A COMPARATIVE STUDY OF ANALGESIC EFFECT OF CAUDAL BUPIVACAINE WITH DEXMEDETOMIDINE VERSUS BUPIVACAINE ALONE FOR INFRAUMBILICAL SURGERIES IN CHILDREN IN WINDHOEK CENTRAL HOSPITAL

A THESIS IN PARTIAL FULFILMENT FOR THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE

(ANEASTHESIOLOGY, CRITICAL CARE AND PAIN MANAGEMENT)

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ABSTRACT

Background: Paediatric pain is frequently underassessed and undertreated due to challenges in pain expression among children, which can result in its under recognition. Untreated pain can potentially lead to long-term consequences on children's emotional and psychological welfare. The use of caudal blocks has evolved to become the most common regional anaesthesia technique for providing intraoperative and postoperative analgesia in children undergoing infraumbilical surgeries. Existing literature has demonstrated that caudal administration with bupivacaine alone typically has a short duration of action, and its analgesic effect can be prolonged by incorporating adjuvants such as dexmedetomidine. The overall objective of this study is to compare the difference in the duration of analgesic effect between caudal bupivacaine alone and bupivacaine with dexmedetomidine by using first time request of ibuprofen syrup based on the modified Hannallah pain score of ≥ 4. **Methodology:** This was a prospective randomised double-blinded control study and data were collected over a period of five months. The study included children scheduled for elective infra-umbilical surgeries. A total of 50 children, aged 1 – 8 years were recruited and divided into two groups (A and B) of 25 children each. Group A received caudal block with 0.25% bupivacaine at a dose of 0.5 or 1 ml/kg. Group B received 0.25% bupivacaine caudal bupivacaine at a dose of 0.5 or 1 ml/kg with dexmedetomidine (1mcg/kg). Patients were monitored for 24 hours and data were collected using a research questionnaire designed for the study. The data were analysed using SPSS for Windows, version 26.0. (IBM Corporation, Armonk, NY, USA). **Results:** For Group A patients, the mean time to first request for rescue ibuprofen was 471±230 minutes. In contrast, Group B patients had a mean of 1339±210 minutes. These differences were statistically significant. Total consumption of ibuprofen syrup was 298.00±150.665 milligrams in Group A and 53.20±82.952 milligrams in Group B, the difference was statistically significant. No significant difference was observed between the two groups in the incidence of pain scores, haemodynamic parameters and side effects. **Conclusion:** The addition of dexmedetomidine significantly extended the duration of analgesia provided by caudal bupivacaine in paediatric patients undergoing infraumbilical surgeries without an increase in the incidence of haemodynamic changes and side effects

Keywords: Dexmedetomidine, Bupivacaine, Caudal Blocks, Paediatric Regional Anaesthesia, Infraumbilical Surgeries.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS AND/OR ACRONYMS

UNAM	University of Namibia
WCH	Windhoek Central Hospital
MOHSS	Ministry of Health and Social Services
IASP	International Association for the Study of Pain
ERAS	Enhanced Recovery After Surgery
PACU	Post Anaesthesia Care Unit
CPSP	Chronic Post-surgical Pain
ASA	American Society of Anaesthesiologist
FLACC	Face Legs Activity Cry Consolability
PI	Principal Investigator
RA	Research Assistant
AC	Anaesthetic Consultant

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DEDICATION

This thesis is dedicated to all the Namibian children. Children are a vulnerable population unable to advocate for themselves. This study was conducted to enhance postoperative pain management for Namibian children, ensuring their comfort and well-being as they navigate the path to recovery.

May this work serve to improve the health and well-being of children across our nation and may the bravery of the children who participated in the study inspire continued advancements in paediatric care.

DECLARATIONS

I, Niita Nelago Tangi Amaambo, hereby declare that this study is my own work and is a true reflection of my research, and that this work, or any part thereof has not been submitted for a degree at any other institution.

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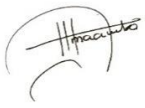


Niita Nelago Tangi		April 2025
Name of Student	**Signature**	**Date**

CHAPTER 1: INTRODUCTION

1.1. Background of the study

Throughout the history of medicine, pain stands as one of the earliest and most enduring medical challenges. Despite this longevity, numerous concerns persist regarding its nature and effective management.[1] In 1644, René Descartes introduced the concept of phantom pain and he suggested that pain was not localised in the periphery but rather experienced within the brain.[1] Presently, the International Association for the Study of Pain (IASP) defines pain as an unpleasant sensory and emotional encounter akin to, or associated with, actual or potential tissue injury.[2] Despite the struggle physicians have with understanding and addressing pain for centuries, the last four decades have witnessed a remarkable surge in pain research.[1] This period has been marked by significant scientific breakthroughs in analgesia, the development of novel techniques, and a widespread acknowledgement of the multidisciplinary approach essential for comprehensive pain therapy.[1] Pain is a prevalent symptom among children undergoing hospital care.[3] Postoperative pain in paediatrics is a frequent concern for both parents and healthcare professionals.[4] Children experiencing pain following surgery may manifest various complications, such as nausea, vomiting, respiratory challenges, disrupted sleep patterns, and reduced physical activity.[4] Moreover, untreated pain can potentially lead to long-term consequences on children's emotional and psychological welfare.[4] Effective management of pain in children and adolescents is paramount, as inadequately treated acute pain may progress to chronic pain.[3] Paediatric pain is frequently underassessed and undertreated due to challenges in pain expression among children, which can result in its under recognition.[3,4] The treatment of postoperative pain in paediatrics often

involves a combination of pharmacological and non-pharmacological strategies.[4] Pharmacological interventions typically adopt a multimodal analgesia approach, combining various analgesics and techniques to address different facets of postoperative pain in children.[4] This may entail the administration of both opioid and non-opioid analgesics, as well as the utilisation of peripheral nerve blocks, local infiltration, or epidural infusions.[4] A diverse array of analgesic medications and techniques that target various mechanisms within the peripheral and/or central nervous system can offer superior pain relief compared to single-modality interventions.[3]

The caudal block was introduced by Meredith Campbell in 1933 in New York for paediatric cystoscopies.[5] The use of caudal has evolved to become the most common regional anaesthetic technique to provide intraoperative and postoperative analgesia in children for infra-umbilical surgeries.[6] Traditionally, opioids have been used for peri-operative analgesia, however, they are associated with short- and long-term adverse effects.[7] Non-opioid analgesics are currently being investigated to provide improved pain control and minimise opioid-related side effects.[7] Caudal block is recognised as a simple, reliable and safe technique in paediatric patients.[8] This method offers additional benefits, including a reduction in the need for general anaesthesia and the attenuation of the stress response to surgery.[8] Existing literature has demonstrated that caudal administration with bupivacaine alone typically has a short duration of action.[9] However, the analgesic effect of caudal blocks can be prolonged by incorporating adjuvants such as dexmedetomidine.[9]

Dexmedetomidine is an alpha-two adrenergic agonist with an approximately eight-fold higher affinity for these receptors, enabling it to offer enhanced analgesic coverage without inducing respiratory depression.[9] Literature has also demonstrated

that dexmedetomidine offers superior hemodynamic stability compared to other adjuvants.[10]

The overall objective of this study is to compare the difference in the duration of analgesic effect between caudal bupivacaine alone and bupivacaine with dexmedetomidine by using first-time use of ibuprofen syrup based on the modified Hannallah pain score of ≥ 4 for all the patients in the study.

1.2. Statement of the problem

Infraumbilical surgeries account for more than 60% of the paediatric surgeries performed in our centre. Brasher et al. state that paediatric postoperative pain is treated sub-optimally in many centres and postoperative pain is a major complaint of paediatric patients following ambulatory surgery.[11] They further stated that despite there being a variety of contributing factors and challenges in managing pain in this group of patients, some institutions provide high-quality pain relief by employing simple therapeutic strategies. Additionally, they highlighted the long-term adverse effects attributed to severe pain namely: the development of hyperalgesia and the progression of acute pain to chronic pain. Adequate postoperative pain management is thus paramount in reducing nociceptive and endocrinological responses, minimises morbidity and mortality and aids in faster return of normal functional status.[12] Based on the Enhanced Recovery After Surgery (ERAS) protocols, adequate perioperative pain management will result in reduced time in the Post Anaesthesia Care Unit (PACU), reduced opioid consumption, earlier hospital discharge and improvement in patient satisfaction.[13]

Traditionally, opioids have been used for peri-operative analgesia, however, they are associated with short- and long-term adverse effects.[3] Non-opioid analgesics are currently being investigated to provide improved pain control and minimise opioid-related side effects.[7]

In WCH, the majority of the infraumbilical surgeries are performed under general anaesthesia in which opioids, non-steroidal anti-inflammatory drugs and paracetamol are used. If there are no contra-indications, caudal blocks also form part of the multimodal analgesic approach, and this technique has become a common practice in the above-mentioned types of surgeries. When caudal blocks are performed, bupivacaine alone is used and the dosage administered is calculated using the Armitage formula, 0.5 or 1ml/kg using 0.25% bupivacaine for infra-umbilical surgeries. Literature shows that caudal bupivacaine alone has a short duration of action and the analgesic effect can be prolonged when adjuvants such as alpha-two adrenergic agonists are used.[9] Dexmedetomidine is one type of alpha-two agonists used in caudal blocks and it has been shown to have an eight-fold greater affinity to these receptors than clonidine, another type of alpha-two adrenergic receptor agonist.[9] Dexmedetomidine thus provides better analgesic coverage without respiratory depression.[9] Literature has also demonstrated that dexmedetomidine offers superior hemodynamic stability compared to other adjuvants.[10] Dexmedetomidine is available in the above-mentioned hospital setting, however, it has not been used for caudal blocks.

