“A RANDOMIZED DOUBLE BLIND PROSPECTIVE STUDY COMPARISION BETWEEN DEXMEDETOMIDINE AND FENTANYL ON INTUBATION CONDITIONS DURING AWAKE FIBROPTIC BRONCHOSCOPIC INTUBATION”

Dissertation submitted to

THE TAMILNADU DR.M. G. R.MEDICAL UNIVERSITY

In partial fulfilment for the award of the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

BRANCH X

INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE

MADRAS MEDICAL COLLEGE

CHENNAI - 600003

MAY - 2019

CERTIFICATE

This to certify that the dissertation entitled **"A RANDOMIZED DOUBLE BLIND PROSPECTIVE STUDY COMPARISION BETWEEN DEXMEDETOMIDINE AND FENTANYL ON INTUBATION CONDITIONS DURING AWAKE FIBROPTIC BRONCHOSCOPIC INTUBATION"** submitted by **Dr.E.ARUNMOZHI** in partial fulfillment for the award of the degree of Doctor of Medicine in Anaesthesiology by The Tamil Nadu Dr.M.G.R. Medical University, Chennai., is a Bonafide record of the work done by her in the **INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE,** Madras Medical College and government hospital, during the academic year 2016-2019.

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This to certify that the dissertation entitled **"A RANDOMIZED DOUBLE BLIND PROSPECTIVE STUDY COMPARISION BETWEEN DEXMEDETOMIDINE AND FENTANYL ON INTUBATION CONDITIONS DURING AWAKE FIBROPTIC BRONCHOSCOPIC INTUBATION"** submitted by **Dr.E.ARUNMOZHI** in partial fulfilment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamil Nadu Dr.M.G.R. Medical University, Chennai, is a bonafide record of the work done by her in the **INSTITUTE OFANAESTHESIOLOGY AND CRITICAL CARE,** Madras Medical College and Rajiv Gandhi Government General Hospital, during the academic year 2016 - 2019.

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DECLARATION

I hereby, solemnly declare that this dissertation titled **"A RANDOMIZED DOUBLE BLIND PROSPECTIVE STUDY COMPARISION BETWEEN DEXMEDETOMIDINE AND FENTANYL ON INTUBATION CONDITIONS DURING AWAKE FIBROPTIC BRONCHOSCOPIC INTUBATION."** is a bonafide record of the work done by me in the **INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE,** Madras Medical College and Rajiv Gandhi Government General Hospital, during the academic year 2016 - 2019 under the guidance of **Prof.Dr.SAMUEL PRABHAKARAN. M.D., D.A.,** Professor of Anaesthesiology, Institute of Anaesthesiology and critical care, Rajiv Gandhi Govt.General Hospital, Madras Medical College, Chennai -600 003 and submitted to The Tamil Nadu Dr.M.G.R.Medical University, Guindy, Chennai –32, in partial fulfilment for the requirements for the award of the degree of M. D.Anaesthesiology (Branch X) , examinations to be held on April 2019. I have not submitted this dissertation previously to any university for the award of degree or diploma.

Place : Chennai. **Dr.E.ARUNMOZHI**

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ABBREVIATIONS

ANS	Autonomic nervous system
ASA	American Society of Anaesthesiologists
BP	Blood pressure
CNS	Central nervous system
DBP	Diastolic blood pressure
ECG	Electrocardiaogram
EEG	Electro encephalogram
Inj.	Injection
Tab	Tablet
IM	Intramuscular
IV	IntraVenous
$ETCO_2$	End tidal carbon di oxide
Min	Minute
Bpm	Beats per minute
AFOI	Awake Fibroptic Intubation
FOB	Fibroptic bronchoscope

CONTENT

INTRODUCTION

INTRODUCTION

Awake fibroptic intubation (AFOI) is indicated in patients with anticipated difficult airway, failed tracheal intubation, unstable cervical spine injury where positioning for laryngoscopy is difficult.

It is important to prepare patients including psychological preparation, antisialogogue administration, anaesthetising the upper airway to blunt the airway reflexes, adequate sedation, anxiolysis while preserving airway patency and spontaneous breathing.

There are many drugs that have been used for producing conscious sedation such as Benzodiazepines ,opioids,propofol which can be either used alone or in combination.

Midazolam administration results in amnesia and sedation. Propofol usage produces rapid onset of action and reduced context sensitive half life with profound amnesia. Opioids example:Fentanyl and Remifentanyl administration results in attenuating hemodynamic response and in reduction of discomfort during the passage of FOB through vocal cords. All of the above drugs result in favourable intubating conditions ,the incidence of oxygen desaturation is high.

One must be cautious not to cause hypoxia (which may cause fatal complications) in difficult airway scenarios. Propofol if used in high dosescan cause loss of muscle tone of upper airway muscles which inturn causes difficulty in negotiation of FOB beyond the epiglottis and may even results in apnea.

Therefore an ideal agent for conscious sedation should ensure Spontaneous ventilation with adequate airway patency, patient cooperation favourable intubating conditions and stable hemodynamics and should not produce respiratory depression.

AIM OF THE STUDY

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To compare the effects of dexmedetomidine and fentanyl for favourable intubating condition during awake fibroptic bronchoscopy based on

PRIMARY OUTCOME MEASURES:

Cough score

Post - intubation score

Heart rate, mean arterial blood pressure,spo_2 were measured at baseline and at intervals of 5,10, at intubation and post-intubation 5 min.

SECONDARY OUTCOME MEASURES:

Assesment of sedation by Ramsay sedation score.

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CLINICAL ANATOMY OF

UPPER AIRWAY

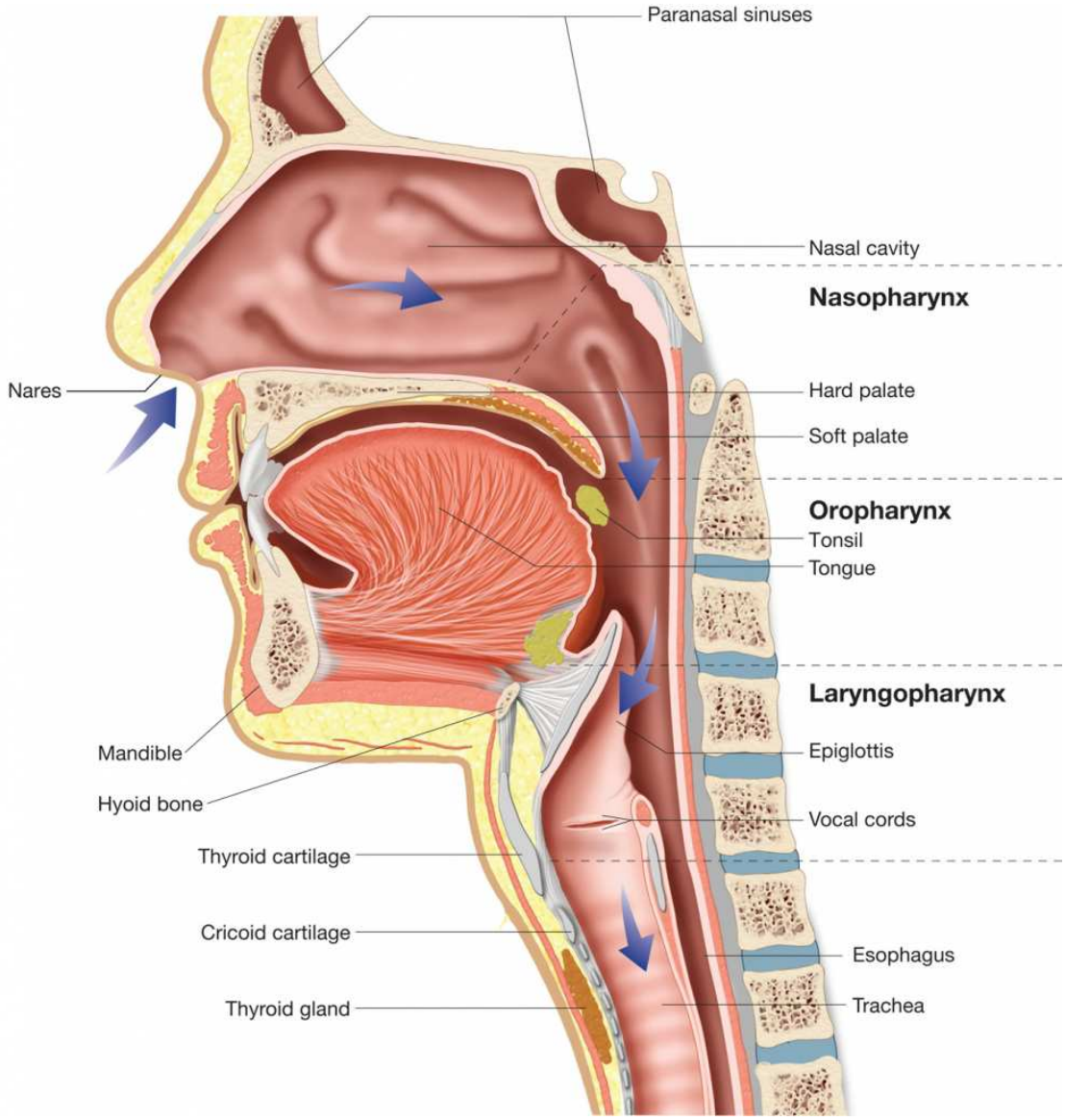
CLINICAL ANATOMY OF UPPER AIRWAY AND LARNYX

The respiratory tract is divided into upper and lower airways. upper airway includes nasal cavity, paranasal sinus,pharynx and part of larynx above the vocal cords. Lower airway includes the part of the larynx below the vocal cord which is trachea, bronchi, bronchioles, alveolar ducts and sac.

NASAL CAVITY:

The airway begins functionally at the nares,the external opening of the nasal passages.Nasal cavity is divided into the right and left nasal passages by the nasal septum which forms the medial wall of the nasal passages.The septum is formed by the septal cartilage anteriorly and by 2 bones posteriorly -the ethmoid and the vomer.

Nasal septal deviation is common in adult population:therefore more patent side should be determined before passsing instrumentation through the nasal passages.The lateral wall of nasal passages consists of three turbinates(or conchae) that divides the nasal passage into three scroll shaped meatuses.


Paranasal sinuses
Nasal cavity
Nasopharynx
Nares
Hard palate
Soft palate
Oropharynx
Tonsil
Tongue
Laryngopharynx
Mandible
Epiglottis
Hyoid bone
Vocal cords
Thyroid cartilage
Cricoid cartilage
Esophagus
Thyroid gland
Trachea

The inferior turbinate and the floor of the nasal cavity is the preferred pathway of nasal airway devices. Because the mucosal lining of nasal cavity is highly vascular, vasoconstrictor should be applied topically before instrumentation of nose to avoid epistaxis. The posterior openings of the nasal passages are the choanae which lead into the nasopharynx.

ORAL CAVITY:

Oral cavity leads to oropharynx and is inferiorly bounded by the tongue and superiorly by the hard palate and soft palate. The hard palate is formed by parts of maxilla and palatine bone makes up the anterior two thirds of the roof;soft palate a fibromuscular fold of tissue attached to the hard palateforms the posterior one third of the roof.

The tongue is anchored to various structures by its extrinsic musculature of these clinically relevent is genioglossus,which connects the tongue to the mandible. Beneath the tongue mylohyoid muscle separate the floor of the mouth into sublingual space superiorly and submental space inferiorly.

Cellulitis (ludwig angina) or hematoma formation in these spaces can cause elevation and posterior displacement of tongue and resultant airway obstruction.

PHARYNX

Pharynx is a muscular tube which extends from the base of the skull down to the level of cricoid cartilage and connects the nasal and oral cavities with the larynx and oesophagus.The posterior wall of the pharynx is made up of buccopharyngeal fascia which separates the pharynx from the retropharyngeal space. Improper placement of gastric or tracheal tube can result in laceration of the fascia and the formation of the retropharyngeal dissection. The pharyngeal musculature in the awake patients helps to maintain airway patency. Loss of pharyngeal muscle tone is one of the primary causes of upper airway obstruction during anaesthesia. A chin lift with mouth closure increases longitudinal tension in the pharyngeal muscles, counteracting the tendency of the pharyngeal airway to collapse.

Pharynx is divided into

Nasopharynx

Oropharynx

Hypopharynx

NASOPHARYNX :

Nasopharynx lies behind the nasal cavity and above the soft palate. It ends at the soft palate. This region is termed as velopharynx and is a common site of airway obstruction in both awake and anesthetised patients. It communicates with the oropharynx through the pharyngeal isthmus which becomes closed off during the act of swallowing. Nasopharyngeal tonsil lies on the roof and posterior wall of nasopharynx. Postero superiorly to the nasopharynx lies the sphenoid sinus that separates the pharynx from the sella turcica containing the pituitary gland. This is the basis of the transnasal approach to the pituitary.

OROPHARYNX:

The oral cavity leads into oropharynx through the oropharyngeal isthmus which is bounded by the palatoglossal arches, the soft palate and the dorsum of the tongue. The lateral wall contains the palatoglossal folds and palato pharyngeal folds. These folds contains palatine tonsil which can hypertrophy and cause airway obstruction. The base of the tongue lies on the anterior aspect of the oropharynx connected to the epiglottis by the glosso-epiglottic folds which bound paired spaces known as valleculae.

HYPOPHARYNX :

Hypopharynx begins at the level of the epiglottis and terminates at the level of the cricoid cartilage,where it is communicates with the esophagus. The larynx protrudes into the hypopharynx creating two pyriform recesses on either side.

LARYNX :

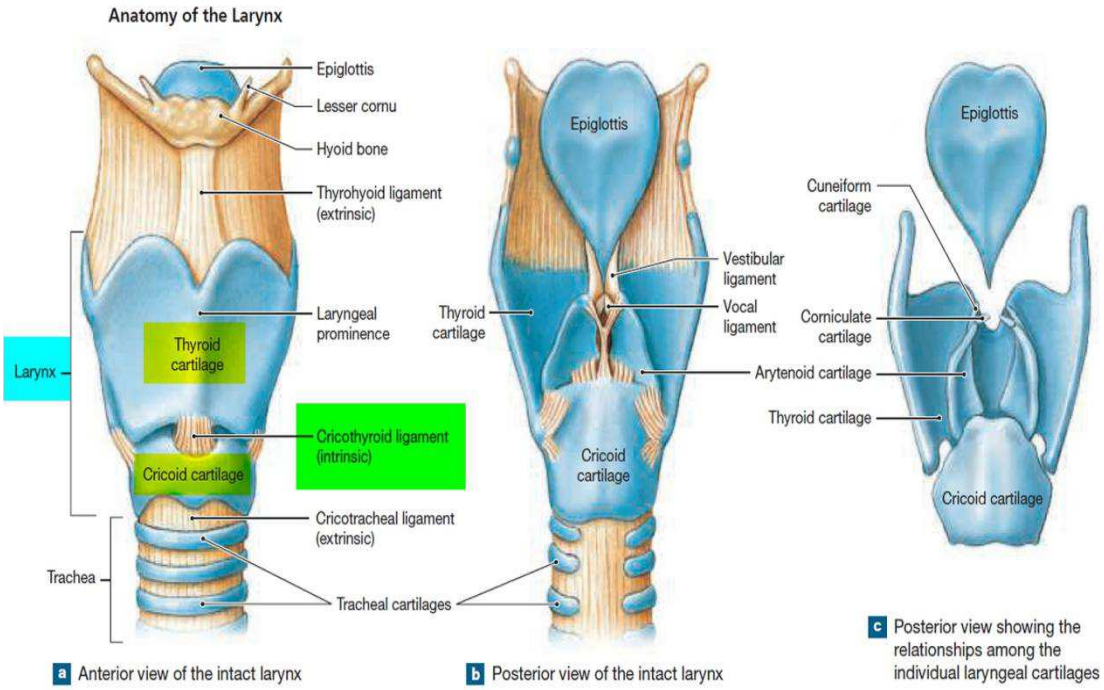
Larynx is the complex structure of cartiliage, muscles and ligaments that serves as the inlet to the trachea and to the thyroid cartiliage by the cricothyroid membrane. It is the only complete cartiliagenous ring in the airway. It lies opposite to the 4, 5 and 6^{th} cervical vertebra. Principal cartiliages are thyroid, cricoid and epiglottis (which are unpaired) and arytenoid, cuneiform and corniculate(which are paired).

