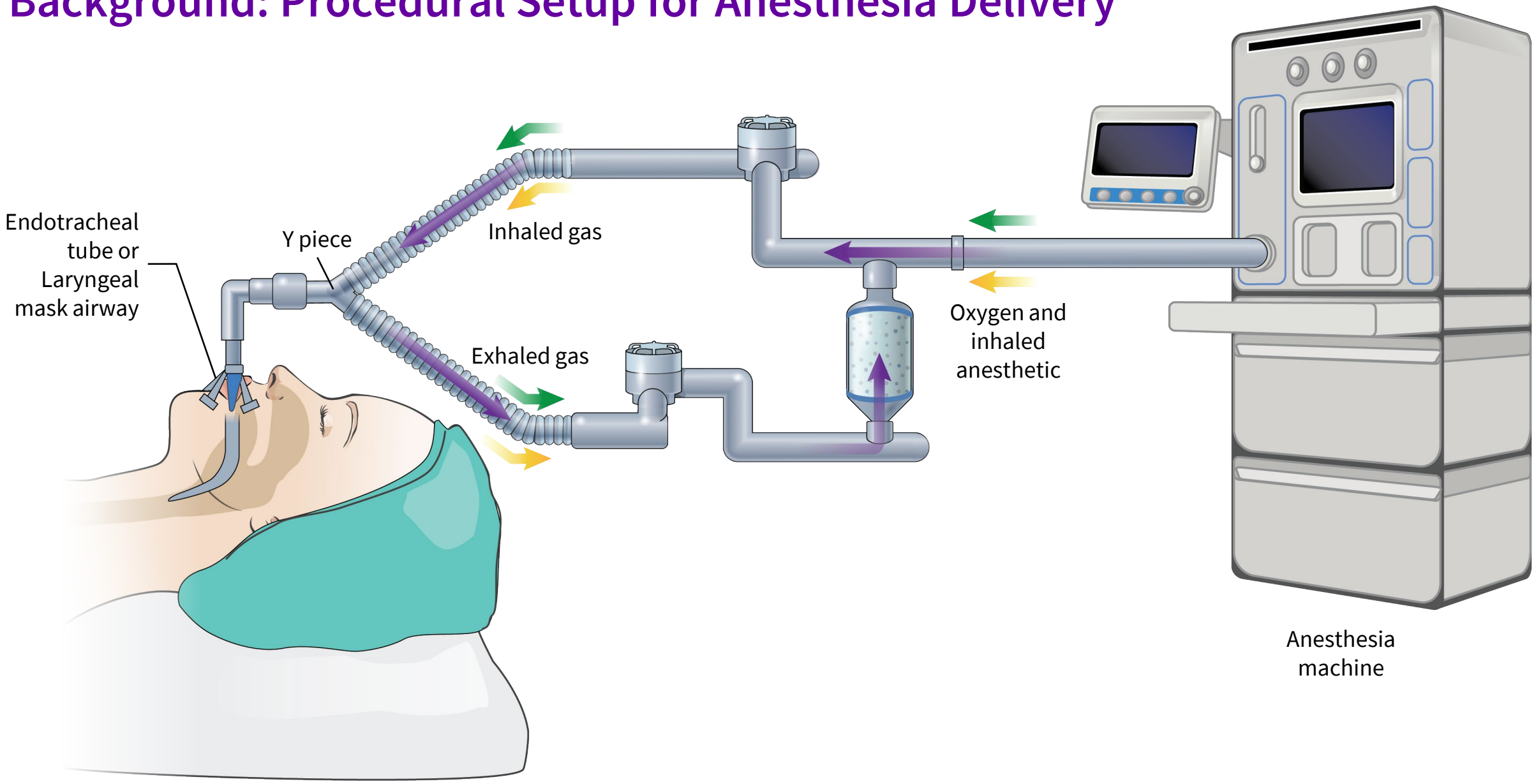
Background: Procedural Setup for Anesthesia Delivery



Background: Procedural Innovation

Current Practice for Anesthetic Delivery

- An endotracheal tube or laryngeal mask airway is placed
- The anesthesia provider determines target inhaled gas concentrations and uses an anesthesia machine to deliver inhaled anesthetics and oxygen to approximate those targets
- Anesthesia provider manually adjusts multiple settings which control the input of anesthetic and oxygen throughout the surgical procedure

Computer-aided Anesthesia and Oxygen Delivery System

- An endotracheal tube or laryngeal mask airway is placed
- The anesthesia provider determines target exhaled gas concentrations and utilizes “Et Control" integrated into the anesthesia machine to administer computer-aided delivery of anesthesia and oxygen
- Et Control utilizes “fuzzy logic” software which automatically adjusts oxygen and anesthetic inflows to meet exhaled gas targets
- This is a semi-closed loop technology, indicating that the anesthesia provider remains responsible for the judgment, decision-making and therapeutic requirements involved in monitoring the patient and adjusting exhaled targets

Implications of Use

End-tidal Control is new technology described by a novel FDA product code and does not have an ICD-10-PCS code

- Pre-market FDA approval for the device “End-tidal Control” (Et Control)
  - New FDA Product Code QSF
    - “Software Option For Anesthesia Gas Machine To Achieve And Maintain Targeted End Tidal Oxygen And Anesthetic Agents[1].” By definition, the device is indicated for use with the anesthesia delivery system to support clinicians in maintaining the clinician determined, patient specific, targeted end tidal oxygen and anesthetic agent concentrations by making adjustments to the oxygen and anesthetic composition and total flow.
  - PMA# P210018, March 2022, Class III software medical device, required a prospective randomized controlled clinical trial
  - FDA-approved training is required prior to implementation
  - Approved for use with patients 18 years and older
- Post-market surveillance requirements address clinician complaints but do not enable procedure tracking outside of these individual reports
- The patient, clinician, operational and environmental impacts of Et Control require reporting, tracking and analysis for US clinicians and regulators to properly assess the impact of the technology

[1]https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=246

Estimated Frequency of Use

US procedural volumes suggest many patients may be cared for and benefit from this technology

- 60,000 people in the US/day have in-patient surgery under general anesthesia[1]; about half of these are Medicare beneficiaries. Since most of these procedures are performed using inhaled anesthetics, they are candidates for this procedure.
- There are more than 8000 surgical procedures described by ICD-10-PCS codes[2], each of which may benefit from computer-aided, delivery of anesthesia and oxygen.

[1]https://newsinhealth.nih.gov/2011/04/waking-up-anesthesia#:~:text=Every%20day%20about%2060%2C000%20people,from%20moving%20during%20the%20operation
[2]https://www.cdc.gov/nhsn/xls/icd10-pcs-pcm-nhsn-opc.xlsx

Summary

- Naming conventions for End-tidal Control include:
  - End-tidal Control
  - Et Control
- Documentation of system use
  - As a new technology and procedure, standardized documentation has not been established
  - Use is expected to be documented by the anesthesia provider as one of the following:
    - Anesthesia provider procedure note (line placement and intraoperative procedures are also noted here)
    - Data output from the anesthesia machine directly recorded in the anesthesia record and saved in the electronic health record
    - Text entry in the events section of the anesthesia record
    - Manual tick box in anesthesia record
  - Until broad standardization, it is expected that site specific practices will continue to evolve with localized coding strategies
- The patient, clinician, operational and environmental impacts of Et Control require reporting, tracking and analysis for US clinicians and regulators to properly assess the impact of the technology

Thank you

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