This study is imperative, considering that currently no studies have been done in our centre to assess the duration of pain relief of caudal bupivacaine with dexmedetomidine. Furthermore, through an extensive Google Scholar and PubMed

literature search, none of the similar studies used ibuprofen syrup as a rescue analgesic to treat breakthrough pain. The medical fraternity is increasingly advocating for clinicians to embrace evidence-based medicine and adopt opioid-sparing techniques for managing postoperative pain.[7]

1.3. Research questions and/or objective of the study:

The overall objective of this study was to compare the difference in the duration of analgesic effect between caudal bupivacaine alone and bupivacaine with dexmedetomidine by using first-time use of ibuprofen syrup based on the modified Hannallah pain score ≥ 4 for all patients in the study.

Specific objectives:

1. To compare postoperative pain scores at time 0, 30 minutes, 1 hour, 2 hours, 4 hours, 6 hours, 12 hours, and 24 hours between the patients in the two groups after infra-umbilical surgery.
2. To compare the difference in the duration of analgesic effect between caudal bupivacaine alone and bupivacaine with dexmedetomidine by using first-time use of ibuprofen syrup based on the modified Hannallah pain score of ≥ 4 for all the patients in the study.
3. To determine total ibuprofen syrup consumption in (mg) in the first 24 hours after infraumbilical surgery between the group that received caudal bupivacaine alone and the group that received caudal bupivacaine with dexmedetomidine.
4. To evaluate the adverse effects of bupivacaine with dexmedetomidine.
5. To assess patient/parent satisfaction with post-operative pain relief between the two groups.

1.4. Hypothesis of the study

Null hypothesis

- There is no difference in the duration of analgesic effect between caudal with bupivacaine alone versus bupivacaine with dexmedetomidine in paediatric infraumbilical surgeries

Alternate hypothesis

- There is a difference in the duration of analgesic effect between caudal with bupivacaine alone versus bupivacaine with dexmedetomidine in paediatric infra umbilical surgeries.

1.5. Significance of the study

In our hospitals in Windhoek, caudal block is a standard of care for infraumbilical surgeries for postoperative analgesia. This study mainly assessed the duration of analgesia of caudal blocks performed with bupivacaine alone in one group and bupivacaine with dexmedetomidine in the second group. A study of this nature has not been done in the Namibian population before.

Caudal blocks are simple to perform, and studies have shown that they have minimal side effects, and they provide effective perioperative analgesia. Caudal blocks with bupivacaine only offer a short duration of pain relief. Adding adjuncts like dexmedetomidine to bupivacaine extends the duration of analgesia.

Dexmedetomidine (the study drug) is registered in Namibia and is on the Namibian markets as Precedex or Dexisum. Dexmedetomidine reduces the use of anaesthetic agents and opioid requirements.

This study will contribute to safety and improved care for Namibian children. There is a need to provide evidence to improve post-operative pain management in the paediatric population in the centre. Adequate post-operative pain management will reduce post-operative complications related to inadequate pain management and better pain management results in enhanced recovery and reduced hospital stay.

1.6. Limitations of the study

The infraumbilical surgeries in the study only included Circumcisions, Inguinal Hernia Repairs, Hydrocelectomies and Orchidopexies. All these procedures had different operating times; however, they were all performed within 1 hour and 30 minutes. To mitigate this limitation, all caudal blocks were performed before the skin incision. The rate of failure or patchy caudal block was mitigated by ensuring that the caudal blocks were done by the Principal Investigator (PI), who is a senior registrar. The caudal block was aborted on failure of the third attempt and those patients were excluded from the study.

1.7. Delimitations of the study

The study population was limited to Windhoek Central Hospitals and data were collected for a duration of four months (October 2023 to February 2024).

CHAPTER 2: LITERATURE REVIEW

2.1. Introduction

Throughout the progression of medical and surgical practices, the evolution of anaesthesia has facilitated the development of complex surgical procedures by mitigating pain.[2] As the discipline of anaesthesiology has advanced, the scope of anaesthesiologists' responsibilities has expanded beyond the confines of operating theatres and PACU to encompass surgical wards as well.[2] Notably, effective pain management during the postoperative period is paramount in the continuum of postsurgical patient care.[2] According to the IASP, pain is defined as "an unpleasant sensory and emotional encounter linked with, or resembling, the experiences attributed to actual or potential tissue impairment."[2,14,23] Pain manifests as a multidimensional phenomenon encompassing various components, including objective, subjective, physiological, emotional and psychological facets.[2] Variations in the experience of pain are influenced by a multitude of factors, including, biological responses, psychological states, personality traits and social characteristics.[15] Paediatric pain management is an integral facet of healthcare, with the primary goal of alleviating suffering, fostering healing, and enhancing the overall well-being of young patients.[4]

Over the years, substantial advancements have been achieved in comprehending and addressing paediatric pain.[4] Nevertheless, challenges endure, prompting an increasing acknowledgement of the necessity for a more holistic and patient-centred approach to paediatric pain management.[4] Despite the availability of evidence-based guidelines, half of the children and adolescents still experience moderate to severe pain.[3] Paediatric pain is frequently underassessed and undertreated due to challenges in pain expression among children, which can result in its under recognition.[3,4]

2.2. Classification of pain

The heterogeneity of pain, stemming from differences in its duration, anatomical presentation, aetiology, intensity and pathophysiology, necessitates diverse classification methods to comprehensively capture its nuanced manifestations.[16] Pain classification according to duration includes acute or chronic categories and it is determined by the duration of time the patient experiences pain.[16] Acute pain is characterised as a physiological reaction and sensation triggered by noxious stimuli, which may potentially evolve into pathological states.[17] Typically, it manifests abruptly, has a finite duration and instigates behaviour aimed at averting actual or potential tissue damage.[17] Acute pain typically subsides within a period of fewer than seven days, though it frequently persists for up to thirty days.[18] Moreover, certain medical conditions may entail recurrent acute pain episodes.[18] Notably, acute pain may endure and transition into chronic pain in certain individuals.[18] Acute pain is anticipated following surgery and adequate postoperative pain management is paramount.[19] The principal decision-making challenge in acute pain management revolves around choosing interventions that offer adequate pain relief.[19] Furthermore, factors pertaining to the patient, such as age, gender, racial or ethnic background, severity of pain, presence of comorbidities, and genetic predispositions, significantly influence the management of acute pain.[19]

2.3. Postoperative pain

Surgery stands as a prevalent medical intervention employed for the treatment of diverse medical conditions.[20] In paediatric medicine, surgical interventions are frequently indispensable for treating congenital disorders, developmental abnormalities, or traumatic injuries.[20] While surgery holds considerable therapeutic

value, the occurrence of postoperative pain represents a common consequence that can impede a patient's recuperative process.[20] Acute postsurgical pain arises as a result of inflammation resulting from tissue trauma or direct nerve damage, and it can be categorised into nociceptive or neuropathic types.[21] Despite significant strides in the realms of anaesthesia and medicine, the effective management of postoperative pain remains deficient in a notable portion of patients.[2] The repercussions of inadequately managed pain are detrimental for both patients and the healthcare system.[2]

2.3.1. Pain physiology

Nociception refers to the physiological process through which information concerning tissue damage is transmitted to the central nervous system.[2] Nociceptors, specialised nerve endings, play a pivotal role in this process, as they are free, unmyelinated structures responsible for relaying diverse stimuli to the brain, which interprets them as pain.[2] Notably, many patients can perceive pain even in the absence of an evident noxious stimulus.[2] Figure 2.1 illustrates the process of pain transmission in the nociceptive pathway and encompasses four sequential steps.[2]

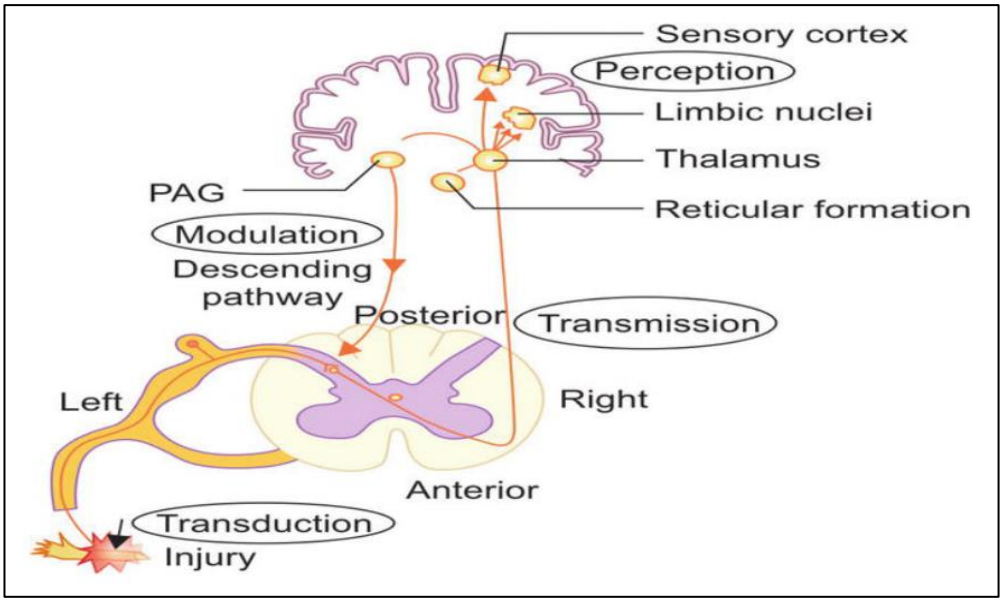


Figure 0-1: Nociceptive pain pathway[2]

- The process of pain transmission involves four fundamental steps namely:[2]
- *Transduction*: This initial stage entails the conversion of energy originating from a noxious thermal, mechanical, or chemical stimulus into electrical energy by nociceptors.
- *Transmission*: Subsequently, these electrical signals are conveyed from the peripheral nervous system to the spinal cord and ultimately to higher brain structures.
- *Perception*: At this juncture, the higher brain structures interpret and acknowledge these transmitted signals as the sensation of pain.
- *Modulation*: Finally, modulation occurs, wherein descending inhibitory or facilitatory inputs from the brain exert influence over nociceptive transmission at the level of the spinal cord, thereby modulating the perception of pain.