Thyroid cartiliage is shield like and consists of two laminae that meet in the midline inferiorly leaving the thyroid notch between them above. This junction is well marked in the male forming the laryngeal prominence but in the female it is not obvious. The lamina carry superior and inferior horns or cornua at the upper and lower extremities of their posterior borders; the inferior horn bears a circular facet on its inner surface of the cricoid cartiliage.

Cricoid cartiliage is in the shape of the signet ring; Signet lies postereiorly as a quadrilateral lamina joined in front by the thin arch. The side of the lamina bears two articular facet, one for the inferior horn of the thyroid cartiliage and the other near its upper extremity for the arytenoid cartiliage.

Epiglottis is likened to a leaf. It is attached at its lower tapering and to the back of the thyroid cartiliage by means of the thyro-epiglottic ligament. Its superior extremity projects upwards and backwards behind the hyoid and the base of the tongue and overhangs the inlet of the larynx. The posterior aspect of the epiglottis is free and bears a bulge termed the tubercle in its lower part. The upper part of the anterior aspect of the epiglottis is also free. Its covering mucous membrance sweeps forward centrally onto the tongue and on either side onto the side walls of the oropharynx to form respectively, the median glosso-epiglottic and the lateral glosso-eppiglottic folds. The valleys on either side of the median glosso-epiglottic fold are termed the valecullae. They are common sites for impaction of sharp swallowed objects such as fish bone. Lower part of the anterior surface of epiglottis is attached to the back of the hyoid bone by the hyo-epiglottic ligament.

ANATOMY OF LARYNX- LARYNGEAL CARTILAGES



The corniculate cartiliage is the small nodule lying at the apex of the arytenoid. Cuneiform cartiliage is the flake of cartiliage within the marigin of ary-epiglottic fold.

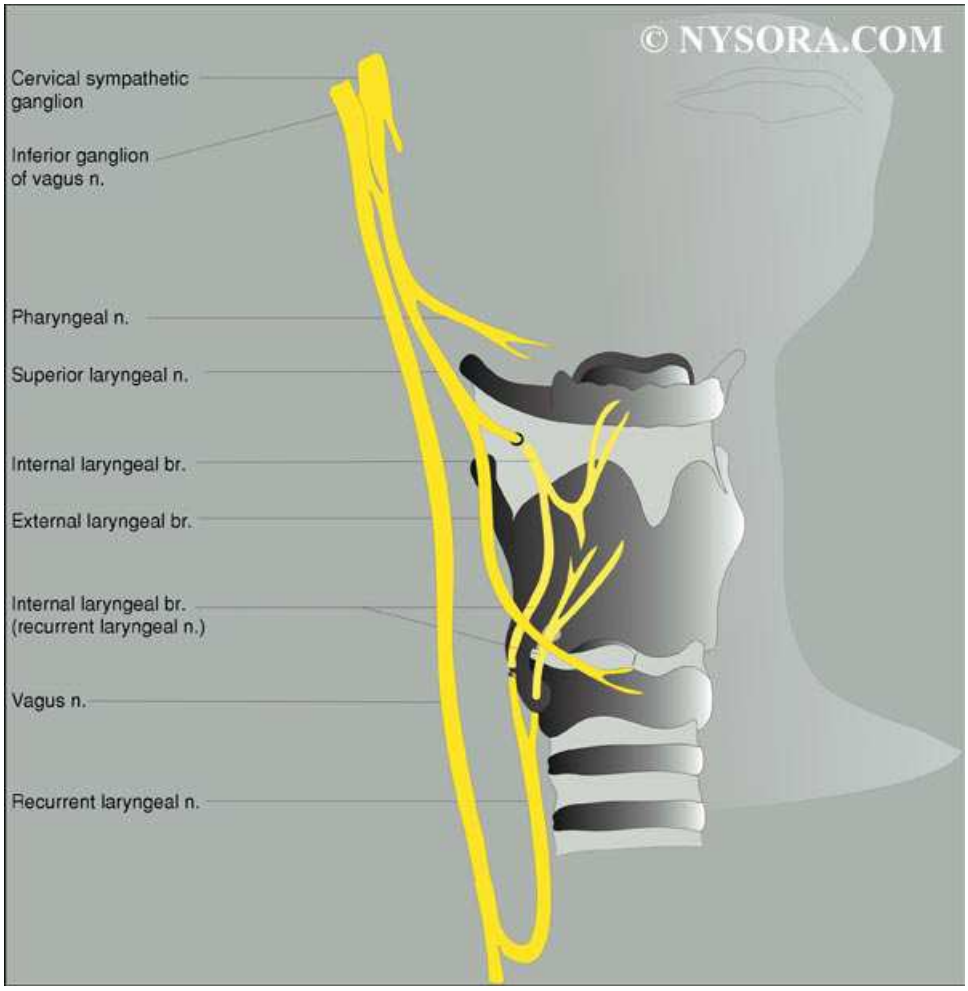
LARYNGEAL MUSCLES:

Abductor of vocal cord - posterior cricoarytenoid

Adductors of vocal cord -lateral cricoarytenoid, interarytenoid.

Sphincters to vestibule - aryepiglottic, thyro-epigloyttic

Regulators of cord tension – cricothyroid (tensors), thyroarytenoid (relaxors), vocalis(fine adjustment).



NERVE SUPPLY :

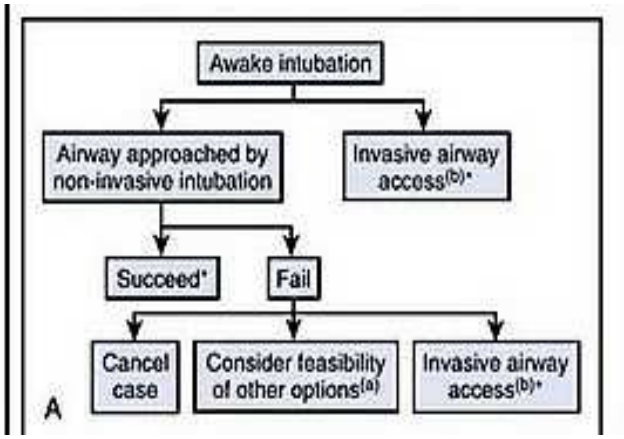
Nerve supply of larynx is from vagus via its superior and recurrent laryngeal branches.

Superior laryngeal nerve divided into external and internal laryngeal nerve. External laryngeal nerve supplies crico thyroid muscle. Internal laryngeal nerve provides sensory supply to the larynx above the vocal cords.

Recurrent laryngeal nerve provide motor supply to the intrinsic muscles of the larynx except cricothyroid. It provides sensory supply to the laryngeal mucosa below the vocal cords.

DIFFICULT AIRWAY

The ASA defines the difficult airway as the situation in which the "conventionally trained anesthesiologist experiences difficulty with mask ventilation or both."



This evaluation should direct the clinician to enter the ASA algorithm at one of its two root points: A—awake intubation, or B—intubation attempts after the induction of general anesthesia. In most instances, awake intubation is successful if approached with care and patience. When awake intubation fails, the clinician has a number of options. First, one can consider cancellation of the surgical case. In this situation, specialized equipment or personnel can be assembled for a return to the operating room. Where cancellation is not an option, regional anesthetic techniques can be considered, or, if demanded by the situation, a surgical airway (e.g., tracheostomy) may be called for.

Awake airway management is a mainstay of the ASA's Difficult Airway Algorithm. Awake intubation provides more advantages over anesthetic state, includes maintenance of spontaneous ventilation in case the airway cannot be secured rapidly, increased size and patency of the pharynx.. The effect of sedatives and general anesthetics on airway patency may be secondary to direct effects on the reticular activating system and on motorneurons . Sleep apnea patient may be directly prone to obstruction of the airway with minimal sedation.

The awake state provides maintenance of upper and lower esophageal sphincter tone, thereby reducing the risk of reflux. In case reflux occurs, the patient can themselves close the glottis or expel aspirated foreign bodies .

For Patients at risk for neurologic sequelae (e.g., patients with unstable cervical spine pathology) have sensory-motor monitoring after tracheal intubation.

After choosing awake airway management, patients must be prepared physically and psychologically.

Medication can also be used to alliviate anxiety. If sedatives is used, the clinician should know that producing obstruction or apnea in the difficult airway patients and an overly sedated patient not be able to protect the airway from gastric contents and also for cooperation with procedures.

Smaller doses of benzodiazepines (diazepam, midazolam, lorazapam) may be used to alleviate anxiety without producing significant respiratory depression

These drugs may be given in iv or oral forms (when available) and may be reversed with specific antagonists (e.g., flumazenil). Opioid receptor agonists (e.g., fentanyl, alfentanil, remifentanil) may also be used in titrated doses for their sedative effects.

A specific antagonist (e.g., naloxone) must always be kept available. Ketamine and droperidol and the new agent, dexmetomodine, can also be used.

Administration of antisialagogues is important in sucessful awake intubation techniques. Clearing of airway secretions is essential to the use of indirect optical instruments (e.g., fiberoptic bronchoscope, rigid fiberoptic laryngoscope) because small amounts of secretions can obscure the objective lens.

Glycopyrrolate (0.2 to 0.4 mg im or iv) have other effects: by reducing saliva production, these drugs increase the effectiveness of topically applied local anesthetics by removing a barrier to mucosal contact and reducing drug dilution

Vasoconstriction by drugs such as oxymetazoline or xylometazoline instilled to the nasal passages is needed if there is to be instrumentation of this part of the airway also prudent to supply

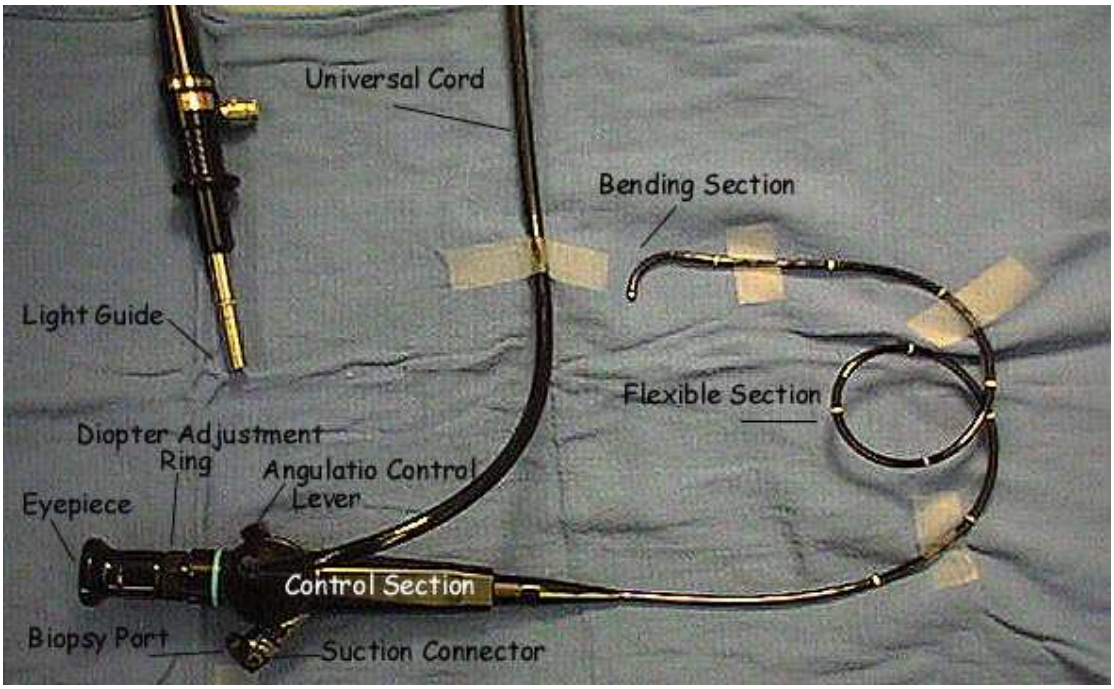
supplemental oxygen to the patient by nasal cannula (which can be placed over the nose or mouth).

Local anesthetics are the cornerstone of awake airway control techniques. The airway, from the base of the tongue to the bronchi, comprises an undeniably sensitive series of tissues. Topical anesthesia and injected nerve block techniques have been developed to blunt the protective airway reflexes.

INTUBATING FIBROPTIC BRONCHOSCOPE

Flexible fibroptic bundle was discovered by Peter murphy in 1954.This device has revolutionised the airway management in anaesthesia and intensive care. Tracheal intubation over a fibroptic scope is an invaluable technique in the airway management in patients with anticipated difficulty in laryngoscopy and intubation.

They are used to perform oral or nasal intubation and to evaluate the airway in trauma,tumour, infection and to confirm the tube placement (trachial, endobronchial,double lumen or tracheostomy tubes)and to perform tracheobronchial toilet.


Universal Cord
Bending Section
Light Guide
Flexible Section
Diopter Adjustment Ring
Angulatio Control Lever
Eyepiece
Control Section
Biopsy Port
Suction Connector

COMPONENTS:

1. Control unit which consists of the following:

    a)tip deflection control knob (the bending angle range is 60-180^0 in the vertical plane)These movements along with the rotation of FOB allows nearly 360^0.

    b)eye piece

    c)diopter adjustment ring (focusing)

    d)suction channel which can also be used to insufflate oxygen and Administer local anaesthetic solutions.

2.The flexible insertion cord consists of bundles of glass fibres.Each fibroptic bundles of glass consists of 10000 - 15000 fibres .Each fibre is7-10 micron in diameter and arranged coherently to transmit the image to the visual section. The glass fibres are sensitive to damage and black dots may be visible when damaged.

3. Light -transmitting cable or universal cord to transmit light from an external source. Light guide bundles made up of non -coherent glass fibers are one or two in number and allow the transmission of light going towards the tip. Each bundle consists of 25000 -30000 light fibers which are of 25 -30 micron in diameter. The newer FOB have miniature battery operated light source at the control section itself.

4. Other equipment may be needed eg.endoscopic face mask,oral airway, bite block,defogging agent.

MECHANISM OF ACTION:

The object is illuminated by the cold light,transmitted through two seperate light transmission bundles.The reflected and back scaterred light then enters distal objective lens and it is transmitted through the fibroptic bundles to the eye piece.

When photons impact the tissues,some reflection occurs depending on both the incident angle of the light and the refractive index of the tissue.Absorption and scaterring substantially decrease the intensity of the light transmitted to the objective lens hence the output power of the light source must be high enough to cope with these conditions.

The image quality depends not only on the quality of the objective and eyepiece lenses but also on the density and number of image or light fibers in the fibroptic bundle.

INDICATIONS FOR FOB INTUBATION:

Awake intubation(patients with anticipated difficult airway or the comorbidities endangered by trauma or hypoxemia of the non FOB intubation techniques like critical coronary artery disease).

