COMPARISON BETWEEN VISCOUS LIGNOCAINE AND RECTAL DICLOFENAC FOR IMMEDIATE POST-OPERATIVE ANALGESIA IN PAEDIATRIC TONSILLECTOMY.

BY :

DR ZAYUAH BT MAT SULAIMAN

Dissertation Submitted In Partial Fulfillment Of The requirement For The Degree Of Master Of Medicine (Anaesthesiology)

UNIVERSITI SAINS MALAYSIA

UNIVERSITI SAINS MALAYSIA
MAY 2009

ACKNOWLEDGEMENT

Bismillahirrahmanirahim...

All Praise and Thanks be to Allah. Since purely due to his virtues was this dissertation possible to be completed. I am deeply grateful to my supervisor Associate Professor Dr Wan Aasim Wan Adnan for his keen interest in my work and with whom I had many invaluable discussions, without him this dissertation cannot have been completed. Also my gratitude and appreciation to my co-supervisor, Dr Rhendra Mohd Zaini and Associate Professor Dr Roskejura @ Rosdan Salim for their valuable advice. I also would like to thanks to Dr Mohd Rahim Sulong and my dear friends for their outstanding assistance in data analysis and to all staff nurses for their enormous assistance in helping to monitor the patients.

For my loving husband, Mohd Shahran Mohd Yakob and my fantastic son, Muhammad Sofwan, who fill my thoughts during the many hours at work. I thank them for their support and understanding during the long hours that were required to complete this dissertation.

To all my lecturers, supporting staff and everybody who help me directly or indirectly in this study, I thank them all. Lastly, I am particularly indebted to the patients for their participation in this study. Without them, this study would not be a reality.

ABSTRAK (BAHASA MALAYSIA)

Perbandingan diantara viscous lignocaine dan suppositori diclofenac untuk sakit selepas "tonsillectomy" dikalangan kanak-kanak.

Latar Belakang

"Tonsillectomy" banyak dilakukan dikalangan kanak-kanak. Kesakitan selepas pembedahan adalah penting bukan sahaja menyebabkan tekanan kepada kanak-kanak malahan ia boleh menyebabkan dehidrasi, kesukaran makan dan melambatkan process pemulihan selepas pembedahan. Banyak ujikaji telah dilakukan dan didapati bahawa penggunaan ubat bius setempat adalah baik bagi merawat kesakitan selepas "tonsillectomy" tetapi masih belum ada yang menggunakan viscous lignocaine bagi tujuan ini. Jadi, adalah penting untuk membuat kajian ini bagi menentukan bahawa bius setempat boleh menggantikan ubatan lain bagi merawat kesakitan selepas "tonsillectomy"

Objektif

Objektif utama kajian ini adalah untuk melihat keberkesanan ubat bius setempat, viscous lignocaine berbanding suppositori diclofenac sebagai ubat tahan sakit selepas "tonsillectomy" dikalangan kanak-kanak. Keberkesanan viscous lignocaine dilihat menggunakan VAS (visual analogue scale), kestabilan tanda-tanda vital dan jumlah penggunaan ubat tahan sakit penyelamat. Jangka-masa pesakit untuk makan dan minum selepas "tonsillectomy" juga dibandingkan.

Kaedah

Seramai 130 kanak-kanak yang berumur diantara 5 hingga 12 tahun terlibat dalam kajian ini (65 orang setiap kumpulan). Kumpulan dibahagi secara rawak kepada 2 kumpulan dengan menggunakan " computer generated simple random sampling". Kumpulan A adalah viscous lignocaine dan kumpulan B adalah suppositori diclofenac. Kumpulan A, pesakit diberi 3 mls viscous lignocaine 2% selepas "tonsillectomy" manakala kumpulan B diberi suppositori diclofenac 1 mg/kg selepas induksi bius general. Semasa di bilik pemulihan, tanda-tanda vital dicatat dan VAS digunakan bagi ukuran kesakitan. Semua data pesakit dimasukkan dalam rekod APS (Acute Pain Service) sebelum dipindahkan ke wad dan seterusnya dilihat di wad dalam masa 24 jam selepas pembedahan. Ukuran kesakitan menggunakan VAS, tekanan darah, denyutan nadi, jumlah penggunaan pethidine dan tempoh bermula makan dan minum direkodkan bagi 1-jam, 2-jam, 4-jam, 12-jam dan 24-jam selepas pembedahan.