2.3.2. Pain pathway of acute postoperative pain

The etiology of acute postoperative pain is multifaceted.[2] Surgical tissue injury prompts the release of histamine and various inflammatory mediators, including bradykinin, prostaglandins, serotonin, and nerve growth factor.[2] These substances activate peripheral nociceptors, specialised nerve endings responsible for detecting noxious stimuli.[2] Subsequently, nociceptors transmit the nociceptive information to the central nervous system through processes of transduction and transmission.[2] The systemic response to surgery can significantly influence perioperative morbidity and mortality.[2] Various systemic responses emerge following surgery, such as activation of the sympathetic nervous system, the neuroendocrine stress response, and

inflammatory immunologic alterations.[2] Pathophysiologic changes as illustrated in Figure 2.2, commonly observed include:[2]

- *Neurohumoral alterations*, such as peripheral sensitisation, occur at the site of injury and in adjacent regions, contributing to heightened sensitivity to pain signals. Additionally, changes in synaptic function and nociceptive processing within the spinal cord and limbic cortex further modulate pain perception.
- *Sympatho-adrenal activation* triggered by surgery results in increased heart rate and blood pressure, accompanied by reduced regional blood flow. Moreover, the neuroendocrine response manifests as hyperglycaemia and a negative nitrogen balance, alongside alterations in synaptic function.

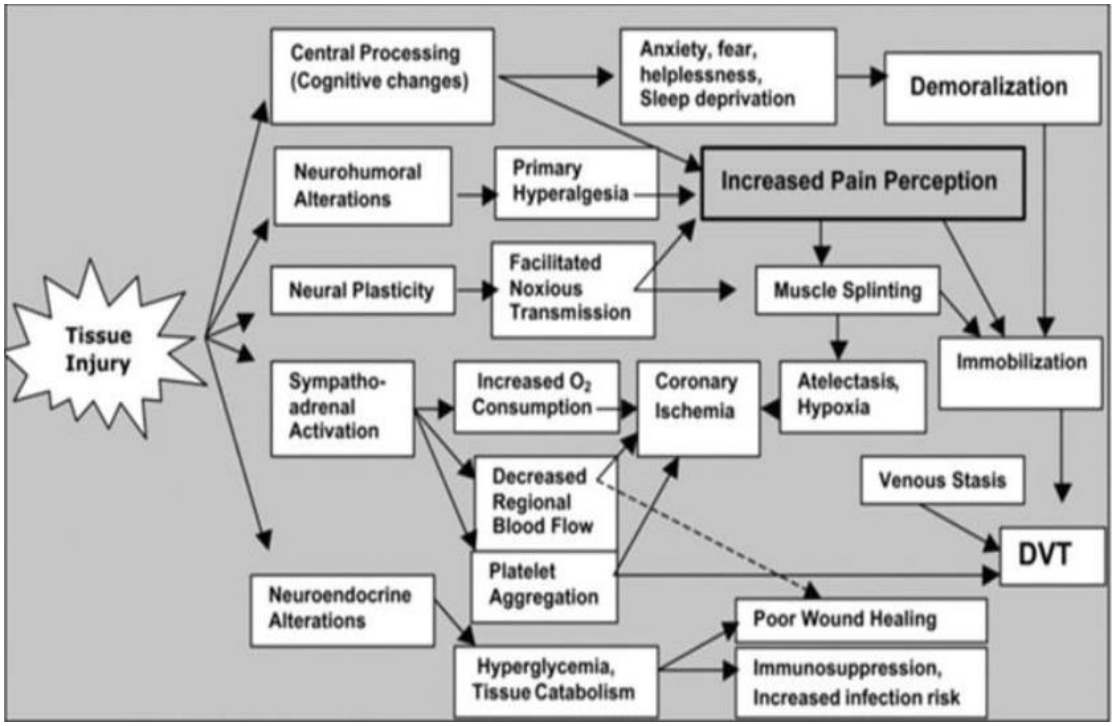


Figure 0-2: Pathophysiology of post-surgical pain[2]

2.3.3. Causes and symptoms of postoperative pain in paediatrics

Postoperative pain in children arises from various factors, which can vary depending on the type of surgery done. Common causes include tissue inflammation, manipulation of organs during surgery, the surgical incision itself, and muscle strain associated with the recovery period.[21] Additionally, psychological factors can also contribute to postoperative pain.[21]

Symptoms of postoperative pain in paediatric patients can manifest diversely, contingent upon the patient's age and the surgical procedure performed.[21] Common indicators of postoperative pain in paediatrics include[21]

- Persistent crying that cannot be comforted.
- Restlessness or irritability.
- Reluctance to consume food or fluids.
- Difficulty in falling or staying asleep.
- Alterations in heart and respiratory rates.
- Excessive perspiration.
- Changes in facial expressions such as furrowing of the brow or shutting of the eyes.
- Adopting a fetal position or displaying muscle tension.
- Reduced physical activity or movement patterns.
- Alterations in urination and bowel habits.

2.4. Challenges in managing pain in paediatrics patients

Identifying pain in paediatric patients poses challenges, particularly in young children or those unable to articulate their discomfort verbally.[4,21] Older children may convey

pain through verbal expressions and exhibit facial and bodily responses to painful stimuli.[21] The available evidence concerning the effectiveness of analgesics for guiding postoperative pain management in paediatric patients is sparse.[4,22] Opioid medications frequently constitute a crucial element of postoperative pain management in paediatric patients; however, their use has been linked to perioperative complications.[22] In their study, Ferland et al. explain that managing interpatient variability in postoperative pain is presently addressed through the application of protocols or via trial and error methods; however, this approach frequently results in patients being either under-treated or over-treated.[22] They further state that there is a scarcity of evidence-based reports available to provide guidance on the use of opioid medications in children.[22] Aziznejadroshan and colleagues, identified eight challenging areas in pain management in the paediatric wards, encompassing limited theoretical knowledge and insufficient skills among nursing staff, the influence of nurses' personal beliefs, organisational barriers, characteristics of parents and children, inadequate professional interaction, the ambiguous role of nurses in pain management, insufficient parental involvement or children's participation in pain management, and the scarcity of local protocols for pain management.[23] Factors such as inadequate training, language barriers, cultural diversity, limited resources, and the burden of disease were described to act as barriers preventing sick and injured children from receiving basic pain care in Sub-Saharan Africa.[24] Some medications lack approval, specifically for paediatric use, and dosing guidelines may not be well-established for this population.[4] This situation presents a challenge in paediatric healthcare, as there is a limited pool of approved drugs to use for paediatric pain management.[4] Therefore, there is a pressing need for further research and development of medications tailored to paediatric patients, as well as the establishment of robust dosing guidelines to ensure

safe and effective treatment.[4] Ethical and legal considerations frequently arise in paediatric pain management, particularly in situations where parents or caregivers hold different views regarding proposed pain management strategies.[4] Striking a balance between the child's best interests and parental preferences can be complex and challenging.[4]

2.5. Multimodal Analgesia

In recent years, important trends have emerged in paediatric pain management, reflecting advancements in understanding, treatment, and the overall approach to addressing pain in children.[4] Multimodal pain management, a prominent trend, involves the utilisation of diverse techniques and medications to tackle pain from various perspectives.[4] This approach recognises the multifaceted nature of paediatric pain and emphasises the necessity of employing a combination of strategies for effective pain relief.[4] Key components of multimodal pain management encompass non-opioid analgesics, regional anaesthesia, and psychological interventions.[4,22] Moreover, there has been a notable shift towards a more nuanced understanding of paediatric pain, acknowledging that children experience pain in distinct ways compared to adults.[25] Psychological and behavioural interventions have become an integral part of paediatric pain management.[25] Cognitive-behavioural therapy, distraction techniques and relaxation exercises are used to help children cope with pain, anxiety and fear related to medical procedures.[25] Non-pharmacological approaches, such as music therapy, art therapy, and virtual reality, are increasingly employed to distract and comfort children during painful procedures.[26]

An increasing focus on patient and family-centred care acknowledges the significance of involving children and their families in decision-making regarding pain

management.[4] This approach seeks to empower families to actively engage in pain control strategies.[4] These interventions not only diminish pain perception but also enhance the overall experience for young patients.[26] Regional anaesthesia techniques, such as epidurals and nerve blocks, are progressively employed for pain management in paediatric patients undergoing surgery or other medical procedures.[4] These techniques offer effective pain relief while reducing the need for systemic medications.[4] Further, opioid stewardship programs are becoming increasingly prevalent in paediatric healthcare settings.[4] These programs are designed to promote the responsible use of opioids, with a specific focus on mitigating the risk of opioid misuse, addiction, and overdose.[4] Employing combinations of nonopioid analgesics in a multimodal approach has the potential to reduce the necessity for opioids, thereby diminishing the risk of toxicity and dose-related side effects.[22]

2.6. Benefits of adequate pain management in paediatrics

Effective pain management in paediatric populations leads to the minimisation of negative physiological and behavioural responses, shortened durations of ventilation and oxygen therapy, facilitation of weight gain, enhancement of the overall treatment process, and reduction in the length of hospital stay.[23] The goals of postoperative analgesia in children are pain eradication, enhanced recovery, resumption of daily activities and prevention of progression of acute postsurgical pain to chronic pain or hyperalgesia.[5]