Routine intubation

Difficult intubation

History of prior difficult intubation

Suspected difficult airway from patient history, physical examination or congenital abnormalities

Prevention of cervical spine movements in at risk patients

Avoidance of traumatic oral or nasal effects of intubation

Avoidance of aspiration in high- risk patients

Diagnostic purposes

Observation of airway pathology (tracheomalacia, tracheal stenosis, vocal cord paralysis)

Removal of pathology (eg.secretions)

Therapeutic purposes beyond planned FOB intubation:

Endotracheal tube exchange

Assistance with airway placement(eg.SGA devices,Retrograde intubation)

Positioning of double lumen tube and bronchial blockers.

Correct positioning of the endotracheal tubes at specific depths.

CONTRAINDICATINS FOR AWAKE FIBROPTIC FOB GUIDED INTUBATION:

1. Absolute contra indications:

- Uncooperative patients
- Inexperienced endoscopist and assistant
- Compromised equipment condition
- Significant upper airway obstruction expect for diagnostic purposes.
- Massive trauma

2. Moderate contra indications

- Relatively uncooperative patients
- Obstructing or obscuring blood, fluid,anatomy or foreign body in the airway that might inhibit the success.
- Very small entry space

Relative contraindications:

- Concern for vocal cord damage that might be caused by blind ETT passage by FOB.
- With some perilaryngeal masses or abscess where blindly advancing the ETT can rupture the abscess or seed the tumor.

-Documented or suspected non conventional infectious agents,agents resistant to multiple drugs or infectious diseases in the absence of a single use device

PHYSIOLOGY OF HEMODYNAMIC RESPONSE

The autonomic nervous system (ANS) divided into sympathetic nervous system and parasympathetic nervous system.Both systems actions in opposite direction.

The sympathetic nervous system is stimulated in response to stressful situations such as fear ,anger,excitement.In these instances,sympathetic nervous system stimulate heart to increase heart rate, bronchial smooth muscles to relax, and cause dilation of blood vessels that supply heart and skeletal muscles.In addition sympathetic nervous system reduces blood supply to kidney ,skin and gastro-intestinal tract.These effects are mediated by the release of catecholemines such as epinephrine(adrenaline) and nor epinephrine (nor adrenaline) from adrenal medulla.

Basal secretion adrenaline is 0.2mcg/kg /min and nor adrenaline is 0.05mcg/kg/min to main body's homeostasis.A noxious stimulus such as laryngoscopy or endotracheal intubation activates hypothalamus and stimulates secretion of sympathetic hormone from adrenal medulla. Activation of sympathetic system increases heart rate and blood pressure which is an indirect indices to measure hemodynamic response clinically.

PHYSIOLOGY OF ADRENO RECEPTORS

Adrenergic receptors are α and β receptors.α recrptors are further divided into $\alpha_{1A,}$ $\alpha_{1B,}$ α_{1D} , α_{2A} , α_{2B} and $\alpha_{2C.}$

ALPHA 2 ADRENERGIC RECEPTORS:

Alpha receptors are transmembrane receptors which has excitable G protein coupled receptors link with ligands which may be endogenous molecules or exogenous molecules such as drugs.α_2 receptors aresituated in central and peripheral nervous system in organs such as vascular smooth muscles,kidney, liver, pancreas,eye and in platelets..α_2 receptors are presynaptic, postsynaptic and extrasyaptic sites.There are three subtypes for α_2 receptors.

Subtype A - Predominatly located in CNS

Responsible for sedative,analgesic and sympatholytic effects.

Subtype B - peripheral blood vessels

Responsible for short term hypertensive response

Supress shivering

Subtype C -CNS

Produces startle response,which in humans withdrawal from the stimuli,contraction of extremity muscle,and variation in blood pressure and breathing patterns.

EFFECTS OF ALPHA 2 STIMULATION:

Stimulation of alpha 2 receptors in brain and spinal cord results in bradycardia,hypotension,sedation,and analgesia.Stimulation of alpha 2 receptors may also results in decreased salivation,gastric motility,inhibit renin secretion,increasing glomerular filtration rate,increased secretions of water &sodium,decreased introcular pressure and decreased insulin secretion.It also decreases calcium entry into the nerve terminals which inhibits neurotransmitter release.

PHARMACOLOGY OF

DEXMEDETOMIDINE

PHARMACOLOGY OF DEXMEDETOMIDINE

Dexmedetomidine is a highly selective and potent alpha 2agonist and it is approved by FDA in 1999 for short term sedation of intubated and mechanical ventilated patients ;In 2008 its aproval has been expanded to its usage in perioperative period and procedural settings.

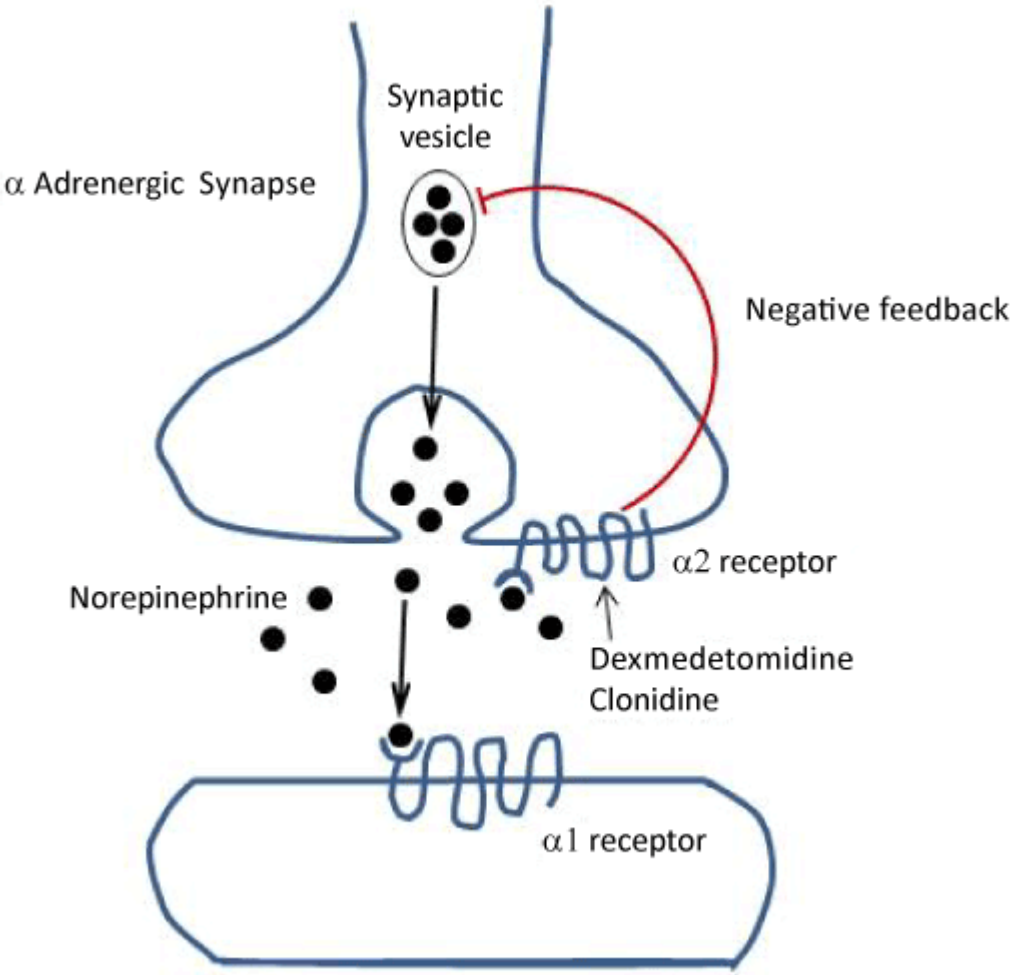
It is highly selective alpha 2 agonist which is about 8 times more potent than clonidine with affinity towards alpha 2 receptor 1600 times than alpha 1 receptor.Its effects are sedation,anxiolysis,analgesic and sympatholytic properties. These effects are achieved with minimum to no observed respiratory depressions at clincal doses.It produces a level of sedation that is characterized by a level of comfort and ease of arousability in patients.

Dexmedetomidine is aimidazole derivative which is a dextro-isomer of medetomidine.

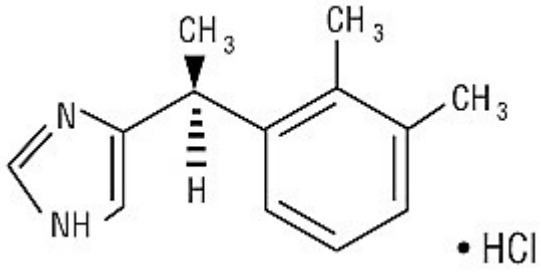
MOLECULAR STRUCTURE AND CHEMISTRY:

It is chemically as (+)-4-(S)-[(2,3-dimethyphenyl)ethyl]-11 H-imidazole monohydrochloride.Its molecular weight is 236.7.Emperical formula is $C_{13}H_{16}N_2HCl$.

MECHANISM OF ACTION OF DEXMEDITOMIDINE



STRUCTURAL FORMULA:



ROUTES OF ADMINISTERATION:

Most commonly by Intravenous route.

Other routes are oral, sub-lingual,intranasal and even intramuscular in uncooperative children and adult patients.

It can be used as an adjuvant in locoregional techniques given via both as peripheral nerve blocks and neuraxial(intrathecal,epidural and caudal)administration.

DOSAGE:

Loading dose:1 mcg/kg IV over 10 min

Maintenance dose 0.2 0.7 mcg /kg/hr IV for a period not exceed 24 hours

MECHANISM OF ACTION:

Dexmedetomidine is highly selective alpha -2 agonist. G protein transmembrane alpha -2 receptors are distributed through out the body topresynaptic.postsynaptic and extrasynaptic sites of activity but many effects of dexmedetomidine are caused by interactions with alpha- 2 receptors located within the brain and spinal cord.Within CNS alpha- 2 receptors are primarily located within pons and medulla of brainstem and are largely responsible for the transmission of soympathetic activity to the peripheral nervous system.Presynaptic alpha- 2 agonism by dexmedetomidine in these areas leads to decreased norepinephrine efflux to the autonomic nervous system wheras postsynaptic alpha- 2 receptors causes hyperpolarisation of neuronal membrane.

Dexmedetomidine also exerts effects at both spinal and supraspinal sites of action to modulate nociceptive input and transmision and thus provide analgesia whereas in the periphery alpha -2 receptors in vascular smooth muscle help to mediate vasoconstriction with more abundant alpha- 1 receptors.

PHARMACOKINETICS:

Dexmedetomidine exhibits linear or zero-order kinetics following intravenous administration. It is a lipophilic molecule that is highly bound to plasma proteins 94% and the protein binding remains constant despite varied concentration of the drug.dose reduction should be done in patients with liver disease.Pharmacokinetic profile is not altered by age. It has high volume of distribution of 118 litres. It has a distribution half life of about 6 min and show linear pharmacokinetics over a24- hour period in patients with normal hepatic and renal function.context sensitive half life of about 4 minutes after a 10 minute bolus to more than 250 minutes after an 8 hour continuous infusion.Elimination half-life of approximately 2 hours.

Metabolism:

1. Direct N_glucoronidation to inactive metabolites
2. Aliphatic hydroxylation mediated by CYP2A6 to generate

   3-hydroxydexmedetomidine and

   3-carboxy-dexmedetomidine.
3. N - methylation to generate

   3-hydroxy-N_methyldexmedetomidine

   3-carboxy-N-methyldexmedetomidine and

   Dexmedetomidine-N-nethyl - O-glucoronide.

PHARMACODYNAMICS:

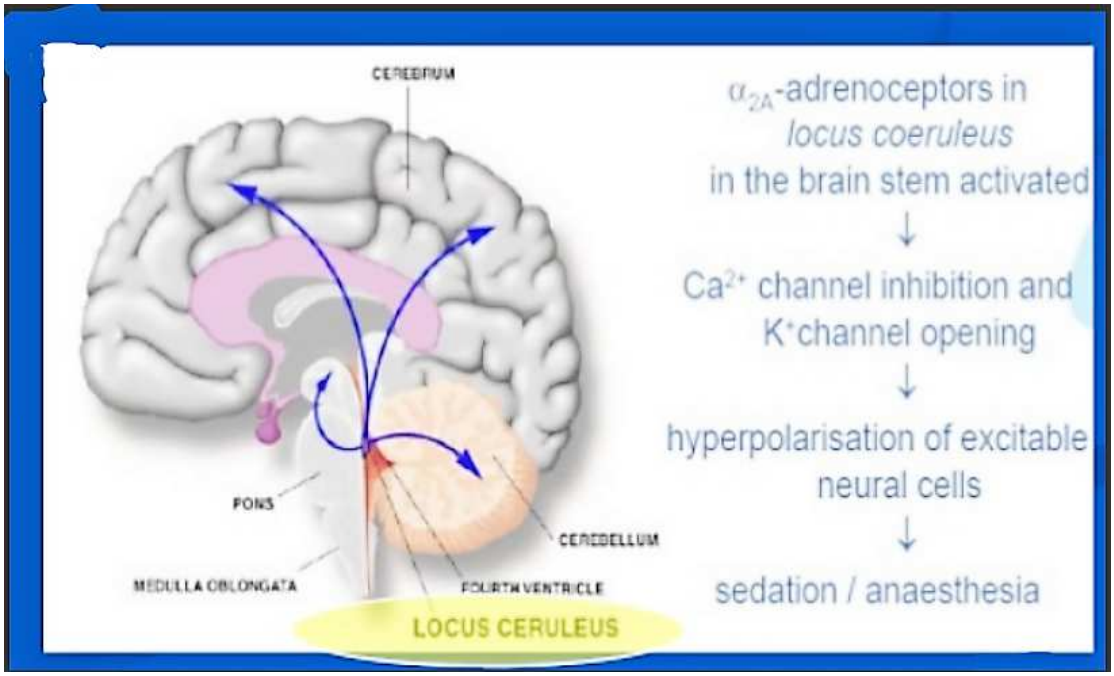
Dexmedetomidine is highly alpha -2 selective. It’s selectivity is dose dependent that higher level of selectivity if from lower to medium doses and on slower infusions.

HEMODYNAMIC EFFECTS:

Dexmedetomidine does not have direct effects on heart. Dose dependent biphasic cardiovascular response has been noted after the initial administration of dexmedetomidine.mechanism behind this response is stimulation of peripheral alpha -2b receptors in the vascular smooth muscles.

This sudden increase in blood pressure is minimized by slow infusion of the drug. This initial rise in arterial pressure lasts for only 5 to 10 minutes and is followed by fall in blood pressure from the baseline because of reduced central sympathetic outflow.

MECHANISM OF SEDATION AND ANAESTHESIA BY DEXMEDETOMIDINE



Another reason for the reduction in BP is the stimulation of presynaptic alpha -2 receptors results in reduction of norepinephrine release and hence the sympatholytic effects(reduction of HR & BP).Administration of dexmedetomidine results in bradycardia and hypotension.Adverse effects is reversed by Atropine,ephedrine or intravenous fluid administrations.