Keputusan

Kesemua 130 kanak-kanak telah berjaya melalui kajian ini. Kumpulan A mempunyai nilai VAS yang tidak significant secara keseluruhannya ($p=0.479$), tetapi menunjukan penurunan nilai VAS dalam 4-jam yang pertama selepas pembedahan. Tekanan darah yang direkod menunjukkan penurunan yang nyata selepas 4 jam pada kumpulan A, $p=0.043$ pada 4-jam, $p=0.040$ pada 12-jam dan $p=0.044$ pada 24-jam. Walaupun begitu, kadar denyutan jantung tidak menunjukkan perbezaan diantara 2 kumpulan ini dengan nilai $p= 0.599$. Manakala penggunaan pethidine adalah rendah dalam kumpulan A pada

2-jam dengan nilai p= 0.023 dan 4-jam selepas pembedahan. Tempoh bermula makan dan minum juga menunjukkan bahawa kumpulan A pesakit minum dan makan makanan lembut lebih awal dengan nilai p= 0.016 dan p= 0.007.

Kesimpulan

Daripada kajian ini kami dapati bahawa viscous lignocaine merupakan ubat tahan sakit yang setanding dengan suppositori diclofenac bagi "tonsillectomy" dikalangan kanak-kanak. Ia memang mempunyai kesan penahan sakit yang lebih baik terutama pada peringkat awal selepas pembedaha dan pesakit boleh minum serta makan lebih awal. Ia adalah selamat dan boleh mengurangkan kesan-kesan sampingan ubat tahan sakit sistemik.

ABSTRACT

Comparison between viscous lignocaine and rectal diclofenac for immediate post-operative analgesia in paediatric tonsillectomy.

Background

Tonsillectomy is a common surgical procedure in children. Pain after tonsillectomy is inevitable and causes not only distress, but also dehydration, difficulty in eating and delayed post-operative recovery. Previous studies in the pediatric population have demonstrated a significant decrease in post operative pain and morbidity by using local analgesic but the effectiveness in relieving pain has not been formally assessed and there is no study done using viscous lignocaine for the pain reduction following tonsillectomy. It is very important to determine weather topical can replace other form of medication in the management of immediate post-operative pain.

Objectives

The goal of this study was to find out the effectiveness of viscous lignocaine for immediate pediatric post-tonsillectomy pain in comparison to rectal diclofenac. Specific objective include to determine weather peri-operative viscous lignocaine effectively reduces immediate incisional pain in tonsillectomy patients using Visual Analogue Score (VAS) between the groups and reduction in post-operative analgesic requirement as a rescue analgesic in pediatric tonsillectomy patients. It also to assess the ability of the patients following tonsillectomy to start oral feeding.

Methodology

130 patients aged between 5 to 12 years old were randomly allocated to two groups to receive either viscous lignocaine or rectal diclofenac as post-operative analgesic. Patients will be randomized into 2 groups, using computer generated simple random sampling. 65 patients are assigned into group A (viscous lignocaine) and another 65 in group B (rectal diclofenac). Group A : Patients given 3 mls of viscous lignocaine 2 % or maximum of 4mg/kg body weight whereas Group B : Patients were given rectal diclofenac 1 mg/kg. All patients will be preoxygenated with oxygen and induced with intravenous fentanyl 1.5mcg/kg, propofol 2 mg/kg and rocuronium 0.5 mg/kg as muscle relaxant. In the recovery room, vital signs will be charted and pain assessment was done using VAS 0.5-hour and before discharge to ward. In the ward, patients is then follow up for 24 hours by Acute Pain Service team and time of resumption oral feeding and total rescue medication is recorded at 1-hour, 2-hour, 4-hour, 12-hour and 24-hour. If patients complaining of intolerable pain, rescue medication will be given, intravenous pethidine 0.5 mg/kg and time, frequency and total doses will be recorded at the same time interval.