2.7. Consequences of undermanaged post-operative pain

Acute postoperative pain represents a typical reaction to surgical procedures and contributes to prolonged recovery periods and delayed discharge post-surgery,

alongside heightened susceptibility to wound infections and respiratory/cardiovascular complications.[21] Untreated post-surgical acute pain diminishes patient satisfaction, elevates rates of morbidity and mortality, and imposes financial strains on both the patient and the healthcare system.[21] When acute pain transitions into a persistent and unmanageable state, it is characterised as Chronic Post-Surgical Pain (CPSP).[21] CPSP exerts a notable influence on the individual's quality of life and daily functioning, often manifesting in disruptions to sleep patterns and affective states.[21] Inadequate pain management further yields various adverse outcomes for patients, including heightened anxiety, diminished communication abilities, disruptions in sleep patterns, impaired mobility, loss of appetite, restlessness, reduced quality of life, and escalated healthcare expenditures and hospitalisation costs.[23] Additionally, the long-term ramifications of poorly managed pain in children extend to an increased apprehension of future medical procedures stemming from prior traumatic experiences, heightened sensitivity to pain due to neurophysiological changes resulting from unaddressed pain, decreased efficacy of opioid medications, challenges in comprehending medical procedures, and the development of needle phobia.[23]

2.8. Caudal block

The caudal block was initially discovered for paediatric application in 1933, by Meredith Campbell for paediatric cystoscopies.[5,27] It stands as a widely recognised and secure technique necessitating minimal training.[27] Presently, it holds the distinction of being the most common nerve-blocking procedure employed in paediatric populations globally.[27,29] The caudal epidural block entails the insertion of a needle through the sacral hiatus to administer medications into the epidural space.[28] The caudal block was initially introduced as a landmark-based, blind technique and in children, the success

rate with this blind technique exceeds 96%.[28] A comprehensive understanding of the pertinent anatomy (see Figure 2.3) may enhance the success rate of caudal epidural needle placement while simultaneously mitigating the risks of complications. The caudal block is commonly complemented with general anaesthesia to achieve effective postoperative analgesia in paediatric patients undergoing procedures below the umbilicus such as inguinal hernia repair, circumcision, hypospadias repair, orchiopexy, lower extremity, perineal, and lower abdominal surgeries.[29,32]

In terms of age, the pubertal growth spurt has been observed to entail cranial migration of the spinal cord termination from the L3 to the L1–L2 level within a span of less than twelve months.[32] Caudal blocks are commonly employed in children under 7-8 years of age.[5] However, in older children, the thickening of the sacrococcygeal ligament poses a challenge in identifying the sacral hiatus, often leading to the omission of the block at this site.[5] From a pharmacological perspective, caudal blocks are both feasible and can be safely administered in children weighing up to 50 kg.[32] Regarding body positioning, Koo and colleagues demonstrated that positioning patients laterally with their neck, hips, and knees maximally flexed was correlated with a notable cephalad shifting of the dural sac.[32] In essence, proper patient positioning can aid in mitigating complications.[32]

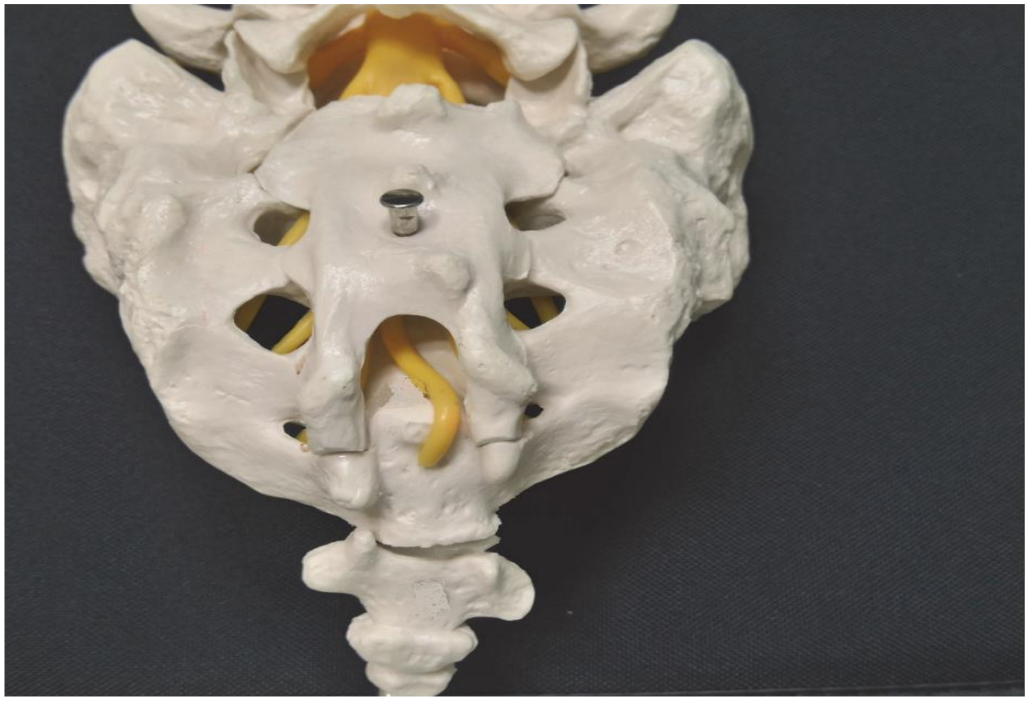


Figure 0-3: The posterior aspect of the sacrum.[28]

2.8.1. Advantages of caudal block

The caudal block procedure is predominantly regarded as safe and straightforward in paediatric patients when an accurate dosage of local anaesthetics is administered.[5] When administered alongside general anaesthesia, it diminishes the intraoperative requirement for inhalational agents or opioids.[29] Furthermore, caudal block may be favoured in high-risk patients as an alternative sole anaesthetic technique.[29] When employed as the sole method, it consistently achieves successful anaesthesia.[29] Day-case surgical procedures constitute the majority of interventions conducted by our paediatric surgery department globally.[29] Consequently, it is imperative to alleviate postoperative pain effectively and safely.[29] Given that these patients have shorter hospital stays and potential side effects may go unnoticed at home, ensuring optimal pain management is paramount.[29] Caudal block plays a crucial role in reducing the requirement for systemic analgesics which may pose various side effects, this technique is thus considered safe for day-case surgery.[29]

2.8.2. Complications associated with caudal blocks

Caudal blocks are associated with potential haemodynamic/systemic or local adverse events.[32] These may include arrhythmia, hypotension when combined with general anaesthesia, respiratory depression due to inadvertent spread of anaesthetics, seizures related to toxicity, infection/inflammation at the puncture site, sacral osteomyelitis, or local nerve injury.[32] However, the morbidity associated with any of these events is generally low.[32]

Suresh et al. conducted a study to assess the overall estimated incidence of complications associated with the performance of caudal block in children.[30] The study included 18 650 children who underwent a caudal block.[30] The overall estimated incidence of complications following caudal blocks was 1.9% (95% confidence interval [CI]: 1.7%–2.1%).[30] Patients who experienced complications were younger, with a median age (interquartile range) of 11 (5–24) months, compared to those without complications, whose median age was 14 (7–29) months (P = 0.001).[30] The most frequent complications observed were block failure, blood aspiration, and intravascular injection.[30] Notably, no instances of temporary or permanent sequelae were detected, resulting in an estimated incidence of 0.005% (95% CI: -% to 0.03%).[30] Moreover, 4406 out of 17 867 subjects (24.6%; 95% CI: 24%–25.2%) received doses exceeding 2 mg of bupivacaine equivalents per kilogram, which could potentially be unsafe.[30]

2.8.3. Contra-indications to caudal block

As with other neuraxial blocks, there are both relative and absolute contraindications to performing caudal blocks.[31] These include coagulation disorders, pilonidal cysts,

infection, and refusal to provide consent.[31,32] Furthermore, any cutaneous abnormalities present over the caudal region should ideally be thoroughly examined prior to performing a caudal block.[31] This assessment aims to rule out underlying spinal cord pathology, such as a tethered cord.[31]

2.8.4. Challenges of performing a caudal block in paediatric patients

Administering a caudal epidural block in paediatric patients demands significant expertise and a heightened level of proficiency, owing to their smaller anatomical proportions.[5] Infants and children exhibit a notably small distance to the epidural space, and the morphological changes accompanying age progression introduce variability, thereby complicating the estimation of the skin-to-epidural space distance.[5] Moreover, the pliable nature of connective tissue in this demographic attenuates the tactile feedback necessary for discerning loss of resistance when locating the epidural space.[5] Additionally, since regional blocks in paediatric populations are typically performed under deep sedation or general anaesthesia, subjective indicators of nerve impairment during needle insertion cannot be identified.[5] If infants and children are awake, they are prone to movement during palpation and needle placement which can result in more detrimental complications.[5] In 2015, The Joint Committee of European Society of Regional Anesthesia and Pain Therapy, and the American Society of Regional Anesthesia and Pain Medicine concluded that performing paediatric regional blocks under deep sedation or general anaesthesia is deemed acceptable in terms of safety and may indeed be established as a standard of care.[5] However, it is imperative to acknowledge the potential for neurological injury associated with epidural blocks, which, while rare, represents a serious complication necessitating vigilant attention and caution.[5]