CENTRAL NERVOUS SYSTEM EFFECTS:

Sedation

Anxiolysis

Analgesia

Amnesia

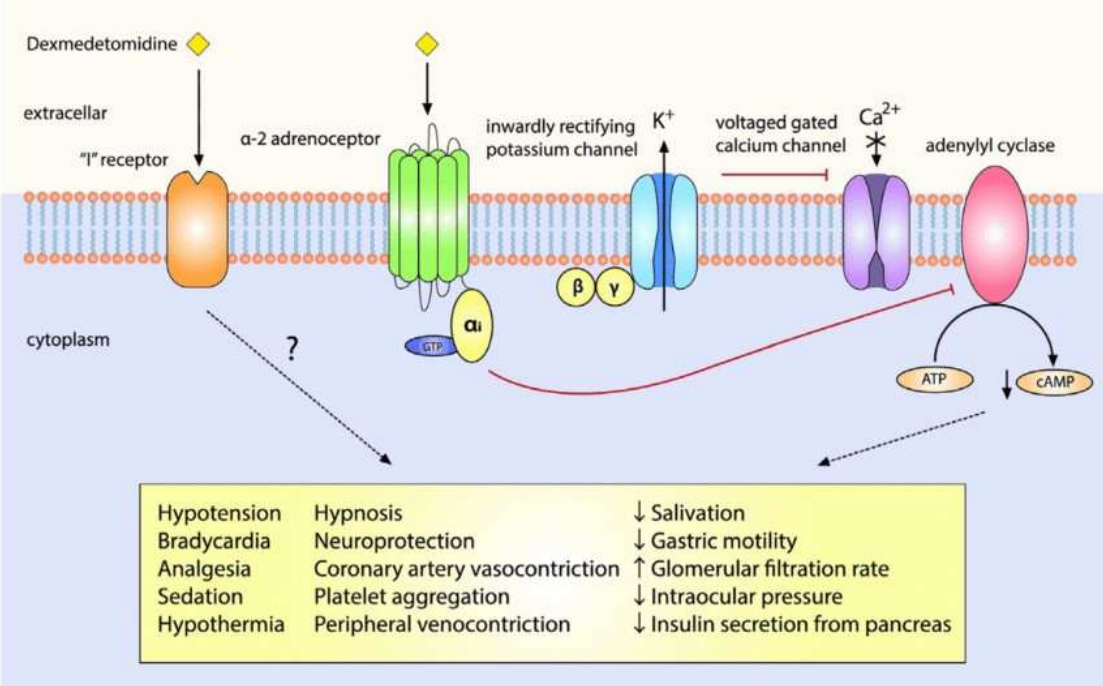
Hypnosis

The above effects are dose dependent.

SEDATION:

Arousability is well maintained even at deeper level of sedation with good correlation between level of sedation and bispectral EEG. This drug activates endogenous non-rapid eye movement pathway and thus sedation caused by the sedtion caused by the drug resembles normal sleep and the patients can be aroused easily. This differentiates dexmedetomidine between other drugs which is acting on other GABA system .Low dose of this drug produces sedation.

EFFECTS OF DEXMEDETOMIDINE



ANALGESIA:

It produces analgesia by acting on spinal and supraspinal levels. It significantly reduces opioid consumption. The mechanismis by the release of encephalin and inhibits the conduction of nerve signals through C and Aδ fibers.

RESPIRATORY EFFECTS:

Dexmedetomidine has less respiratory depression property unlike opioids.This property is used in sedation for awake fibroptic intubation and in difficult airway conditions. It preserves hyperbaric response and also reduces apnea threshold.It also reduces salivation and secretion.

ADVERSE EFFECTS:

Bradycardia and Hypotension:

These side effects are both dose dependent and multifactorial because they are mediated through both central and peripheral mechanism but not from the result of direct myocardial depressant actions.Dexmedetomidine at lower dose leads to decreased central sympathetic outflow by reducing the release of norepinephrine and causing a functional sympatholysis.

Atipamezole is a nonselective alpha - 2 adrenoceptor antagonist.It rapidly reverse the sedation and analgesia induced by dexmedetomidine.

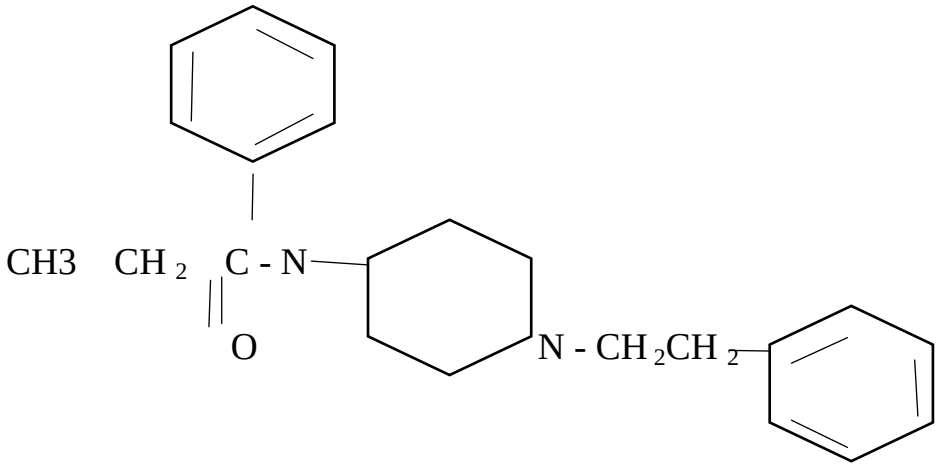
CONTRAINDICATIONS:

This drug is avoided in patients with heart blocks and bradyarrhythmias. In addition, given its vasodilatory effects use of dexmeditomidine is avoided in patients with significant cardiac valvular stenotic lesions or in clinical settings characterized by extreme hypovolemia.

PHARMACOLGY OF FENTANYL CITRATE

Fentanyl citrate is synthetic opioid agonist. It is 75 to 125 times more potent than morphine as an analgesic. It is phenylpiperidine derivative.Fentanyl is a μ-opioid receptor agonist, produces dose-dependent analgesia, ventilatory depression, and sedation, and at very high doses it can produce unconsciousness.

STRUCTURAL FORMULA:



MECHANISM OF ACTION:

Opioids act as agonists at specific opioid receptors at presynaptic and postsynaptic sites in the central nervous system (mainly the brainstem and spinal cord) as well as in the periphery. These opioid receptors normally are activated by three endogenous peptide opioid receptor ligands known as enkephalins, endorphins, and dynorphins.

1. The principal effect of opioid receptor activation is a decrease in neurotransmission that occurs largely by presynaptic inhibition of neurotransmitter release (acetylcholine, , norepinephrine, substance P ,dopamine ,).

2. The intracellular biochemical events initiated by opioid receptors with an opioid agonist are characterized by increased potassium conductance , calcium channel inactivation, or both, which produce an immediate decrease in neurotransmitter release.

PHARMACOKINETICS:

It is highly lipid soluble drug and rapid onset of action and short duration of action. Its short duration of action reflects rapid redistribution to inactive tissues such as fat and skeletal muscles.

METABOLISM:

Fentanyl is extensively metabolized by N-demethylation and the pharmacologic activity of fentanyl metabolites is believed to be minimal.

ELIMINATION HALF LIFE:

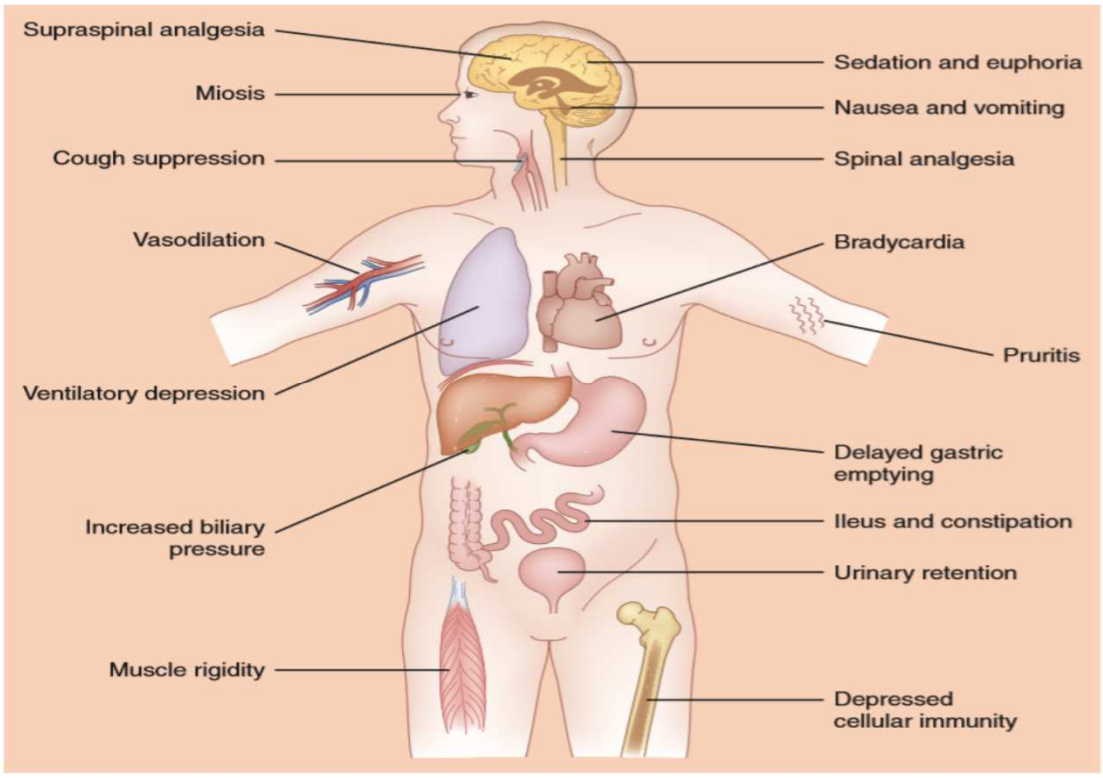
Despite fentanyl has a short duration of action, its elimination half-time is longer than that for morphine . This longer elimination half-time reflects a larger volume of distribution (Vd) of fentanyl due to its greater lipid solubility and thus more rapid passage into highly vascular tissues compared with the less lipid-soluble morphine more than 80% of injected dose leaves the plasma in 5 min.

EFFECTS:

High doses of fentanyl s blunt the “stress response”—hemodynamic and hormonal responses to the surgical stimuli—producing only minimal cardiovascular depression.

Opioids does not produce muscle relaxation, at high-dose fentanyl may produce muscle rigidity, muscle relaxant is required to achieve adequate surgical conditions. This may increase the difficulty in finding signs of intra -operative awareness.

EFFECTS OF FENTANYL



Clinical Uses :

Analgesia (1–2 mcg/kg IV)

Adjuvant to inhaled anesthetics to blunt the response to direct laryngoscopy (2–20 mcg/kg IV).

Decrease doses of inhaled anesthetics to blunt sympathetic nervous system responses to surgical stimulation (1.5–3 mcg/kg IV, 5 min before induction of anesthesia)

Produce surgical anesthesia (50–150mcg/kg IV)

Analgesia for early labor (25mcg intrathecal)

Postoperative analgesia (transdermal patch)

SIDE EFFECTS:

Cardiovascular Effects.:

Fentanyl, even in large doses (50mcg/kg IV), do not release of histamine. Bradycardia is more with fentanyl than morphine and it decreases the blood pressure and cardiac output.

Seizure Activity: In the absence of EEG evidence of seizure activity, it is difficult to distinguish opioid-induced skeletal muscle rigidity or myoclonus from seizure activity.

Respiratory effects:

Respiratory depressants action.Magnitude of respiratory depression can be increased while fentanyl is given in combination with other respiratory depressant such as midazolam.

Fentanyl-induced pruritus presents as facial itching ,but it is generalized.

Fentanyl has also reported to have a tussive effect. Patients may be coughed within 1 minute after receiving a bolus dose of fentanyl (1.5 µg/kg). This is unclear mechanism and it is not attenuated by pretreatment with midazolam or atropine.

DRUG INTERACTIONS:

Analgesic concentrations of fentanyl greatly potentiate the effects of benzodiazepines (marked synergism with respect to hypnosis and depression of ventilation).

In clinical practice, the advantage of synergy between opioids and benzodiazepines for the maintenance of patient comfort is carefully weighed against the disadvantages of the potentially adverse depressant effects of this combination.

REVIEW OF LITERATURE

Tsai CJ et al.,[9] did a double blind ,randomised, prosective clinical study to evaluate the clinical efficacy and safety of dexmedetomidine as premedication with propofol infusion for fibroptic intubation.46 adult patient with temporomandibular joint ankylosis planned for gap arthroplasty was choosen.they were divided into two groups .

Group D &Group P of 23 patients each.Group D patients received premedication dexmedetomidine 1mcg/kg infused over 10 min followed by sedative propfol infusion.the control Group P eceived only propofol infusion for sedation.

They observed that dexmedetomidine with propofol group provided satisfactory intubating conditions than propofol alone.Dexmedetomidine appeare to provide preservation of patent airway better intubating conditions and hemodynamic stability with less adverse effects.

Guler et al .,[28]did a randomisd double blinded study using single bolus of dexmedetomidine to attenuate the airway and circulatory responses of tracheal extubation.

They selected sixty patients randomly divided into 2 groups, of 30 each.First group they gave 0.5mcg/kg dexmedetomidine and saline in the second group 5 min before the end of the surgery over 60 seconds.

Monitoring by the number of cough per patient after extubation.They cocluded that dexmedetomidine group had median cough score less and rise in heart rate blood pressure was comparitively less than placebo group.single dose of dexmedetomidine of 0.5 mcg/kg dexmedetomidine attenuate the hemodynamic response of extubation.

Kenya et al [29]done a controlled study they divided the patients of 60 randomly into two groups of which first group was given dexmedetomidine 1mcg/kg and the second control group was given saline over 10 minutes before induction.Induction was done with thiopentone sodium and intubated using muscle relaxant vecuronium.

They observed that the induction thiopentone dose requirementwas30% less in the dexmeditomidine group compared to the control group.In both groups heart rate,systolic BP,diastolic BP were increased from baseline but the increase was 7%,8%,11% in dexmedetomidine group and 21% ,40%,25% in control group respectively.

The requirement of Inj.Fentanyl was 33% more in control group. They concluded that dexmedetomidine reduces the hemodynamic response of intubation and intra operative anesthetic requirements.

AHO M et al studied the effect of dexmedetomidine on perioperative hemodynamics and isoflurane requirements.They divided 96 patients into 4 groups gave dexmedetomidine 0.6 mcg/kg,0.3 mcg/kg,Fentanyl 2 mcg/kg or saline 10 minutes before induction respectively.

Intubated with succinylcholine and maintained with vecuronium, isoflurane,N_2O.They observed that sedative effect was higher in 0.6 mcg/kg dexmedetomidine group.

They also found that rise in heart rate blood pressure after intubation was comparatively less in 0.6mcg/kg Dexmedetomidine group and requirement of isoflurane was 25% less than saline and fentanyl group.

There is no differances in blood preesure changes between dexmedetomidine and fentanyl group.There was not much difference between 0.3mcg/kg dexmedetomidine group and saline group.

Menda F et al.,[26] dtudied that effect of dexmedetomidine in attenuating hemodynamic responses in endotracheal intubation for patients coming for fast - track coronory artery bypass grafting.

They divided 30 patients into 2 groups one with dexmedetomodine that is compared with placebo. Dexmedetomidine group was given with 1 mcg/kg in 100ml of normal saline over 15 min.and placebo group was given with 100ml of normal saline over 15 min.

They have measured systolic blood pressure,diastolic blood pressure, mean arterial pressure and heart rate at time intervals of 1,3,5 min. After the intubation. All the above mentioned parameters that has been measured for the patients with dexmedetomidine was significantly lowered than the placebo group in reducing hemodynamic response to intubation.

Ryu et al [21]studied by comparing sedative dexmedetomidine and remifentanyl for intubation through fibroptic bronchoscopy.They found that there was no significant difference in sedative effects MAP, heart rate between these two drugs.but patient satisfication score ,desaturation and cough score is significantly lower in dexmedetomidine than remifentanyl.

Chu et al.,[10] observed that dexmedetomidine along with topical anaesthesia provides better intubation conditions,amnesia,patient tolerence, hemodynamic response for Awake fibroptic intubation.they also stated that dexmedetomidine can be effectively used durig AFOI for difficult airway situations with only minimal hemodynamic effects.