Result

130 patients completed the study. The result showed that even though statistically not significant, p=0.479; the VAS score was lower in viscous lignocaine group first 4 hours post-operatively. Haemodynamically, the MAP was significantly reduce in viscous lignocaine group after 4-hour with p=0.043, at 12-hour p=0.040 and at 24-hour p=0.044. The dose of rescue medication was significantly reduced at 2-hour post-operation with p=0.023 and the dose still reduced at 4-hour post-tonsillectomy. The time for resumption oral feeding were also significantly reduced for oral fluid and oral soft

diet in viscous lignocaine group with p=0-016 and p=0.007 respectively.

Conclusion

From our study, we conclude that viscous lignocaine is comparable to rectal diclofenac for post-tonsillectomy analgesia in paediatric patients. Viscous lignocaine does reduced significantly immediate post-operative pain and result in early return of oral feeding. It is safe and can reduce the unnecessary complication of systemic analgesia.

LIST OF TABLES

LISTS OF FIGURES

ABBREVIATIONS

APS	Acute Pain Service
ASA	Amarican Society of Anaesthesiologists
COX	Cyclo-oxygenase
ENT	Ear, nose and throat
ETT	Endotracheal tube
GA	General anaesthesia
LA	Local anaesthetic
HR	Heart rate
IASP	International Association for the Study of Pain
i.v.	Intravenous
MAP	Mean arterial pressure
SPSS®	Social sciences and statistical packages
NSAIDs	Non-steroidal anti-inflammatory drugs
VAS	Visual Analogue Scale
WHO	World Health Organization

CONTENTS

CONTENTS

CONTENTS

CHAPTER 1 : INTRODUCTION

1.0 Introduction

Tonsillectomy is a common surgical procedure in children. Indications for pediatric tonsillectomy include recurrent tonsillitis, tonsillar hypertrophy and obstructive sleep disorder. Pain after tonsillectomy is inevitable and causes not only distress, dehydration but also difficulty in eating and delayed post-operative recovery.

Local anaesthetic agents have been administered to tonsillar region but the effectiveness in relieving pain has not been formally assessed. There were few studies (Bissonnete B., 1995, Kedek et al., 2000, Naja et al., 2000) done to see the effectiveness of topical lignocaine in reducing post-operative pain following tonsillectomy, it is very important to clarify this promising study wheather topical can replaces other forms of medication in the management of immediate post-operative pain in paediatric tonsillectomy.

Several studies over the past decades have supported that injection of local anaesthetic agents during tonsillectomy significantly reduces post-operative pain. A randomised controlled trial of 30 children, American Society of Anaesthesiologist (ASA) physical status I and II by Bissonnete B., 1995, post-tonsillectomy analgesia was compared using 10% aerosol lignocaine 4 mg/kg and intramuscular codeine 1.5 mg/kg showed that it was superior analgesia compared to intramuscular codiene.

Study by Kedek et al., 2000, studied 40 children ASA I and II underwent tonsillectomy, aim to compare the effect of lignocaine and adrenaline with ibuprofen syrup (administered before adenotonsillectomy) on post-operative analgesia and initiation of oral feeding. This study shows that ibuprofen syrup applied pre-incisionally and local infiltration of lignocaine are equally effective post op analgesia.

Another study by Naja et al., 2005, a randomized double-blind clinical trial, recruited 90 patients allocated evenly into 3 groups. It shows that pre-incisional infiltration of lignocaine 2% for paediatric tonsillectomy with GA reduced significantly post-tonsillectomy pain in children and provide more rapid return to activity compare to general anesthesia alone or in combination with placebo. A study by Egeli et al., 2002, a double-blind prospective randomized controlled study, to evaluate the efficacy of topical lignocaine 2% with adrenaline on post-operative morbidity in paediatric patients after tonsillectomy concluded that topical lignocaine was effective, safe and easy medication to use.