2.8.5. Caudal block procedure

The caudal block procedure is performed with the patient positioned laterally with the dorsal aspect facing the individual performing the procedure.[27] The technique of caudal block is relatively straightforward to acquaint oneself with.[5] At birth, the sacral vertebral plate is less ossified, and the sacral vertebrae are connected by cartilage.[5] Over time, progressive ossification and union of the plate occur, culminating in a single structure post-puberty.[5] Conversely, posterior fusion at the S4 and S5 levels remains incomplete, with this region covered by the sacrococcygeal ligament, formed through a firm connection between the ligamentum flavum and other sacral ligaments.[5] The sacral hiatus assumes a triangular shape, bilaterally delimited by the sacral cornua.[5] The entrance to the sacral canal comprises the inferior articular processes of S5 and the lower extremity of the dorsal sacrum.[5] This region serves as the point of access to the sacral epidural canal, allowing for needle insertion through the sacral hiatus.[5] The degree of protrusion of the sacral cornua varies among individuals, with the potential for asymmetry or bluntness; in adults, the hiatus may even be entirely obscured by the complete fusion of the lamina.[5] A line is drawn connecting the bilateral posterior superior iliac crests, serving as one side of an equilateral triangle, to approximate the location of the sacral hiatus.[28] By palpating the sacral cornua as two bony prominences, the sacral hiatus can be identified as a dimple situated between them.[28] A needle is then inserted at a 45-degree angle to the sacrum and redirected if it contacts the posterior surface of the sacral bone.[28] A subjective sensation of "give" or loss of resistance indicates penetration of the sacrococcygeal ligament.[28] Before the administration of local anaesthetic, careful aspiration or passive drainage is necessary to exclude inadvertent intravascular or spinal needle placement.[32]

2.8.6. Local anaesthetic medication used in caudal blocks

In caudal block, the most utilised local anaesthetic agent is bupivacaine.[29] This preference is due to its ready availability, prolonged duration of action, and well-established understanding of its side effects.[29] A caudal injection of bupivacaine as the sole local anaesthetic yields effective postoperative analgesia for 2 to 4 hours without the need for additional analgesics.[29] Levobupivacaine, an isomer of bupivacaine, offers several advantages when compared to bupivacaine.[29] It tends to induce less motor blockade while prolonging sensory blockade.[29] Moreover, it exhibits reduced toxicity to the central nervous and cardiovascular systems.[29] Given these advantages, anaesthetists may prefer levobupivacaine.[29] Levobupivacaine is not available in our setting.[32] Armitage, a British anaesthesiologist, introduced the caudal block dosing regimen of local anaesthetic agents for various surgical levels.[27] The Armitage formula is outlined below:[33]

- 0.5ml/kg of 0.25% bupivacaine for a lumbosacral block
- 1ml/kg of 0.25% bupivacaine for a thoraco-lumber block
- 1.25ml/kg of 0.25% bupivacaine for a mid-thoracic block.

The inventor of the above formula, Armitage, further recommends the administration of 0.25% (levo)bupivacaine for caudal block up to a maximum of 20 ml.[34] For larger volumes he recommends making 0.19% bupivacaine by adding one part of 0.9% NaCl to three parts local anaesthetic agent.[34] A concentration of 2.5 mg/ml for bupivacaine should not be exceeded.[32]

Ropivacaine is another local anaesthetic agent used at concentrations from 0.1% to 0.375% for caudal block. Current guidelines advise that the ropivacaine dose should

not surpass 2 mg/ml. Ropivacaine is recognised for inducing less postoperative motor blockade compared to bupivacaine.[32] Its systemic absorption from the caudal epidural space is prolonged, although this can be further extended by the addition of epinephrine, typically diluted at a ratio of 1:200,000.[32]

Systemic toxic events resulting from local anaesthetics may encompass cardio- or neurotoxicity.[32] Current guidelines advocate for the treatment of any hemodynamic deterioration with Intralipid® 20% as the first-line therapy, accompanied by epinephrine/adrenaline for cardiopulmonary resuscitation until circulation is restored or extracorporeal membrane oxygenation is initiated.[32] Intralipid® should be administered intravenously in these situations as a rapid bolus injection of 1 to 1.5 ml per kilogram followed by continuous infusion (0.25 mg per kilogram per minute) and repeated boluses every 3 to 5 minutes up to 2 to 5 (approximately 10) ml per kilogram.[32] Some protocols suggest the administration of maintenance fluid (0.25 ml per kilogram per minute) as beneficial.[32] Neurotoxic seizures should be managed with propofol, benzodiazepines, or barbiturates.[32] Recent discussions concerning the influence of cardiac output on the vascular absorption of drugs from tissue have proposed that adjusting doses of local anaesthetics to account for the higher heart rate in children under two years old may reduce the risk of systemic toxicity further.[32]

2.8.7. Adjuvants used in caudal block

Local anaesthetic agents used alone for caudal blocks provide a relatively short duration (four to eight hours) of analgesia following a single-shot injection.[36] The duration of the caudal block analgesic effect can be prolonged by administering adjuvant drugs into the caudal space alongside a local anaesthetic agent, resulting in more effective postoperative analgesia.[29] To achieve this goal, various drugs are

employed as adjuvants, including epinephrine, ketamine, opioids, and α2-adrenergic agonists, amongst others.[29,36] Other adjuvants such as ketamine, morphine and diamorphine are no longer recommended because of the high incidence of side effects like neuronal apoptosis and urinary retention, respectively.[35]

Dexmedetomidine was the adjuvant of choice in this study.

2.8.8. Dexmedetomidine as an adjuvant to caudal blocks

Dexmedetomidine, the active dextro-isomer of medetomidine, functions as a highly selective α2-adrenergic agonist, exhibiting an eight-fold greater affinity for the α2-adrenergic receptors compared to clonidine.[36] Stimulation of postsynaptic α2-adrenergic receptors within the central nervous system activates pertussis toxin-sensitive G proteins, resulting in sedation and anxiolysis.[36] Dexmedetomidine's sedative properties mimic those of natural sleep, with minimal impact on central control of ventilation, rendering it a preferred agent for sedation in intensive care unit settings.[36] Its analgesic properties stem from interactions with central α2-adrenergic receptors within the central nervous system and spinal cord, leading to reduced release of nociceptive substances, including substance P.[36]

Saadawy et al. conducted the first randomised controlled study of dexmedetomidine in caudal block in the paediatric population. They studied sixty children (ASA status I) aged 1–6 years undergoing unilateral inguinal hernia repair/orchidopexy. In this study, patients were randomly assigned to one of two groups (N=30 each) to receive a caudal epidural injection of 0.25% bupivacaine at a dose of 1 mL/kg with or without dexmedetomidine at a dose of 1 μg/kg.[37] The authors observed both local analgesic effects and systemic effects in patients who received caudal dexmedetomidine. They

found that intraoperative sevoflurane requirements were significantly lower in patients receiving bupivacaine-dexmedetomidine compared to those receiving bupivacaine alone (0.5±0.2% versus 1.3±0.2% before starting skin closure).[37] Additionally, the incidence of postoperative agitation was significantly lower in the bupivacaine-dexmedetomidine group (7% versus 27%).[37] Moreover, the duration of analgesia was significantly longer, and the total consumption of rescue analgesics was significantly lower in patients who received caudal epidural dexmedetomidine.[37] During the 24-hour postoperative period, 77% of children in the bupivacaine-dexmedetomidine group did not require additional analgesia, compared to only 10% in the bupivacaine group. Importantly, there was no difference in the hemodynamic pattern between the two groups.[37] The authors concluded that caudal epidural dexmedetomidine provided excellent analgesia without adverse effects over a 24-hour period, with the additional benefit of providing anxiolysis and sedation.[37]

Meenakshi Karuppiah et al. conducted a study involving children aged 6 months to 8 years undergoing elective sub-umbilical surgery, a cohort of 84 patients was divided into three groups:

1. Group BD0 receiving bupivacaine 0.25% at a dose of 1 mL/kg as a control group
2. Group BD1 receiving bupivacaine 0.25% at a dose of 1 mL/kg along with dexmedetomidine at a dose of 1 μg/kg.
3. Group BD2 receiving bupivacaine 0.25% at a dose of 1 mL/kg along with dexmedetomidine at a dose of 2 μg/kg.

The demographic characteristics were comparable among the groups. Anal sphincter relaxation 5 minutes after administration of the caudal block (CB) was observed in

89.3%, 82.1%, and 75% of cases in the BD0, BD1, and BD2 groups, respectively.[38] Sphincter relaxation was achieved at the end of surgery in all cases. Comparable hemodynamics were noted, with a significantly prolonged duration of analgesia in the BD1 (964.2 ± 309 minutes) and BD2 (1152.6 ± 380.4 minutes) groups compared to the control (444.6 ± 179.4 minutes).[38] While no complications were encountered in groups BD0 and BD1, bradycardia was observed in four cases of the BD2 group, accompanied by hypotension in one case.[38] They concluded that dexmedetomidine, as an adjuvant to bupivacaine, improves the quality of caudal block, provides good operating conditions, and increases the duration of postoperative analgesia.[38] The study suggests that a dose of 1 μg/kg of dexmedetomidine is as effective as 2 μg/kg with a better safety profile.[38]