Sulaiman s et al.,[25] studied the effectiveness of dexmedetomidine compared with placebo in attenuating the stress response to the endotracheal intubation for patients undergoing off pump CABG. They observed that dexmedetomidine pretreatment with the dose of 0.5mcg/kg as 10 min infusion prior to induction is effectivein attenuating the hemodynamic responsefor laryngoscopy and intubation

Bergese et al. found that dexmedetomidine in combination with low dose midazolam is effective than midazolam alone for sedation in AFOI.Dexmedetomidine dose in excess of 1 mcg/kg/h with midazolam produced airway obstruction, which was managed by simple chin lift.

MATERIALS AND METHODS

Sixty patients of ASA physical status 1 or 2 for elective surgical procedures being done under general anaesthesia with endotracheal tube was taken into account for my study.

Patients under age groups between 25 to 60 years of both sexes were taken for the prospective,randomised,double blinded study by comparing dexmedetomidine and fentanyl for intubation using fibroptic bronchoscopic technique.This study was approved by our ethical committee in our institution and informed consent was obtained from the patients and then the study was conducted.

INCLUSION CRITERIA:

ASA 1 & 2 Patients.

Age :25 to 60 years

Surgery : Elective

Mallampatti I and II

Who have given valid informed consent.

EXCLUSION CRITERIA:

Not satisfying inclusion criteria

Emergency surgery

Lack of written informed consent

Patient with difficult airway

Pregnant female

Allergic to drugs used

Poor lung compliance

Full stomach patients

Coagulopathies

Bradycardia <60/min

Patients with severe cardiovascular,respiratory,renal and hepatic diseases.

MATERIALS REQUIRED:

18 G venflon

Drugs:

Inj.Glycopyrrolate ,Inj,Fentanyl,Inj.Dexmedetomidine,Inj,Atropine, Inj.Epidrene ,Emergency drugs kept ready,and normal saline.

2% ,4% ,lignocaine

10% lignocaine spray

Nebulizer

Xylometazoline nasal drops

Fibroptic brochoscope,Endotracheal tubes

Monitors:ECG ,NIBP,SPO_2,$ETCO_2$.

METHODOLOGY:

All patients who satisfy the inclusion criteria should do the pre operative assessment.they were done investigations such as complete hemogram,rrandom blood sugar,blood grouping and cross matching,serum urea and creatinine,ECG,chest X-rayPA view,.the eligible patients were randomised under closed envelope method and were informed about the procedure and got written and informed consent .Age,weight aand height was noted.All patients was premedicated with tab.Alprazolam in the previous night.

Inj.Glycopyrrolate 0.2 mg I.M. given 45 min before intubation.Patient was shifted to the operating theatre.all monitors such as ECG,NIBP,SPO_2 connected and Baseline was noted.I.V access was obtained with 18G venflon.4% lignocaine 4 ml was used for nebulizing the upper and lower airway.10% Lignocaine oral spray.xylometazoline nasal drops was instilled.

Group A patients: Inj Dexmedetomidine hydrochloride 1 mcg / kg infused over 10 min

Group B patients:Inj Fentanyl citrate 2 mcg/kg infused over 10 min.

Sedation score is Ramsay seadtion score.After achieving the ramsay sedation score more than 2, flexible fibroptic bronchoscopy guided tracheal intubation with appropriate sized endotracheal tubes were done.Intubation conditions was evaluated by cough score and Post intubation score.

Hemodynamic parameters such as Heart rate,mean arterial blood pressure,spo_2 were measured at baseline and at intervals of 5,10,intubation and post-intubation 5 min. were also noted.Surgery proceeded with maintenance of anaesthesia.

Adverse affects were noted and treated as follows:

Bradycardia with Inj.Atropine 0.6 mg I.v.

Hypotension with IV fluids and Inj.Ephedrine 6 mg I.v bolus.

Desaturation managed by connecting oxygen cannula through side port of FOB.

SCORES:

RAMSAY SEDATION SCORE:

Level of sedation is assessed by Ramsay sedation score. 1 = Anxious, agitated or restless, 2 = cooperative, oriented and tranquil, 3 = sedated but responds to command, 4 = asleep, brisk glabellar reflex responds to loud noise, 5 = asleep, sluggish glabellar reflex or responds to loud noise, 6 = asleep with no response to a painful stimulus.

COUGH SCORE:

Intubation condition was evaluated by cough score during bronchoscopy .1 = no cough, 2 = slight cough (no more than two cough in sequence), 3 = moderate cough (3-5 cough in sequence), 4 = severe cough (>5 cough in sequence).

POST-INTUBATION SCORE:

Tolerance to intubation was evaluated by post-intubation score after placement of tube in the trachea.

1 = Co-operative, 2 = minimal resistance, 3 = severe resistance

OBSERVATION AND RESULTS

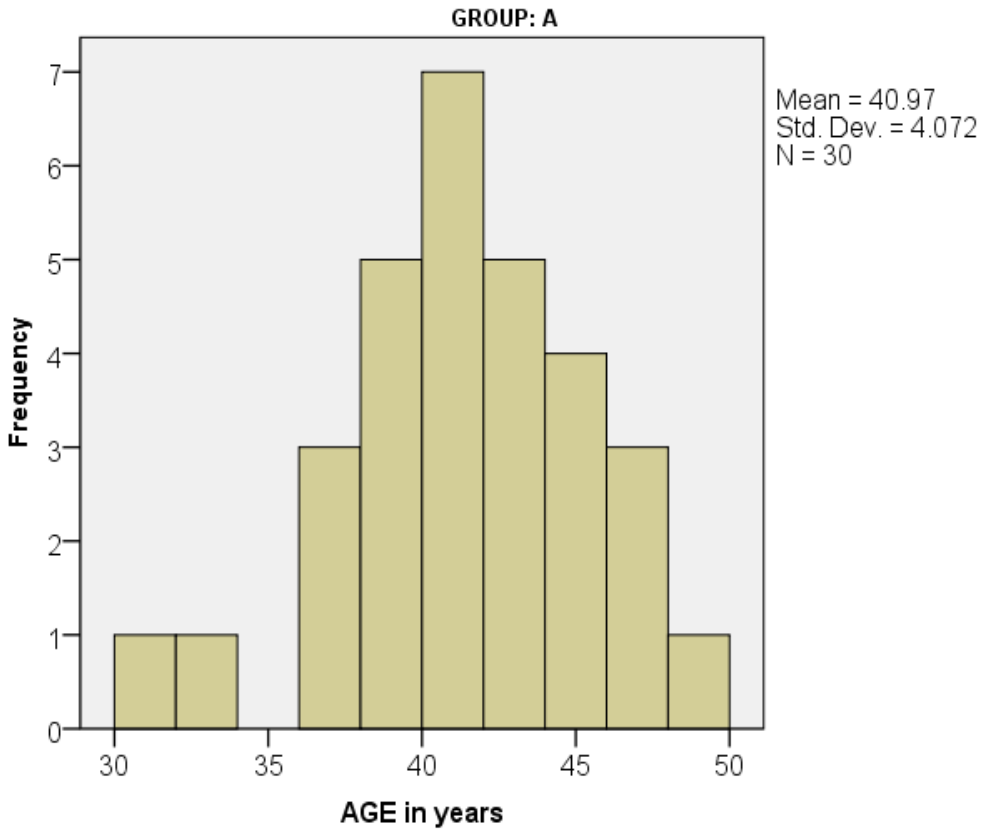
OBSERVATION AND RESULTS

TABLE: AGE DIFFERENCE BETWEEN TWO GROUPS

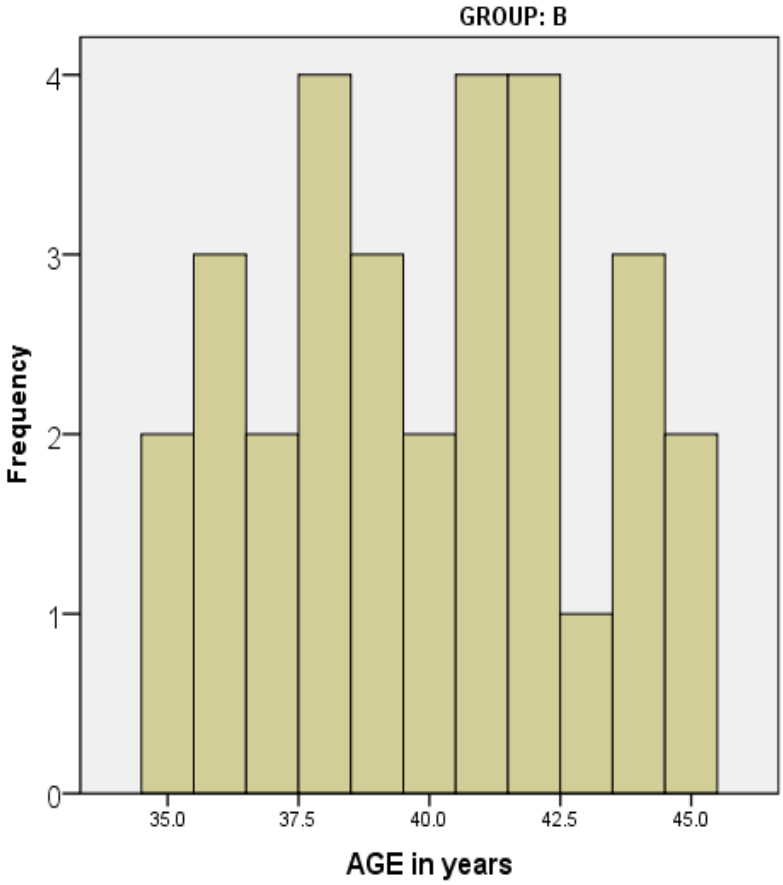
AGE	GROUP A	GROUP B
TOTAL	30	30
MEAN	40.97	39.93
STANDARD DEVIATION	4.07	3.00
P value by ‘t’test		0.268

Age distribution of these patients in the two groups in the above table showed that 40.97 ± 4.07 and 39.93 ± 3 in years is the mean age group of the Group A and Group B respectively. This showed that there was no significant statistical difference occurred between Group A and Group B in age distribution according to the p value of 0.268.

Graph:Age distribution in Group A



Graph:Age distribution in Group B



WEIGHT DISTRIBUTION BETWEEN TWO GROUPS

WEIGHT	GROUP A	GROUP B
TOTAL	30	30
MEAN	60.3	60
STD.DEVIATION	3.385	2.761
P value by ‘t’ test	0.668	

Weight distribution of the patients in both groups in the above table shows that 60.3 ± 3.385 and 60 ± 2.761 is the mean weight of Group A and Group B respectively.It showed that there was no significant statistical difference between Group A and Group B in weight distribution according to p value of 0.668

TABLE :ASA STATUS BETWEEN TWO GROUPS

GROUP	ASAPS		Total	Fisher exact p value
	1	2		
A	26 (86.66%)	4 (13.33%)	30 (100%)	0.238
B	28 (93.33%)	2 (6.66%)	30 (100%)	
Total	54 (90%)	6 (10%)	60 (100%)	

The ASA status of the two groups are as follows,Group A has 26 patients under ASA I (86.6%) and Group B has 28 patients under ASA I (93.33%).Group A has 4 patients under ASA II (13.3%) and Group B has 2 under ASA II (6.66%).There was no significant statistical difference between these groups given by fisher p value of 0.238.

GRAPH : ASA STATUS BETWEEN TWO GROUPS

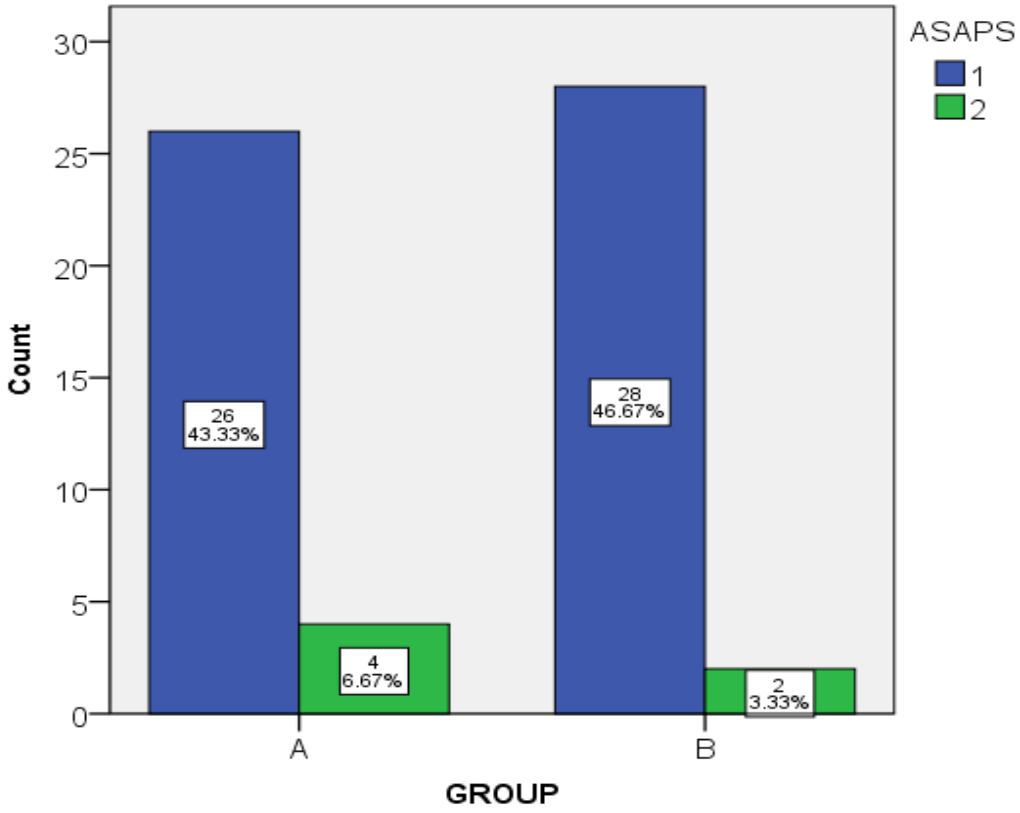


TABLE : INTER GROUP COMPARISON FOR HEART RATE

BETWEEN GROUP A AND GROUP B

HR	GROUP	N	MEAN	STD. DEVIATION	p VALUE BY 't' TEST
Baseline	A	30	80.03	5.81	0.942
	B	30	80.13	4.74	
5 min	A	30	76.73	5.51	0.184
	B	30	78.57	5.04	
10 min	A	30	73.63	5.99	0.025*
	B	30	76.93	5.11	
Intubation	A	30	76.37	8.11	< 0.001*
	B	30	102.30	4.21	
5 min post intubation	A	30	75.03	7.94	< 0.001*
	B	30	99.37	4.02	

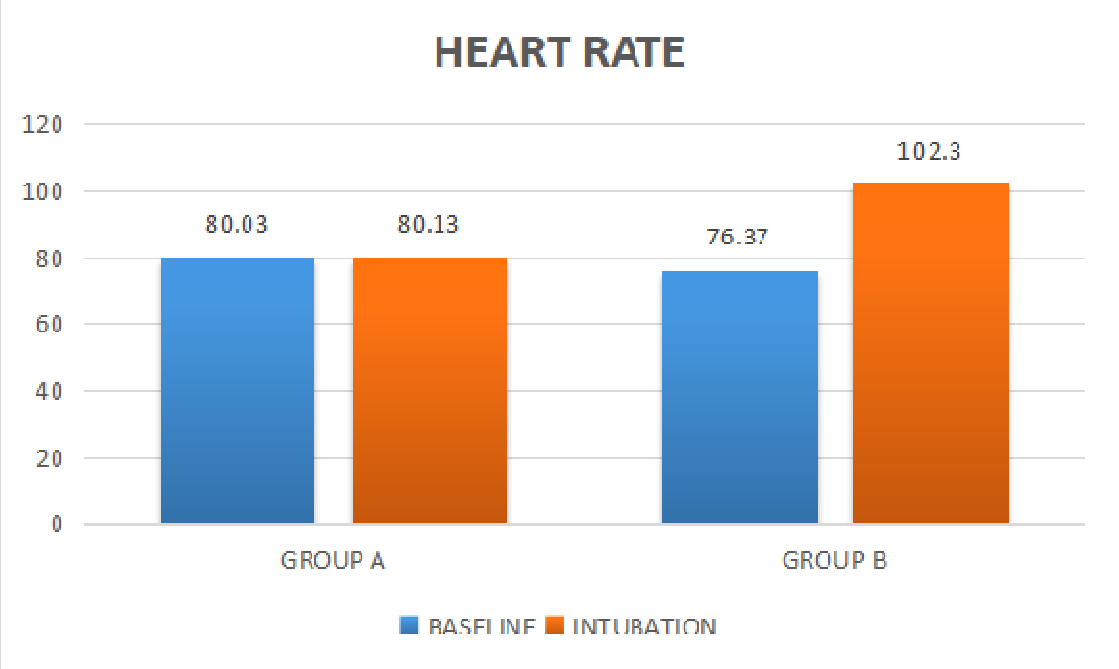
In Group A, the basal mean heart rate was 80.03 ±5.81 bpm. The mean heart rate after 5min 10 min after administration of study drug in 5 min ,10,intubation,post intubation 5 min are 76.73 ±5.51,73.63 ±5.99,76.37 ±8.11and 75.03 ± 7.94 respectively.