Sorenson et al., 2003, recruited 52 patients for randomised double-blind study to investigate the effect of pre-incisional infiltration of lignocaine with adrenaline in tonsillectomy and he also concluded that lignocaine had significantly reduced the immediate post-operative pain and reduce blood loss in tonsillectomy.

Kaygusuz et al., had recruited 80 patients that had undergone tonsillectomy and compared the effect of dexamethasone, bupivacaine and topical lignocaine on pain after tonsillectomy. This study showed that lignocaine was more preferable than dexamethasone and bupivacaine in reducing pain up to post-operation day 3.

Susaman et al., recruited 60 patients underwent tonsillectomy and they evaluated the lignocaine aerosol as post-operative pain relief. This study also concluded that lignocaine aerosol exerted a therapeutic effect on post-operative pain control in tonsillectomy patients.

Non steroidal anti-inflammatory drugs (NSAIDs) are commonly used in children for their potent anti-pyretic and analgesic effects. NSAIDs therapy has been reported to provide effective pain control after tonsillectomy and other paediatric surgical patients. NSAIDs are as effective as morphine for pain relief after surgery but are associated with a lower risk of nausea and vomiting. Thus, they are considered the agent of first choice for controlling post-operative pain after paediatric surgery.

Few studies had demonstrate that the use of rectal diclofenac is effective analgesic for paediatric tonsillectomy. Bone & Fell., 1988 studied analgesic effect of rectal diclofenac 2mg/kg after induction compared with papaveratum 0.2mg/kg intramuscularly after induction, showed that diclofenac group needed less rescue analgesic.

Mendham & Mather., 1996, compared rectal diclofenac 1mg/kg during anaesthesia to intravenous tenoxicam 0.4mg/kg during anaesthesia showed significant reduction in pain score in diclofenac group compared with tenoxicam and less rescue analgesic were used. Oztekin et al., 2002 using rectal diclofenac 1mg/kg compared to placebo, morphine as rescue a analgesic, patients given diclofenac had lower pain scores and lower total morphine consumption than control.

Yet, there is still limited data and literature in comparing the efficacy of local analgesic such as viscous lignocaine with rectal diclofenac as a standard post-operative pain relief. The knowledge regarding efficacy, safety and patient satisfaction with viscous lignocaine need to be reviewed in providing optimal post-operative analgesia with minimal complication possible and improves patients quality of life post-operatively.

1.1 Objective

The goal of this study was to find out the effectiveness of viscous lignocaine compared to rectal diclofenac as conventional analgesic following paediatric tonsillectomy. We also compared the pain scores, haemodynamic stability, reduction in rescue medication used and the duration to tolerate oral feeding post-operatively.

CHAPTER 2 : LITERATURE REVIEW

2.1 Pain

2.1.1 Definition

Pain is defined as an "unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in term of such damage". (Internasional Association for the Study of Pain / IASP Subcommittee of Toxonomy, 1994). Pain varies in character, site, severity, timing and affect. Pain is always subjectives. Each individual learns the application of the word pain through experiences related to injury in early life.

Many people report pain in an absence of tissue damage or any likely pathophysiological cause, usually this occurs for psychological reason. Activity induced in the nociceptor and nociceptive pathways by pain, most often has proximate physical cause. Pain is the most common symptom that brings the patients to see a doctor and serves as a warning of damage to the individual. Pain promotes an avoidance of further damage.