Al-Zaben et al. conducted a study in which 75 children aged 1-6 years undergoing elective lower abdominal and perineal surgery were recruited and the children were divided into three groups.[39] The study aimed to compare the analgesic efficacy and safety profile of these three regimens in paediatric patients undergoing elective lower abdominal and perineal surgery.[39] All patients received 1 mL/kg caudal 0.25% bupivacaine. Additionally, patients in Group B (n = 25) received 10 mL IV saline, those in Group B-Dcau (n = 25) received 1 μg/kg caudal dexmedetomidine and 10 mL IV saline, and those in Group B-DIV (n = 25) received 1 μg/kg IV dexmedetomidine in 10 mL saline.[39] Intraoperative mean blood pressure, heart rate, peripheral oxygen saturation, end-tidal sevoflurane, and bispectral index, as well as postoperative pain and behaviour scores and time to first analgesia, were assessed.[39] The main results indicated that Group B-Dcau had a significantly longer time to first rescue analgesia compared to groups B-DIV and B, with mean (SD) values of 14.4 (7.5), 9.18 (2.7),

and 6.6 (2.5) hours, respectively ($P < .05$).[39] Fewer patients in Group B-Dcau required rescue analgesia during the first 24 hours postoperatively compared to Group B and Group B-DIV ($P < .05$).[39] Furthermore, groups B-Dcau and B-DIV had lower pain and behaviour scores than Group B.[39] Eight patients in Group B experienced agitation compared to 2 in Group B-DIV and none in Group B-Dcau.[39] Four patients in Group B-DIV developed bradycardia and hypotension during surgery.[39] This study suggested that caudal administration of dexmedetomidine during caudal bupivacaine anaesthesia provided prolonged postoperative analgesia and a greater analgesic-sparing effect without significant side effects compared to IV administration.[39] This suggests a greater role of neuraxial compared to peripheral α-2 adrenoceptors in pain management.[39]

Goyal et al. studied 100 children categorised as ASA physical status I and II, aged 2–10 years, scheduled for elective infraumbilical surgeries.[40] They were divided into two groups: Group A received (0.25%) bupivacaine 1 ml/kg + normal saline (NS) 1 ml, while Group B received (0.25%) bupivacaine 1 ml/kg + 1 µg/kg dexmedetomidine in 1 ml NS.[40] Patients were randomly assigned to receive either (bupivacaine + saline) or (bupivacaine + dexmedetomidine) in each group. Hemodynamic stability, respiratory depression, and postoperative pain were monitored using the Face, Legs, Activity, Cry, Consolability (FLACC) pain scale for 24 hours postoperatively.[40] A FLACC score is used for nonverbal or preverbal patients who are unable to self-report. The pain is assessed through observation of five categories. A score of 0 to 3 is classified as none or mild pain, 4 to 6 as moderate pain and 7 to 10 is classified as severe pain. Statistical Analysis Used: Unpaired Student's t-test was employed for statistical analysis.[40] The results showed that the mean duration of effective analgesia in Group A patients was

4.33 ± 0.98 hours, compared to 9.88 ± 0.90 hours in Group B patients.[40] Furthermore, the difference in mean FLACC score between the two groups was statistically significant, with values of 7.21 ± 0.76 and 6.49 ± 1.72 in Group A and Group B, respectively.[40] The study concluded that dexmedetomidine, when used as an adjuvant to bupivacaine, increases the duration of caudal analgesia and improves hemodynamic stability without an increase in adverse effects in children undergoing infraumbilical surgeries.[40]

2.9. Pain Assessment tools in paediatrics patients

Effective pain management in children commences with comprehensive pain assessment.[23] The assessment of paediatric pain has evolved to encompass a more nuanced approach, considering factors such as the child's developmental stage, communication abilities, and emotional responses.[4] To ensure accurate assessment of paediatric pain, age-appropriate pain assessment tools and scales have been developed.[4] These tools consider the cognitive and linguistic abilities of children at various developmental stages, thereby ensuring effective assessment and management of pain.[4] It is imperative for healthcare professionals attending to paediatric patients to possess proficiency in pain assessment techniques and employ appropriate assessment tools tailored to the child's age and developmental stage, thereby ensuring accurate identification and management of pain.[21]

Appropriate assessment of pain in paediatric patients includes evaluating pain location, quality, duration, and intensity.[41] This assessment necessitates the use of a developmentally appropriate tool tailored to the child's age and cognitive abilities.[41] In addition to initial assessment, repeated assessments post-intervention is crucial for

evaluating the effectiveness of pain management strategies and ensuring ongoing comfort and well-being in paediatric patients.[41]

2.9.1. Self-reporting pain scales

Self-reported pain scales are essential tools used to assess pain in paediatric patients. These scales typically include age-appropriate visual analogue scales (VAS), numerical rating scales (NRS), faces pain scales (FPS), or other tools that allow children to communicate their pain intensity effectively.[41] These scales are valuable for obtaining subjective pain ratings directly from the child, enabling healthcare providers to monitor pain levels and adjust treatment accordingly.[41] Whenever feasible, it is preferable to assess children's pain through self-reporting rather than relying on proxy reports.[41] Pain scales should be utilised according to guidelines, ensuring consistent and standardised scale anchors to facilitate accurate comparison and interpretation of pain intensity over time.[41] This approach enhances the reliability and validity of pain assessment in paediatric patients.[41]

2.9.2. Observational pain assessment

Observational pain measures are essential tools for assessing pain in non-verbal or pre-verbal paediatric patients who are unable to self-report their pain.[41] These measures involve observing behavioural cues and physiological responses that indicate pain, such as facial expressions, body movements, vocalisations, changes in vital signs, and changes in sleep patterns.[41] Healthcare providers trained in recognising these signs can use observational pain measures to assess pain and guide pain management interventions effectively in this population.[41] Changes in vital signs, such as heart rate, respiratory rate, and blood pressure, can sometimes indicate pain in infants but are not

consistently reliable indicators of pain in older children.[41] It is important to note that the absence of changes in vital signs does not necessarily imply the absence of pain in children.[41] In situations where self-report of pain is not feasible, such as in young children, those with cognitive impairments, or those on mechanical ventilation, behavioural pain scales or checklists should be utilised instead.[41] These tools allow healthcare providers to assess pain based on observable behaviours and responses, providing valuable insight into the child's pain experience.[41] Out of the numerous observational pain instruments currently available, only a select few are recommended for clinical use.[41] For infants, the Neonatal Infant Pain Scale (NIPS) and the FLACC scale are most commonly recommended.[41] However, recent systematic reviews have also suggested that the EValuation ENfant DOuLeur (EVENDOL), COMFORT, and Neonatal Facial Coding System (NFCS) scales may have a lower risk for bias compared to other tools.[41] These recommended scales provide healthcare providers with reliable and validated methods for assessing pain in infants and young children who are unable to self-report their pain.[41]

CHAPTER 3: RESEARCH METHODOLOGY

3.1. Introduction

This chapter describes the procedural framework employed in conducting the study, offering a comprehensive overview of its design, materials implemented, and the methodologies undertaken.

3.2. Study location

The research was conducted at Windhoek Central Hospital, which serves as a tertiary referral hospital located in Windhoek, Namibia. The hospital has two dedicated general paediatric surgical wards, one with a 30-bed capacity, and the other with a capacity of 15 beds.

3.3. Study population

3.3.1. Inclusion criteria

The research comprised a population size of 50 children aged 1 year to 8 years going for infra-umbilical surgeries belonging to the American Society of Anaesthesiologists (ASA) physical class I. The participants were recruited in the study after a written informed assent form was signed by the participants' parent(s) or legal guardian.

3.3.2. Exclusion criteria

1 Children below the age of 1 year and above the age of 8

2 Children with an ASA status from 3 and above

3 Children with coagulation disorders, anatomical abnormalities of the spine

4 Patients with body weight > 25 kg

5 local infection at the site of needle entry

6 History of allergy to local anaesthetic agents and dexmedetomidine.

7 Parent or legal guardian refusal

8 Parents/legal guardians who cannot speak any of the translated languages for the assent form.

9 If an emergency arises, the incident will be recorded however the patient will be withdrawn from the study.

10 Absence of a translator to explain the study to the patients' parents/legal guardians.

3.4. Research design

The study conducted was a prospective randomised double-blinded control study, and it was done over a period of 4 months (October 2023 to February 2024). The study included children scheduled for elective infra-umbilical surgeries namely: circumcisions, inguinal hernia repairs, hydrocelectomies and orchidopexies on general paediatric surgery and urology lists. The participants were reviewed the day before surgery for a pre-operative assessment, during which the principal investigator (PI) introduced herself to the patients' parents or legal guardians. The PI provided a detailed explanation of the study, elucidating the benefits of the caudal block procedure and the potential side effects it may cause. All queries and concerns were addressed by the PI before obtaining voluntary signed written assent forms from the patients' parent(s) or legal guardian. These assent forms were translated into eight different languages to ensure comprehension by the parent(s) or legal guardian, and they were provided in the language understood by the recipient. In cases where a language barrier existed between the PI and the parent(s) or legal guardian, a translator was engaged. The

translator also signed a form attesting to the accurate translation of information. Additionally, an information sheet detailing the caudal block procedure was handed out to all participants' parent(s) or legal guardian to keep.

The recruited 50 participants were divided into two groups, namely Group A and Group B, each comprising 25 children. Group A received a caudal block with 0.25% bupivacaine at a dose of 0.5 or 1ml/kg, whereas Group B received a caudal block with 0.25% bupivacaine, calculated at a dose of 0.5 or 1ml/kg, supplemented with dexmedetomidine (1mcg/kg). The dosage of bupivacaine was determined using the universal weight-based Armitage formula, outlined below:[33]

- 0.5ml/kg of 0.25% bupivacaine for a lumbosacral block
- 1ml/kg of 0.25% bupivacaine for a thoraco-lumber block
- 1.25ml/kg of 0.25% bupivacaine for a mid-thoracic block.

The inventor of the above formula, Armitage, further recommends administration of 0.25% bupivacaine for the caudal block up to a maximum of 20ml.[34] For larger volumes he recommends making a 0.19% bupivacaine by adding one part of 0.9% NaCl to three parts local anaesthetic agent.[34] In this study, the dosage of bupivacaine for caudal blocks administered to participants undergoing circumcisions was calculated at 0.5ml/kg of 0.25% bupivacaine. For procedures such as hydrocelectomies and inguinal hernia repairs, a dosage of 1ml/kg of 0.25% bupivacaine was uniformly applied.[33]

3.5. Sample size determination

The sample size was derived from a similar study done in Cairo.[42] It assessed pain scores between caudal bupivacaine with dexmedetomidine and caudal bupivacaine with morphine in paediatric infra-umbilical surgeries.