In Group B, the basal mean heart rate was 80.13 ±4.74 bpm. The mean heart rate after 5min,10min after administretion of study drug in 5 min,10min,intubation,post inbution are 78.57±5.04,76.93 ±5.11,103.30 ±4.21 and 99.37 ±4.02 respectively.

There is no statistical difference in the mean heart rate of base line,5 min and 10 min between Group A and Group B. There was significant statistical difference in the mean heart rate at intubation and post intubation p value less than 0.05.

GRAPH : INTER GROUP COMPARISON FOR HEAR RATE

BETWEEN GROUP AAND GROUP B



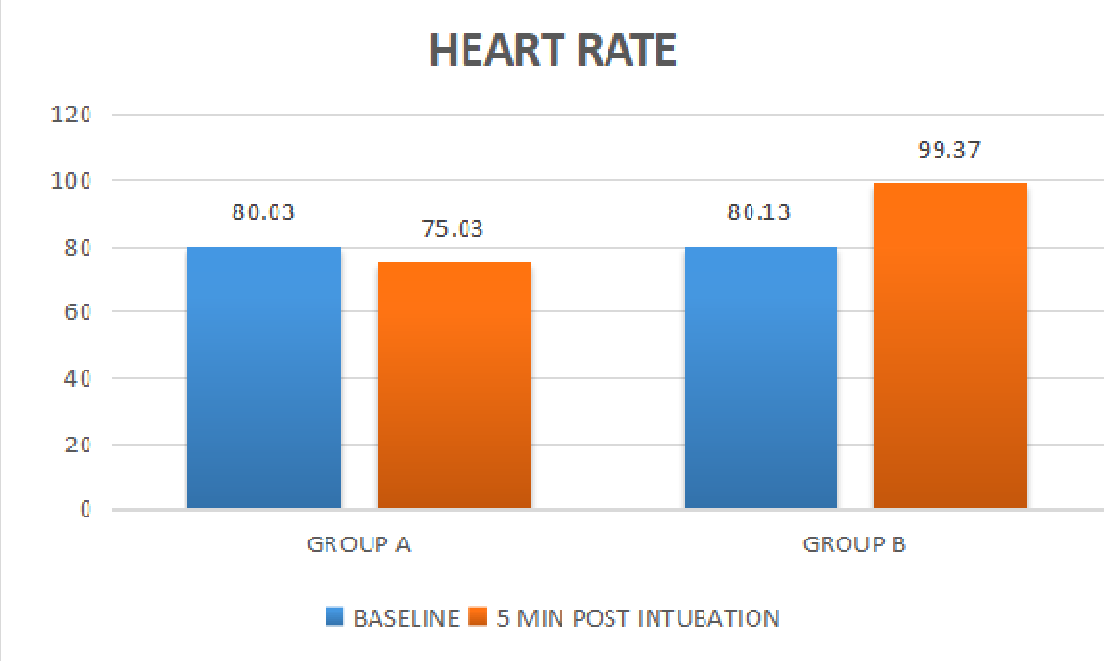


TABLE: INTER GROUP COMPARISON FOR MAP BETWEEN GROUP A AND GROUP B

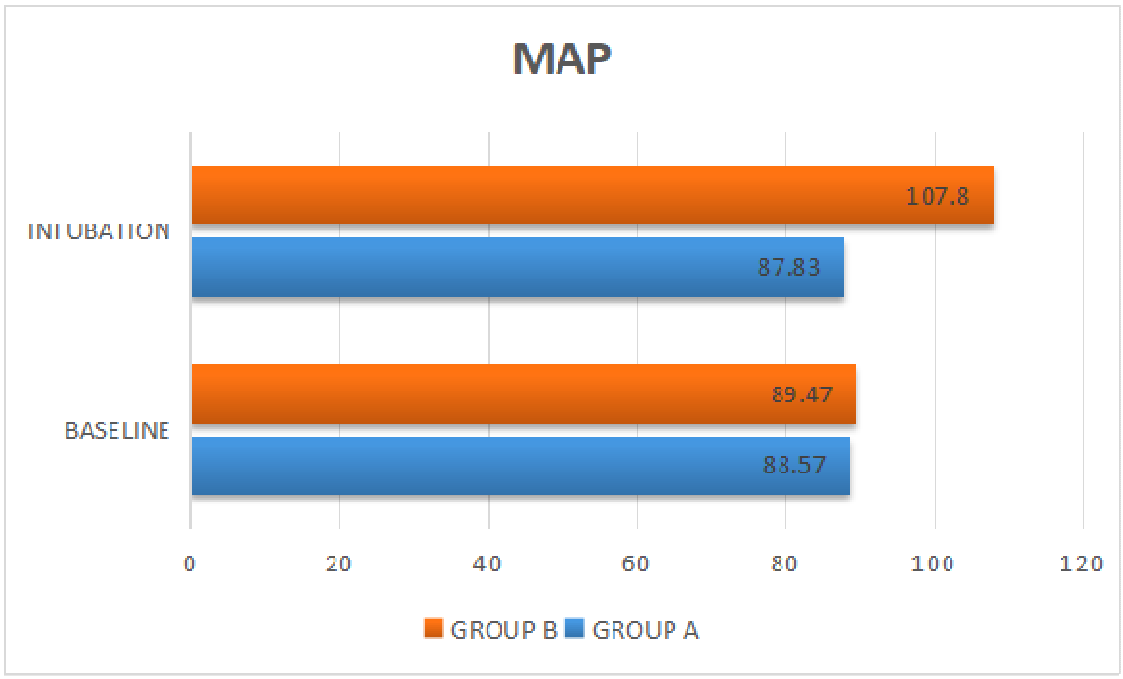
MAP	GROUP	N	MEAN	STD. DEVIATION	p VALUE BY 't' TEST
Baseline	A	30	88.57	2.69	0.269
	B	30	89.47	3.51	
5 min	A	30	86.80	2.33	0.470
	B	30	87.37	3.58	
10 min	A	30	85.77	2.56	0.869
	B	30	85.63	3.58	
Intubation	A	30	87.83	5.73	< 0.001*
	B	30	107.80	2.59	
5 min post intubation	A	30	87.30	4.94	< 0.001*
	B	30	105.00	2.52	

In Group A, basal mean MAP was 88.57 ±2.69 mmHg.The mean MAP after 5min 10 min after administration of study drug in 5 min ,10,intubation,post intubation 5 min are 86.80±2.33,85.77 ±2.56,87.83 ±5.73 and 87.30 ± 2.52mmHg respectively.

In Group B, basal mean MAP was 80.13 ±4.74 mmHg.The mean heart rate after 5min,10min after administretion of study drug in 5 min,10min,intubation,post inbution are 87.37±3.58,85.63 ±3.58,107.80 ±2.59 and 105.00 ±2.52 mmHg respectively.

There is no statistical difference in the mean MAP of base line,5 min and 10 min between Group A and Group B. There was significantstatistical difference in the mean MAP at intubation and post intubation p value less than 0.05 by ‘t’ test.

GRAPH : INTERGROUP COMPARISON FOR MAP BETWEEN GROUP A AND GROUP B.



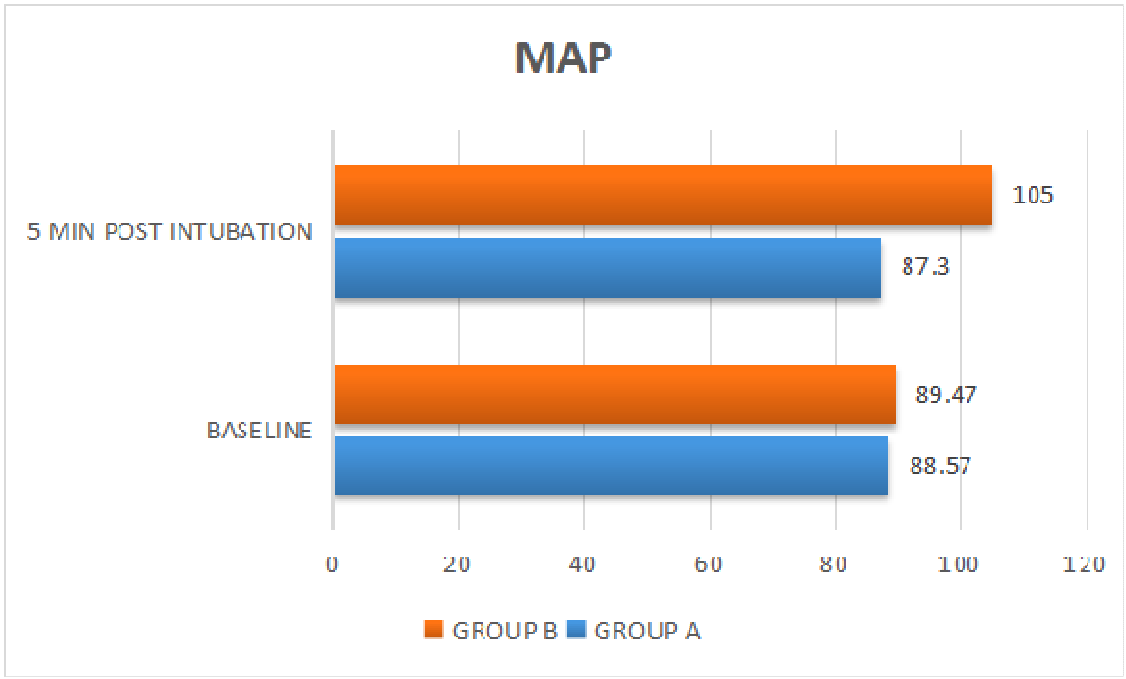


TABLE: INTERGROUP COMPARISON FOR SPO_2 BETWEEN GROUP A AND GROUP B

SPO2	GROUP	N	MEAN	STD. DEVIATION	p VALUE BY 't' TEST
Baseline	A	30	99.27	0.48	0.860
	B	30	99.00	0.20	
Intubation	A	30	97.10	1.77	< 0.001*
	B	30	93.43	1.17	

In Group A ,mean base line SPO_2 was 99.27 ± 0.48 % and In Group B mean base line SPO_2 was 99.00 ±0.20% .There was no statistical difference in SPO_2 in baseline between these groups and p value is > 0.05.The post intubation SPO_2 was 97.10 ±1.77 and 93.43± 1.17 % for Group A and Group B respectively with p value is <0.001.

GRAPH : INTER GROUP COMPARISON FOR SPO_2 GROUP A AND GROUP B

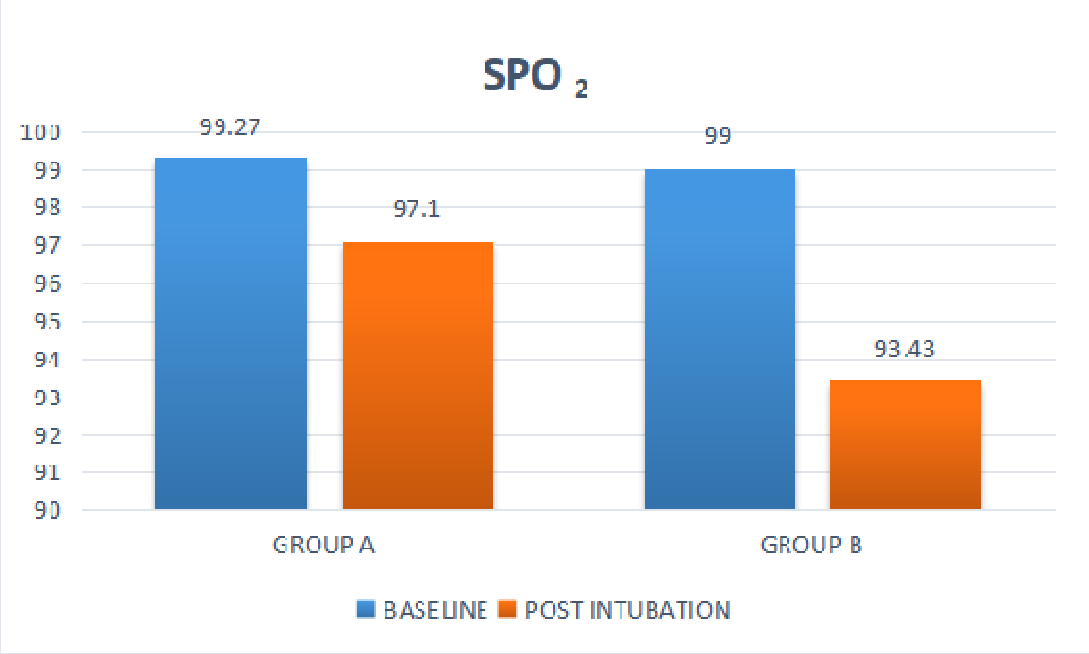
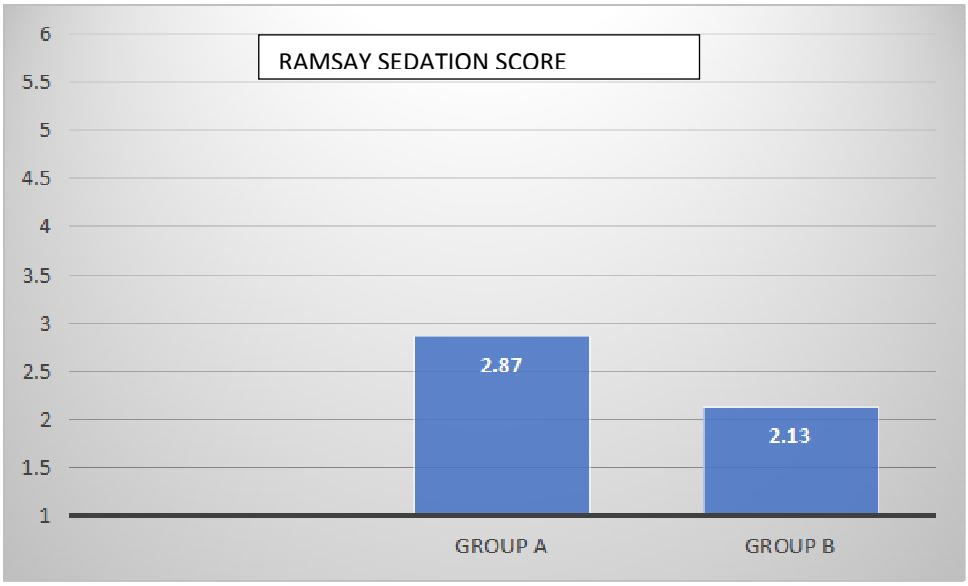