2.1.2 Physiology of pain

Since Serturner isolated morphine in the first decade of the 19th century, we have seen the development of many opioids, the introduction of aspirin in 1899 and non steroidal anti-inflammatory drugs (NSAIDS), the discovery of local anaesthetics in 1884, and the discovery of surgical anaesthesia in 1846. Concurrently, we have learned much about the biology of pain, identifying cells that sense noxious stimuli and conduct information to

the brain and chemicals that act as intermediaries in the response of pain of the whole organism and each of its parts. Traditionally, the word "pain" includes many conditions not necessarily associated with medicine, deprivation, mental depression, poverty, loss of political freedom or social status, physical or mental discomfort, or hardship (Caton, 1994).

Pain perception is normally dependent on specialized neurons that function as receptors, detecting the stimulus and then tranducing and conducting it into the central nervous system. Sensation often described as either protopathic (noxious) or epicritic (non-noxious). Protopathic sensation is subserved by high-threshold receptors and conducted by smaller, lightly myelinated (A-δ) and unmyelinated (C) nerve fibers. In contrast, epicritic sensation such as light touch, pressure, propioception and temperature discrimination are characterized by low-threshold receptors and generally conducted by large myelinated nerve fibers (Table 1).

Clinically, pain can be divided into two categories: i) Acute pain, which is primarily due to nociception, and ii) Chronic pain, which may be due to nociception but in which psychological and behavioral often play a major role. Most common forms of acute pain include post-traumatic, post-operative and obstetrical pain as well as associated with acute medical illnesses such as myocardial infarction, pancreatitis and renal calculi. Acute pain can be divided further into superficial, deep somatic and visceral which are differentiated based on origin and features. Superficial pain is due to nociceptive input arising from skin, subcutaneous tissues and mucous membranes.

Table 1. Classification of nerve fibers.

(Adapted from textbook of clinical anaesthesiology by Morgan & Mikhail, 2002).

Fiber type	classification	modality	Diameter(um)	Conduction(m/s)
A-α		Motor	12-30	70-120
A-α	Type Ia	Propioception	12-30	70-120
A-α	Type Ib	Propioception	12-30	70-120
A-β	Type II	Touch, pressure, propioception	5-12	30-80
A-γ		Motor to muscle spindle	3-6	15-30
A-δ	Type III	Pain, cold, temperature, touch	2-5	12-30
B		Preganglionic autonomic fibers	<3	3-14
C dorsal root	Type IV	Pain,Warm and cold temperature, touch	0.4-1.2	0.5-2
C sympathetic		Post ganglionic sympathetic fibers,	0.3-1.3	0.7-2.3

It is described as sharp, pricking, throbbing or burning sensation. Deep somatic pain arises from muscles, tendons, joints, or bones which has a dull, aching quality and is less well-localized. Visceral pain is due to disease process or abnormal function of an internal organ or its covering for example parietal pleura, pericardium or peritoneum.

Chronic pain is the pain that persists beyond the usual course of an acute disease or after a reasonable time for healing to occur which varies between 1-6 months. This

type of pain may result from peripheral nociception, or peripheral or central nervous system dysfunction. Chronic pain which has been commonly encountered are those associated with musculoskeletal disorders, chronic visceral disorders, lesions of the nervous system and cancers.

Peripheral nerve fibers and their respective neurons are classified from A to C according to axonal diameter, covering (myelinated or unmyelinated) and conduction velocity. Sensory fibers also are categories as I to IV. Type C (Sensory type IV) are unmyelinated fibers while type A-δ fibers are lightly myelinated.

2.1.3 Pain Pathways

The human nervous system has a mechanism to detect and respond to noxious stimuli. The three-neuron pathways transmit noxious stimuli from the periphery to cerebral cortex. Primary afferent neurons are located in dorsal root ganglia, which lie in the vertebral foramina at each spinal cord level. Each of the neuron has a single axon which bifurcates, sending one end to the peripheral tissue it innervates and the other into the dorsal horn in the spinal cord. In the dorsal horn, primary afferent neuron synapse with the second-order neuron whose axon cross the midline and ascend in the contralateral spinothalamic tract to reach the thalamus. In the thalamus, second-order neuron synapse with the third-order neurons which in turn send projection into the internal capsule and corona radiata to the post-central gyrus of the cerebral cortex (Figure 1).