The sample size was calculated using Kirkwood formula for more than one group for Two Independent Samples:

$$n = \frac{2\sigma^2 [Z(1-\alpha/2) + Z(1-\beta)]^2}{\delta^2}$$

δ is the target or anticipated difference in mean outcomes between the two groups

σ is the SD of the outcome post-randomisation (which is assumed to be the same in both groups)

$Z1 - \alpha/2$ *and* $Z1 - \beta$ are the appropriate values from the standard normal distribution for the $100\ (1 - \alpha/2)$ and $100\ (1 - \beta)$ percentiles, respectively

With 80.0% = power of test/study, $Z(1-\beta) = 1.282$

$Z(1-\alpha/2) =$ 95% confidence level $= 1.96$

Therefore,

$$n = \frac{2(4.1)^2\ (1.96 + 1.282)^2}{4^2}$$

$$= \frac{33.62 \times 10.51}{16} = \frac{353.35}{16}$$

$$= 22.08$$

$$n = 22$$

With 10% attrition, $N = 24.5$

Therefore, for each group, the number to consider will be 25

For the two groups = 50

The required sample size for this study will be 50

A standard deviation of 4.1 from the study done in Cairo is used.

3.6. Randomisation and Blinding

Following the recruitment of eligible participants, a research assistant (RA) engaged with the participants' parent(s) or legal guardian the day before surgery, subsequent to the principal investigator's (PI) explanation of the study details, acquisition of informed assent forms, and confirmation of patients' suitability for anaesthesia. Randomisation was accomplished by instructing each participant's parent or legal guardian to blindly select a ballot paper from an opaque brown envelope initially containing 50 papers of which 25 were labelled with letter A belonging to Group A of participants and 25 were labelled with letter B belonging to Group B. These papers were uniform in shape and size, shuffled, and enclosed in a sealed envelope stored in a locker accessible to the RA. This process occurred in the absence of the PI.

Upon drawing a letter from the envelope, the RA recorded each selection in a logbook accessible only to her and an Anaesthetist Consultant (AC) responsible for drug preparation. Each drawn letter was then placed in a separate opaque brown envelope, labelled with the participant's unique serial number, and sealed. These envelopes were exclusively opened by the AC responsible for drug preparation on the day of surgery. Following the drug preparation procedure adhering to aseptic techniques, the AC

handed the drugs to the PI for the caudal block procedure. The syringe with the drugs for the caudal block solely featured the patient's unique serial number, thus only the RA and the AC knew the drugs administered for the caudal block for every participant. The logbook and the sealed envelope were kept in a safe locker on the hospital premises in case of an emergency.

Subsequently, the PI monitored patients both intra- and post-operatively. Besides, two ward nurses (one each for day and night shifts) received training in utilising pain and sedation scoring systems, as well as determining the appropriate administration of rescue ibuprofen syrup. The PI, surgeon, and the two ward nurses remained blinded to the group assignment of each participant, including the drugs administered for the caudal block.

3.7. Data collection method

The data were collected using a structured questionnaire for all the eligible participants.

3.7.1. Anaesthesia

Pre-operative

Patients were recruited in the study, and signed informed assent forms were collected. A preoperative assessment of anaesthesia was conducted the day before surgery, during which patient details were documented, and baseline vital signs (blood pressure, heart rate, respiratory rate, oxygen saturation) were measured. Further, patients blindly selected their group assignments the day before surgery. All recruited patients adhered to paediatric fasting guidelines as outlined in Table 3.1, ensuring

appropriate fasting prior to the procedure. Notably, none of the patients received premedication.

Table 0-1: Paediatric fasting times[43]

Substance	Fasting period
Clear fluids	1 h
Breast milk[a]	3 h if <12 months age
Formula milk[a]	4 h if <12 months age
Solids, cow's milk	6 h

Intra-operatively

Upon arrival in the operating theatre, all patients underwent general anaesthesia with inhalation induction. Standard monitoring devices, including a non-invasive blood pressure cuff, electrocardiograph leads, oxygen saturation probe, and temperature probe, were placed on every patient. Intravenous access was established, and Ringer's lactate solution was administered according to each patient's maintenance fluid requirements based on the 4:2:1 rule. Induction agents, namely, Fentanyl at 2mcg/kg and Propofol at 2mg/kg, were administered. A weight-appropriate laryngeal mask airway device was inserted for most patients; however, in one case where such a device was unavailable, endotracheal intubation with an age-appropriate endotracheal tube was done. Following airway securing, the principal investigator (PI) performed a caudal block procedure with the patient in a lateral position, with hips and knees flexed. The caudal block was administered using a 22-gauge cannula under an aseptic technique and landmark guidance. Drugs for the caudal block were prepared by the assigned anaesthetic consultant, with the syringe provided to the PI labelled solely with the participant's unique serial number. Subsequently, the time of caudal block administration was recorded, and the patient was repositioned supinely.

Adequate analgesic coverage post-caudal block was ensured by monitoring hemodynamic stability, defined as the absence of a more than 15% increase in systolic blood pressure and/or heart rate from baseline at the time of surgical incision. Surgical incision commenced ten minutes following caudal block administration. In cases where an intraoperative increase exceeding 15% in systolic blood pressure and/or heart rate was observed, rescue analgesic agents were administered, resulting in exclusion from the study. All surgical procedures were completed within 1 hour and 30 minutes.

Intraoperatively, all patients received intravenous paracetamol at 20mg/kg as part of a multimodal analgesia approach, alongside prophylactic antibiotics of cefuroxime at 50mg/kg. Intraoperative monitoring was conducted by the PI, and all children were safely extubated and transferred to the Post-Anaesthesia Care Unit (PACU) in a fully awake state.

Post-operatively

Postoperatively, patients' vital signs (blood pressure, heart rate, respiratory rate, and oxygen saturation) were monitored at specified time intervals: 0, 30 minutes, 1 hour, 2 hours, 4 hours, 6 hours, 12 hours, and 24 hours. Pain and sedation levels were assessed concurrently using modified Hannallah Pain scores and Ramsay sedation pain scores at the same time intervals as the vital sign monitoring.

All patients received oral paracetamol at 15ml/kg every 6 hours postoperatively as part of a multimodal analgesic approach. Additionally, oral ibuprofen syrup, calculated at 10mg/kg, was administered as a rescue drug when the modified Hannallah Pain score was ≥4 for any participant. Ibuprofen syrup administration was continued every 8 hours thereafter. The time of rescue ibuprofen syrup administration was recorded in

minutes, and the analgesic efficacy of drugs administered in the caudal block was calculated from the time of the caudal block performed to rescue ibuprofen syrup administration. The total consumption of ibuprofen syrup over 24 hours for each patient was also determined.

Common side effects of caudal blocks, including nausea, vomiting, pruritis, and urinary retention, were monitored throughout the observation period. Patient satisfaction with the analgesic treatment postoperatively was evaluated.

Patients were accommodated in rooms near the nursing station, and parents or caregivers were instructed to notify nurses or doctors of any unusual symptoms. Emergency drugs and resuscitative equipment, including an emergency airway trolley and defibrillator, were readily available. The PI remained on standby and in close proximity to the hospital in case of emergencies, with a consultant anaesthetist also available for assistance.

All forms were collected daily, securely stored, and sealed envelopes with patient-assigned group numbers. These envelopes were kept in a separate locker accessible only to the research assistant (RA) and the consultant anaesthetist responsible for drug preparation. Subsequently, all forms and assigned group numbers were handed over to a statistician for data capture and analysis.

3.8. Data analysis

The statistician compiled data from all 50 questionnaires, captured them and statistical analysis was performed using the Statistical Package for Social Sciences (SPSS version 26 software). Continuous variables were expressed as mean ± standard deviation (SD), while proportions were presented as percentages. Nominal variables

were represented as numbers with corresponding percentages. Descriptive statistics were employed to summarise patient demographics, procedure types, patient satisfaction, and side effects.

Differences between Group A, which received 0.25% bupivacaine alone, and Group B, which received 0.25% bupivacaine with dexmedetomidine, were assessed using Student's t-test for continuous variables and the chi-square test for nominal variables. A significance level of $p < 0.05$ was considered statistically significant. Results were tabulated and graphically presented in tables and figures. Data interpretation was conducted with assistance from the statistician.

3.9. Research Ethics

The researcher obtained ethical clearance from both the University of Namibia Human Research Ethics Committee (Appendix i) and approvals from the Ministry of Health and Social services and Windhoek Central hospital (Appendix ii and iii respectively) to conduct the research study. This clearance ensured that the study adhered to ethical standards and regulations governing research involving human participants.

3.9.1. Informed assent

Informed assent was obtained from the patient's parent(s) or legal caregivers. This process involved a detailed explanation of the research purpose, procedural steps, and potential complications, both verbally and in written form. The patient's parent(s) or caregiver signed the written form in the presence of the principal investigator (PI). Additionally, an information sheet outlining the caudal block procedure was provided to each participant's parent or legal guardian for reference. Assent forms were provided in the language understood by the participant's parent(s) or legal guardian, and in cases

of language barriers, a translator was utilised. The translator also signed a form affirming the accurate translation of information.

3.9.2. Voluntary participation

Participation in the study, as well as the option to withdraw from it, was entirely voluntary. No implicit or explicit benefits were promised or implied to the participants.

3.9.3. Confidentiality of data

All patient information was handled with strict confidentiality. The collected data was securely stored in a lockable safe and will be disposed of through shredding and burning when it is no longer needed.