TABLE: COMPARISON OF SCORES FOR INTUBATION BETWEEN GROUP A AND GROUP B

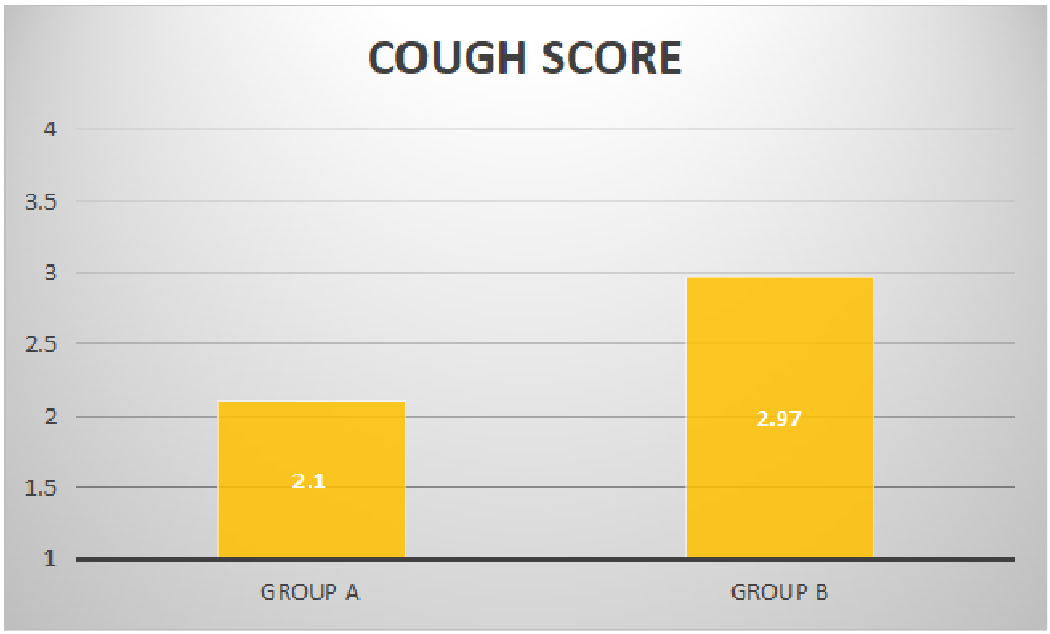
	GROUP	N	MEAN	STD. DEVIATION	p VALUE BY 't' TEST
RAMSAY SEDATION SCORE	A	30	2.87	0.43	< 0.001*
	B	30	2.13	0.35	
COUGH SCORE	A	30	2.10	0.40	< 0.001*
	B	30	2.97	0.41	
POST INTUBATION SCORE	A	30	1.27	0.45	< 0.001*
	B	30	1.90	0.31	

In Group A Ramsay sedation score mean 2.87± 0.43 and Group B the mean was 2.13 ±0.35 ther was significant statistical difference between these two groups by the p value <0.001.

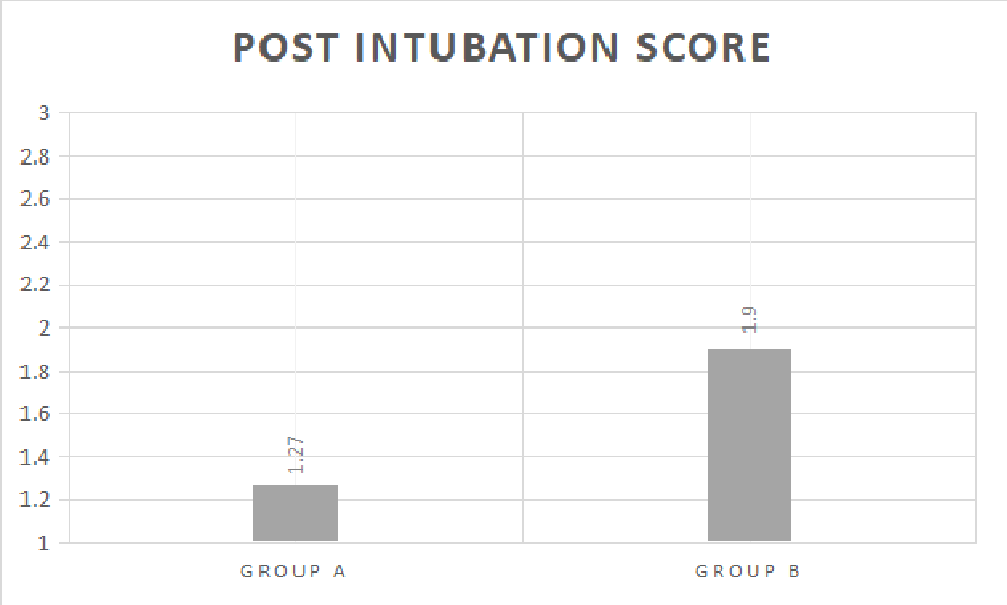
GRAPH - COMPARISON OF RAMSAY SEDATION SCORE BETWEEN GROUP A AND GROUP B

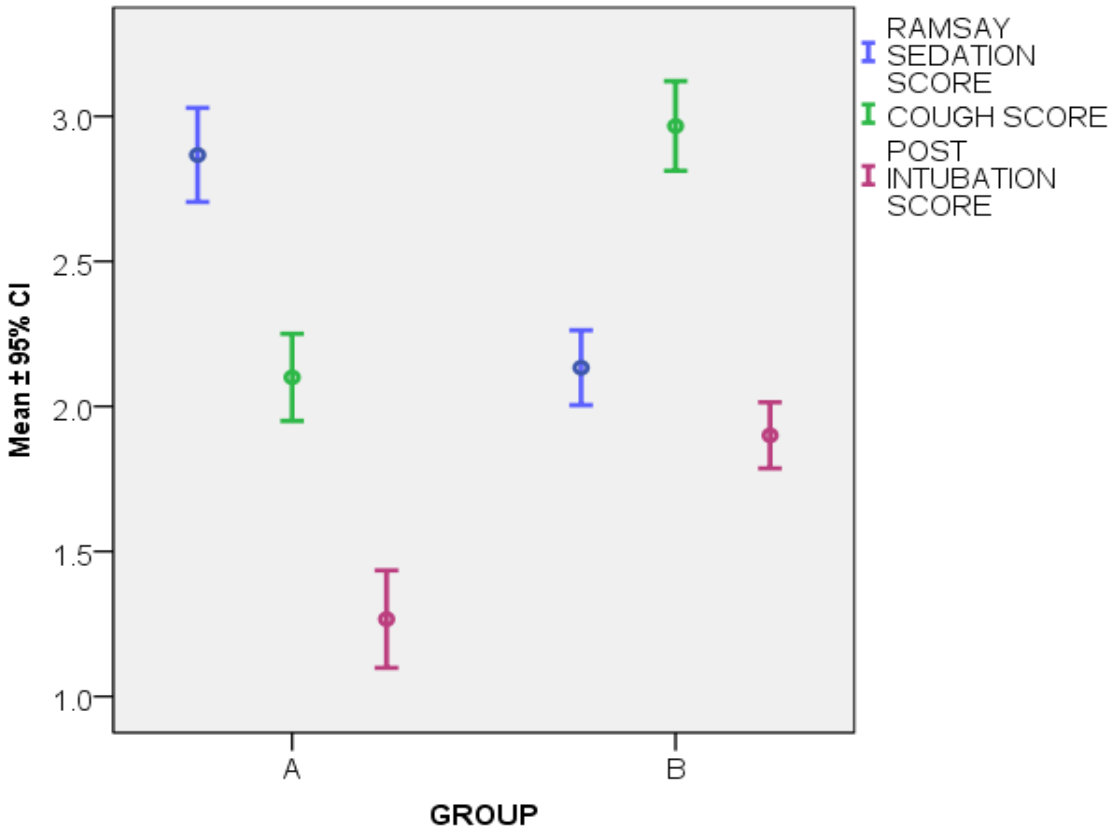


GRAPH - COMPARISION OF COUGH SCORE BETWEEN GROUP A AND GROUP B



GRAPH: COMPARISON OF POST INTUBATION SCORE BETWEEN GROUP A AND GROUP B




RAMSAY SEDATION SCORE
COUGH SCORE
POST INTUBATION SCORE
Mean ± 95% CI
3.0
2.5
2.0
1.5
1.0
A
B
GROUP

DISCUSSION

DISCUSSION

In case of difficult airway scenarios, awake intubation is essential Awake fibroptic bronchoscope guided intubation is one of the best method in securing airway in a case of difficult airway. For AFOI ,many drugs has been used for producing sedation while preserving spontaneous respiration.

Dexmedetomidine which is alpha - 2 agonist produces sedation, anaelgesia, adequate hemodynamic stability, amnesia, and anti-sialogue effects which are beneficial during AFOI. It produces sedation which resembles natural sleep but arousable through the post synaptic receptors in locus ceruleus with minimal respiratory depression action.

Fentanyl citrate is phenylpiperidine, which is synthetic opioids which produces sedation, hemodynamic stability, analgesia which are useful AFOI. But there is risk of respiratory depression ,chest wall rigidity, vomiting, nausea as their side effects.

We have compared dexmedetomidine and fentanyl for conscious sedation for awake fibroptic intubation.Group A was given with Dexmedetomidine 1 mcg/kg and Group B was given with Fentanyl 2 mcg/kg and parameters such as Ramsay sedation score,cough score,post

intubation score,SPO_2 ,Heart rate and Mean arterial pressure were measured and compared.Sampling size 60 each group had 30 patients each.

We observed that post intubation score in Group A (out of 30 patients) 22 patients has better tolerance endotracheal tube than Group B (out of 30 patients) 5 patients with p value <0.01.

Majority of the patients in Group A (27 out of 30) were having cough score <2 and in Group B (4 out of 30) patients were having cough score<2 with p value <0.001.

Penden et al., found that that bradycardia was observed in the patients of healthy volunteers following dexmedetomidine administration and that can be prevented by administration of glycopyrrolate before intubation thereby preventing the side effects of dexmedetomidine.

Bergese et al found that dexmedetomidine when administered at dose of 1 mcg/kg was beneficial for intubation through bronchoscope even without topical anaesthesia or airway nerve block.

In our study ,comparison of heart rate and mean arterial pressure were compared between the two groups.We observed that dexmedetomidine group had better hemodynamic stability than fentanyl

group.The baseline heart rate and mean arterial pressure was no significant difference in both the groups. There was a statistical significant in Heart rate in post intubation when compared with the base line in Group B p value <0.001.There is no change in the heart rate in the group A in the post intubation period when compared with the baseline with p value <0.001.

Dexmedetomidine results in stable hemodynamic parameters because of its inhibition of noradrenline thereby reducing the sympathetic response to intubation.Dexmedetomidine infusion can cause bradycardia, hypotension ,atrial fibrillation and hypertension particularly in high doses.However in our study there was no incidence of bradycardia because of glycopyrrolate administration.

Side effects:

Fentanyl has a respiratory depressent action and also chest wall rigidity effects which can leads to desaturation and hypoxia that can be treated with insufflation of oxygen through the side port in the bronchoscope.

But in case of dexmedetomidine it results in sedation without respiratory depression and airway obstruction. In our study the incidence of desaturation was observed less in Group B than Group A patients of p value <0.001.

SUMMARY

SUMMARY

This study is a randomized ,prospective ,double blind study were designed to compare the effects of Dexmedetomidine and Fentanyl for favorable intubating conditions ,stable hemodynamics and adequate conscious sedation for Awake flexible fibroptic bronchoscopic intubations.

A total number of 60 patients belonging to ASA I and II were chosen randomly.They were divided into two groups.Group A was received Dexmedetomidine of dose 1 mcg/kg infusions for 10 min and Groups B was received Fentanyl of dose 2 mcg/kg infusions for 10 min.

The following observations were:

1 . Patients in Group A shows a significant difference in better tolerance in endotracheal tube .

2. Patients in Group B showed a significant desaturation during fibroptic bronchoscope insertion.

3.Patients in Group A showed a significant hemodynamic stability

4.In our study we also observed that no patient had bradycardia and hypotension during the study.

CONCLUSION

CONCLUSION

From the above study it is concluded that dexmedetomidine provides favourable intubating conditions fibroptic bronchoscope guided intubation, had better hemodynamic conditions and provided adequate sedation than fentanyl without desaturation.

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BIBLIOGRAPHY

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ANNEXURE

PROFORMA

DATE:

NAME AGE: SEX

DIAGNOSIS:

IP NO:

SURGICAL PROCEDURE DONE:

Ht: Wt: BMI

PRE OP ASSESSMENT:

HISTORY: Any Co-morbid illness

H/O previoussurgeries

GENERAL EXAMINATION:

HR BP SpO2

METs

SYSTEMIC EXAMINATION

CVS:

RS:

AIRWAY EXAMINATION

MMS- DENTITION TMD IID

INVESTIGATIONS

ASA PS CLASSIFICATION:

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு

டெக்ஸ்மிடிடோமிடின் அல்லது பெண்டனில் மருந்து கொடுத்து ஃபைபர் ஆப்டிக் பிராக்கோஸ்கோப் மூலம் மூச்சுக்குழலில் குழல் பொருத்தி ஒப்பிடுதல்.

ஆராய்ச்சியாளர் பெயர் :

பங்கேற்பாளர் பெயர் :

ஆராய்ச்சியின் நோக்கம்

டெக்ஸ்மிடிடோமிடின் அல்லது பெண்டனில் மருந்து கொடுத்து ஃபைபர் ஆப்டிக் பிராக்கோஸ்கோப் மூலம் மூச்சுக்குழலில் குழல் பொருத்தி ஒப்பிட்டுப் பார்த்தல்.

- இரத்த அழுத்தம் நாடித்துடிப்பு மாறுதல்கள்
- அறுவை சிகிச்சையின் பொழுது தணிப்புத் தன்மையை அளவிடுதல் (ராம்சே தணிப்பு தன்மை அளவுகோல்)
- பின்விளைவுகளை அளவிடுதல்

ஆய்வின் தன்மை

ஆய்வில் பங்குபெறும் நோயாளிகள் இரண்டு குழுக்களாகப் பிரிக்கப்படுவர்.

குழு-1 டெக்ஸ்மிடிடோமிடின் (1மைக்ரோகிராம்/ கிலோ எடை 10 நிமிடங்களில்) ஃபைபர் ஆப்டிக் பிராக்கோஸ்கோப் மூலம் மூச்சுக்குழலில் குழல் பொறுத்துதல்.

குழு-2 பஎண்டனில் (2மைக்ரோகிராம்/ கிலோ எடை 10 நிமிடங்களில்) ஃபைபர் ஆப்டிக் பிராக்கோஸ்கோப் மூலம் மூச்சுக்குழலில் குழல் பொறுத்துதல்.

நன்மைகள்

1) அறுவை சிகிச்சையின்போது தணிப்புத்தன்மை அதிகரிக்கப்படும்.

2) இரத்த அழுத்தம் மற்றும் நாடித்துடிப்பு சீராக்கப்படும்.