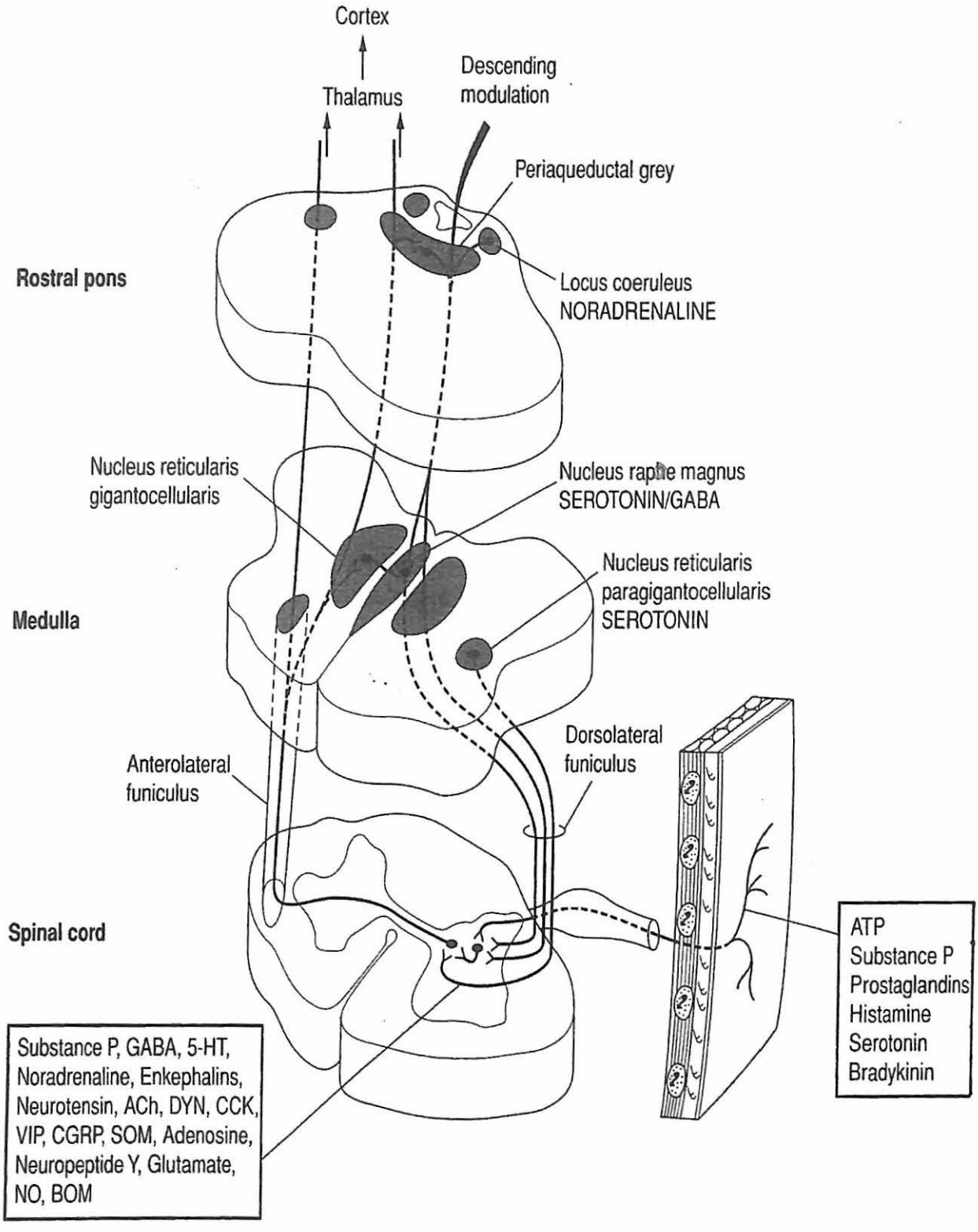

Figure 1. Pain pathways