பக்கவிளைவுகள்

மருந்து கொடுப்பதால் குறைந்த இரத்த அழுத்தம், குறைந்த நாடித்துடிப்பு ஏற்படலாம். அதற்கு மாற்று மருந்துகள் உடனடியாக கொடுக்கப்படும்.

இந்த முறையான ஆய்வு ஏற்கனவே பல இடங்களில் நடத்தப்பட்டுள்ளது. மேலும் இதன் பாதுகாப்பு உறுதிசெய்யப்பட்டுள்ளது. நீங்கள் இந்த ஆய்வில் பங்குகொள்ள விரும்பவில்லை என்றால் எப்போதும் உபயோகிக்கப்படும் மருந்தே கொடுக்கப்படும். உங்கள் பாதுகாப்பே எங்களின் முக்கிய நோக்கம்.

இந்த ஆய்வு சம்பந்தமான எல்லா புள்ளி விவரங்கள் மற்றும் நோயாளிகளின் விவரங்கள் ரகசியமாக வைக்கப்படும். இந்த ஆய்வு சம்பந்தப்பட்ட எல்லா பரிசோதனைகள், மருந்துகள் மற்றும் மருத்துவ சேவைகள் அனைத்தும் நோயாளிகளுக்கு இலவசமாக வழங்கப்படும்.

ஆய்வாளரின் பெயர் **பங்குபெறுபவரின் பெயர்**

ஆய்வாளரின் கையொப்பம் **பங்குபெறுபவரின் கையொப்பம்**

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சியின் தலைப்பு

டெக்ஸ்மிடிடோமின் அல்லது பெண்டனில் மருந்து கொடுத்து ஃபைபர் ஆப்டிக் பிராக்கோஸ்கோப் மூலம் மூச்சுக்குழலில் குழல் பொருத்தி ஒப்பிடுதல்.

ஆய்வு நிலையம் : மயக்கவியல் துறை, சென்னை மருத்துவக் கல்லூரி சென்னை – 3.

பங்கு பெறுவரின் பெயர் :

பங்குபெறுபவரின் எண் :

பங்குபெறுபவர் இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது. ☐

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன். ☐

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். ☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கின்றேன். ☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன் 'இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிகிறேன். ☐

பங்கேற்பவரின் கையொப்பம் ..... இடம்..... தேதி.....

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் ..... இடம்..... தேதி.....

ஆய்வாளரின் பெயர் .....

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013
Telephone No.044 25305301
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CERTIFICATE OF APPROVAL

To

Dr.E.Arunmozhi
I Year PG in MD Anaesthesiology
Institute of Anaesthesiology & Critical Care
Madras Medical College
Chennai 600 003

Dear Dr.E.Arunmozhi,

The Institutional Ethics Committee has considered your request and approved your study titled **"COMPARISON BETWEEN DEXMEDETOMIDINE AND FENTANYL ON INTUBATION CONDITIONS DURING AWAKE FIBROPTIC BRONCHOSCOPY" - NO.25052017**

The following members of Ethics Committee were present in the meeting hold on **02.05.2017** conducted at Madras Medical College, Chennai 3

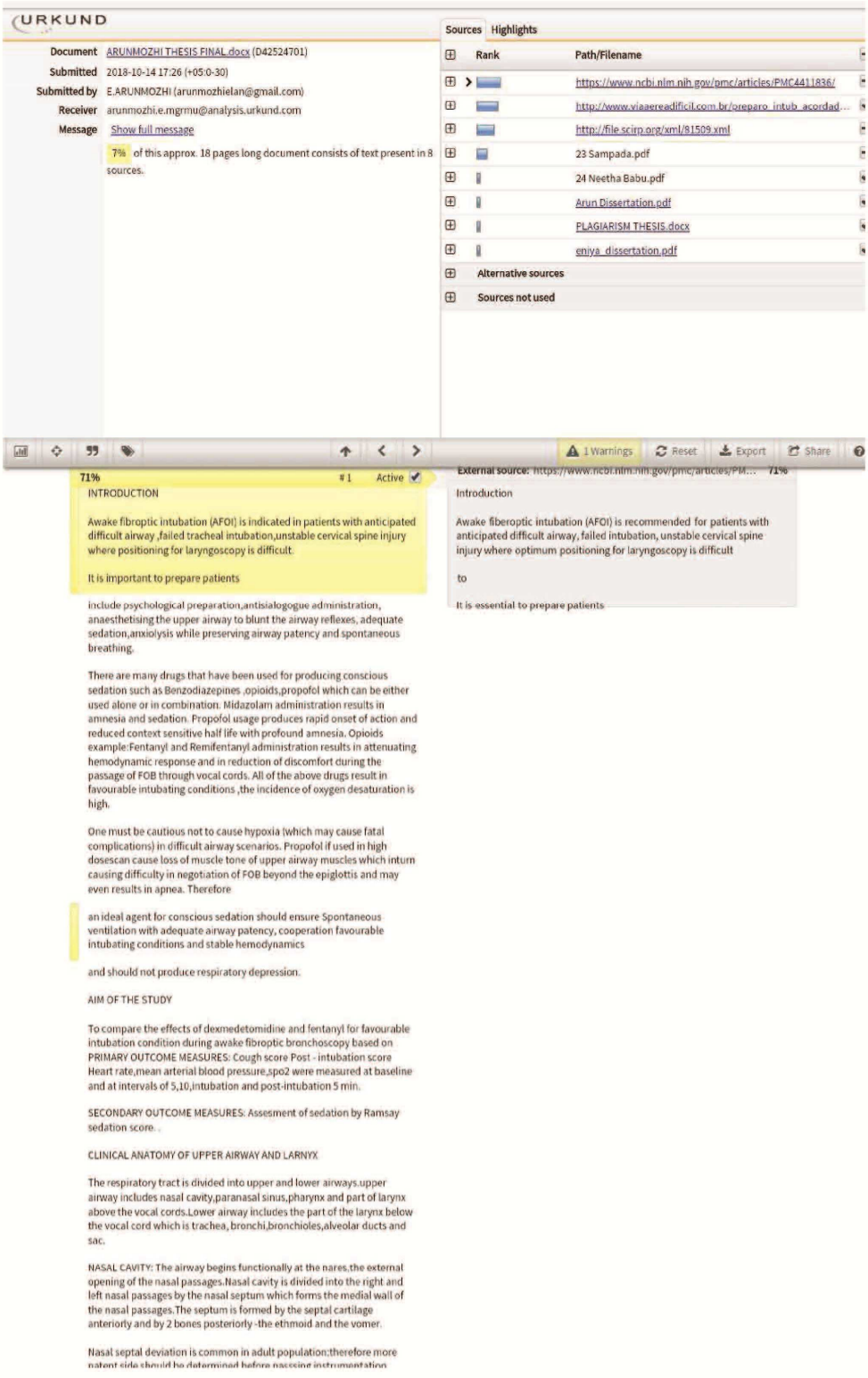
1.Prof.Dr.C.Rajendran, MD.,	:Chairperson
2.Prof.R.Narayana Babu, MD.,DCH.,Dean, MMC,Ch-3	:Deputy Chairperson
3.Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3	:Member Secretary
4.Prof.S.Suresh,MS.,Prof.of Surgery,MMC, Ch-3	: Member
5.Prof.S.Mayilvahanan,MD,Director,Inst. of Int.Med,MMC, Ch-3	: Member
6.Tmt.J.Rajalakshmi, JAO,MMC, Ch-3	: Lay Person
7.Thiru S.Govindasamy, BA.,BL,High Court,Chennai	: Lawyer
8.Tmt.Arnold Saulina, MA.,MSW.,	:Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003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INTRODUCTION
Awake fibroptic intubation (AFOI) is indicated in patients with anticipated difficult airway ,failed tracheal intubation,unstable cervical spine injury where positioning for laryngoscopy is difficult.
It is important to prepare patients
include psychological preparation,antisialogogue administration, anaesthetising the upper airway to blunt the airway reflexes, adequate sedation,anxiolysis while preserving airway patency and spontaneous breathing.
There are many drugs that have been used for producing conscious sedation such as Benzodiazepines ,opioids,propofol which can be either used alone or in combination. Midazolam administration results in amnesia and sedation. Propofol usage produces rapid onset of action and reduced context sensitive half life with profound amnesia. Opioids example:Fentanyl and Remifentanyl administration results in attenuating hemodynamic response and in reduction of discomfort during the passage of FOB through vocal cords. All of the above drugs result in favourable intubating conditions ,the incidence of oxygen desaturation is high.
One must be cautious not to cause hypoxia (which may cause fatal complications) in difficult airway scenarios. Propofol if used in high dosescan cause loss of muscle tone of upper airway muscles which inturn causing difficulty in negotiation of FOB beyond the epiglottis and may even results in apnea. Therefore
an ideal agent for conscious sedation should ensure Spontaneous ventilation with adequate airway patency, cooperation favourable intubating conditions and stable hemodynamics
and should not produce respiratory depression.
AIM OF THE STUDY
To compare the effects of dexmedetomidine and fentanyl for favourable intubation condition during awake fibroptic bronchoscopy based on PRIMARY OUTCOME MEASURES: Cough score Post - intubation score Heart rate,mean arterial blood pressure,spo2 were measured at baseline and at intervals of 5,10,intubation and post-intubation 5 min.
SECONDARY OUTCOME MEASURES: Assesment of sedation by Ramsay sedation score. .
CLINICAL ANATOMY OF UPPER AIRWAY AND LARNYX
The respiratory tract is divided into upper and lower airways.upper airway includes nasal cavity,paranasal sinus,pharynx and part of larynx above the vocal cords.Lower airway includes the part of the larynx below the vocal cord which is trachea, bronchi,bronchioles,alveolar ducts and sac.
NASAL CAVITY: The airway begins functionally at the nares,the external opening of the nasal passages.Nasal cavity is divided into the right and left nasal passages by the nasal septum which forms the medial wall of the nasal passages.The septum is formed by the septal cartilage anteriorly and by 2 bones posteriorly -the ethmoid and the vomer.
Nasal septal deviation is common in adult population:therefore more patent side should be determined before passing instrumentation
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Introduction
Awake fiberoptic intubation (AFOI) is recommended for patients with anticipated difficult airway, failed intubation, unstable cervical spine injury where optimum positioning for laryngoscopy is difficult
to
It is essential to prepare patients

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Urkund Analysis Result

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PLAGIARISM CERTIFICATE

This is to certify that this dissertation work titled **"A RANDOMIZED DOUBLE BLIND PROSPECTIVE STUDY COMPARISION BETWEEN DEXMEDETOMIDINE AND FENTANYL ON INTUBATION CONDITIONS DURING AWAKE FIBROPTIC BRONCHOSCOPIC INTUBATION"** of the candidate **Dr .E.ARUNMOZHI** with registration number for the award of M.D. in the branch of **ANAESTHESI OLOGY.** I personally verified the urkund. com website. for the purpose of plagiarism check. I found that the uploaded thesis file contains from introduction to conclusion pages and the result shows percentage of plagiarism in the dissertation.

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					HEART RATE					MAP					SPO				
S.No	GROUP	AGE	WEIGHT	ASA PS	Base line	5 min	10 min	Intubation	5min	Baseline	5 min	10 min	Intubation	5 min	Baseline	Intubation	RAMSAY SEDATION SCORE	COUGH SCORE	POST INTUBATION SCORE
1	A	40	62	1	84	78	76	78	77	90	88	86	88	90	99	98	3	2	1
2	A	43	58	1	86	79	76	79	76	92	90	92	91	90	98	97	2	2	1
3	A	45	60	1	88	84	82	80	81	93	88	86	88	86	99	98	3	2	1
4	A	42	63	1	87	84	82	79	78	92	90	88	89	88	99	98	3	2	2
5	A	39	65	1	75	72	69	71	70	88	86	88	86	88	99	98	3	2	1
6	A	45	58	1	78	72	70	73	71	86	85	86	86	85	98	92	3	2	1
7	A	40	60	1	74	72	66	69	67	89	86	85	87	88	98	97	3	2	2
8	A	38	62	1	78	75	70	72	71	91	90	88	86	87	99	98	4	2	2
9	A	41	66	1	80	76	74	76	75	92	90	88	86	88	98	97	3	2	1
10	A	38	65	2	72	68	63	64	63	88	86	85	86	88	99	98	3	3	1
11	A	36	60	1	84	80	76	78	77	94	90	89	88	87	98	93	3	2	1
12	A	39	58	1	88	85	83	84	82	86	84	82	80	82	99	98	3	2	2
13	A	43	65	1	74	71	65	68	67	88	86	84	88	86	99	98	3	2	1
14	A	46	58	1	89	86	84	85	84	87	86	84	86	85	99	98	2	2	1
15	A	41	66	1	90	85	83	86	85	86	84	83	84	84	98	97	3	2	1
16	A	42	60	2	74	72	68	67	66	85	84	83	84	84	98	94	3	2	1
17	A	48	66	1	78	76	72	73	72	88	87	86	85	85	99	98	3	1	1
18	A	45	56	1	76	74	69	68	66	89	88	87	86	85	99	98	3	2	2
19	A	41	57	1	79	75	74	74	73	87	86	85	86	85	98	97	3	2	1
20	A	43	56	1	74	70	67	66	65	90	86	85	86	85	99	98	3	2	1

21	A	46	55	1	73	70	68	72	70	87	86	85	85	84	99	98	3	2	1
22	A	36	56	1	84	82	80	78	77	86	85	84	85	84	99	99	3	2	1
23	A	31	58	2	88	85	79	80	79	86	85	84	85	84	99	98	3	2	1
24	A	32	57	1	84	81	78	79	76	88	87	86	87	86	98	93	3	3	2
25	A	41	57	1	82	80	76	77	76	89	88	88	89	88	99	98	3	2	1
26	A	45	59	1	84	81	78	80	79	94	93	92	93	92	99	99	3	2	1
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28	A	37	62	1	76	72	68	69	68	87	86	85	87	85	98	97	2	2	1
29	A	41	63	1	75	74	73	98	96	86	84	82	105	103	99	96	2	3	2
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31	B	40	63	1	85	84	82	106	105	91	90	88	110	108	99	96	2	3	2
32	B	38	64	1	88	87	85	108	103	92	90	88	111	107	99	94	2	3	2
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41	B	38	60	1	83	81	80	104	100	89	86	84	111	108	99	94	2	3	2
42	B	44	62	1	84	84	82	105	102	97	95	93	110	109	99	94	2	3	2
43	B	45	59	1	81	81	80	100	98	96	93	91	106	105	99	93	2	3	2
44	B	41	58	1	72	71	70	97	95	87	84	82	109	104	99	92	2	3	2
45	B	40	58	2	74	72	69	98	97	86	83	81	106	105	99	92	2	3	2
46	B	42	59	1	76	73	71	97	94	86	84	83	105	101	99	93	2	3	2
47	B	41	60	1	74	71	70	98	94	88	86	85	104	104	99	94	2	4	2
48	B	42	61	1	79	78	76	98	96	89	86	84	108	103	99	92	2	3	2

49	**B**	**39**	**62**	**1**	**83**	**81**	**80**	**104**	**100**	**96**	**94**	**92**	**111**	**107**	**99**	**97**	**2**	**3**	**1**
50	**B**	**37**	**60**	**1**	**84**	**83**	**81**	**108**	**104**	**84**	**83**	**81**	**103**	**101**	**99**	**93**	**2**	**2**	**2**
51	**B**	**41**	**62**	**1**	**76**	**74**	**72**	**100**	**98**	**87**	**85**	**84**	**106**	**104**	**99**	**92**	**2**	**3**	**2**
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