3.9.4. Anonymity

The researcher took deliberate measures to safeguard the rights of participants and uphold the anonymity of all participants throughout the study. Serial numbers were employed as identifiers for patients, ensuring confidentiality. Any complications observed in participants during the study were going to be promptly and adequately managed, with reports submitted to the ethics and research committee, and parents or guardians were also going to be informed. Fortunately, no side effects or emergencies were reported or encountered during the research period.

3.9.5. Beneficence to participants

All patients recruited in the study were managed in strict accordance with the ethical standards outlined by the Ministry of Health and Social Services and the Health Professions Council of Namibia. Postoperative analgesia was provided to all patients as necessary to effectively manage postoperative pain. No patient was deprived of

essential treatment solely for the purpose of the study. All analgesic agents were administered punctually according to the prescribed schedule.

3.9.6. Non-Maleficence to participants

All safety and precautionary measures were observed throughout the study. The caudal block was performed under an aseptic technique and the procedure was aborted after the third attempt of being unsuccessful. Safe anaesthesia was also provided to all patients. Emergency airway trolleys, emergency drugs, and resuscitative equipment were all readily available in theatres and wards in case of complications and adverse effects. The anaesthetic consultants covering the theatre suite were also informed before the procedure was started to assist should a need arise. The PI remained on standby and in close proximity to the hospital in case of emergencies, with a consultant anaesthetist also available for assistance throughout the period of the study.

3.9.7. Dissemination of results

The outcomes of the study will be disseminated locally within relevant departments and may be published in Anaesthesia or other scientific journals for broader dissemination and contribution to the scientific community.

CHAPTER 4: RESULTS

Fifty (50) children aged 1 to 8 years booked for elective infraumbilical surgeries from general paediatric surgery and urology lists were recruited for the study. The 50 children were randomly divided into two groups (A and B) of 25 children as shown in Table 1. Group A received a caudal block with 0.25% bupivacaine at a dose of 0.5 or 1ml/kg depending on the level of surgery. Group B received a caudal block with 0.25% bupivacaine at a dose of 0.5 or 1ml/kg depending on the level of surgery with dexmedetomidine 1mcg/kg. All children recruited were ASA 1.

4.1. Gender distribution

Out of the 50 children recruited for the study, there was only one female patient, who happened to be in Group A.

4.2. Age distribution of participants

Table 0-1: Age distribution of the study participants

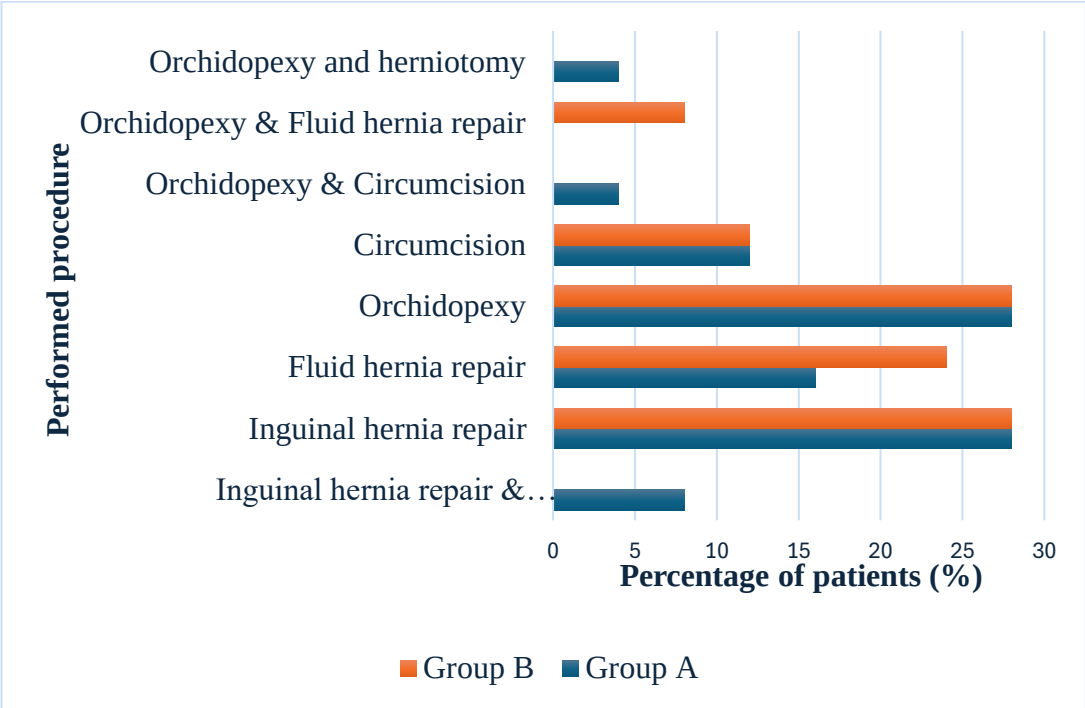
Variable	Group A	Group B
Total number	25	25
Mean age (years) ± SD	3.3 ± 2.1	4.4 ± 2.3
Minimum Age	1	1
Maximum age	8	8

Group A patients were relatively younger than the Group B participants. However, this difference is not statistically significant.

4.3. Surgical procedures performed on the study participants

Figure 4.1 below indicates the procedures performed on the study participants, comparable between Group A and Group B.

Figure 0-1: Surgical procedures performed on the study participants



4.4. Comparison of the postoperative pain scores between the two groups

According to Table 4.2, the mean pain scores were comparable at most intervals of measurement postoperatively. However, at time 0 (zero), time 240 min (4 h) and time 360 min (6 h), the pain scores were significantly lower in Group B participants than in Group A, $p < 0.05$. After the 6 h measurement point, low pain scores were recorded between both groups with no significant difference.

Table 0-2: Postoperative pain score for the two groups

Time (min)	Group A (n=25)	Group B (n=25)	P value
0 (in PACU)	1.76 ± 1.20	0.92 ± 1.02	0.01*
30	1.45 ± 1.05	0.96 ± 1.02	0.08
60	0.76 ± 0.93	0.46 ± 0.72	0.21
120	0.56 ± 0.82	0.40 ± 0.65	0.45
240	1.00 ± 1.35	0.28 ± 0.61	0.02*
360	1.36 ± 1.68	0.04 ± 0.20	0.00*
720	0.08 ± 0.40	0.00 ± 0.00	0.33
1440	0.04 ± 0.20	0.08 ± 0.40	0.66

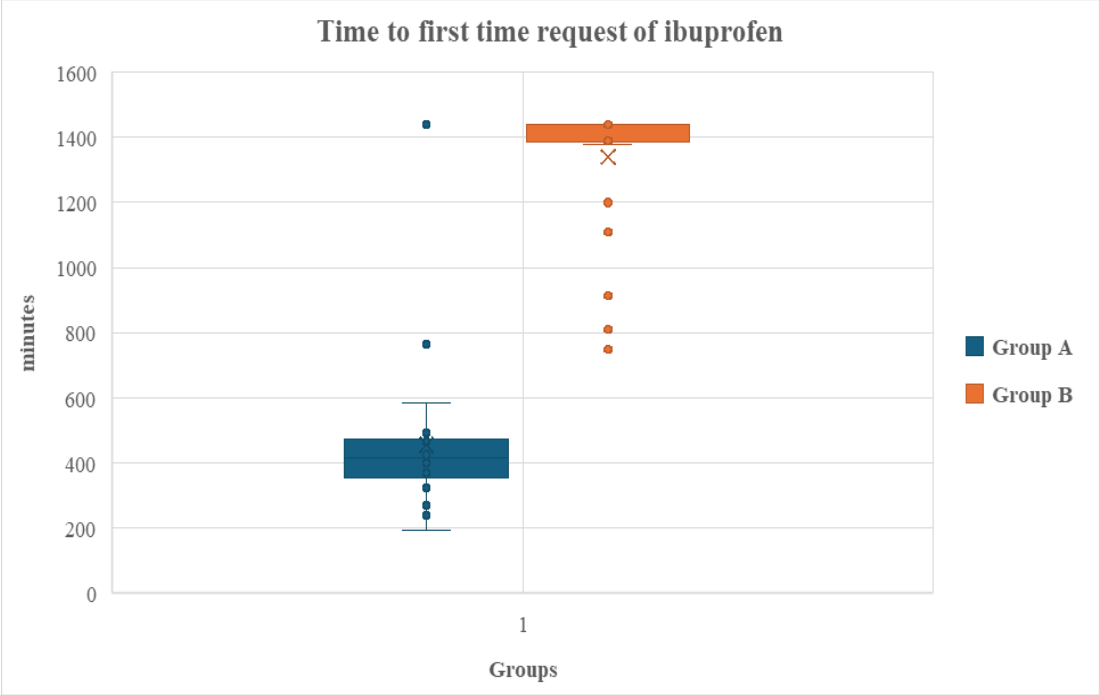
Data are mean ± SD, $p < 0.05$ indicates statistical significance

4.5. Time to first request for rescue ibuprofen

The mean time to first request for rescue analgesic (Ibuprofen) was significantly longer in Group B patients (1339.08 ± 210.56) than in Group A (470.72 ± 230.79), $p = 0.02$. The mean interval between both groups was almost threefold.

The median time to first request for rescue ibuprofen is 450 mins for Group A, with a range of 250 - 580 mins, containing two mild outliers on either side of the range and one extreme outlier above the maximum value. In contrast, Group B has a median time to first request for rescue ibuprofen of 1400 mins, with a range of 1380 - 1800 mins and multiple (five) extreme outliers below the minimum value. This difference is shown in Figure 4-2.

Figure 0-2: Time to first request for rescue Ibuprofen between the two groups



4.6. Total Ibuprofen syrup consumption

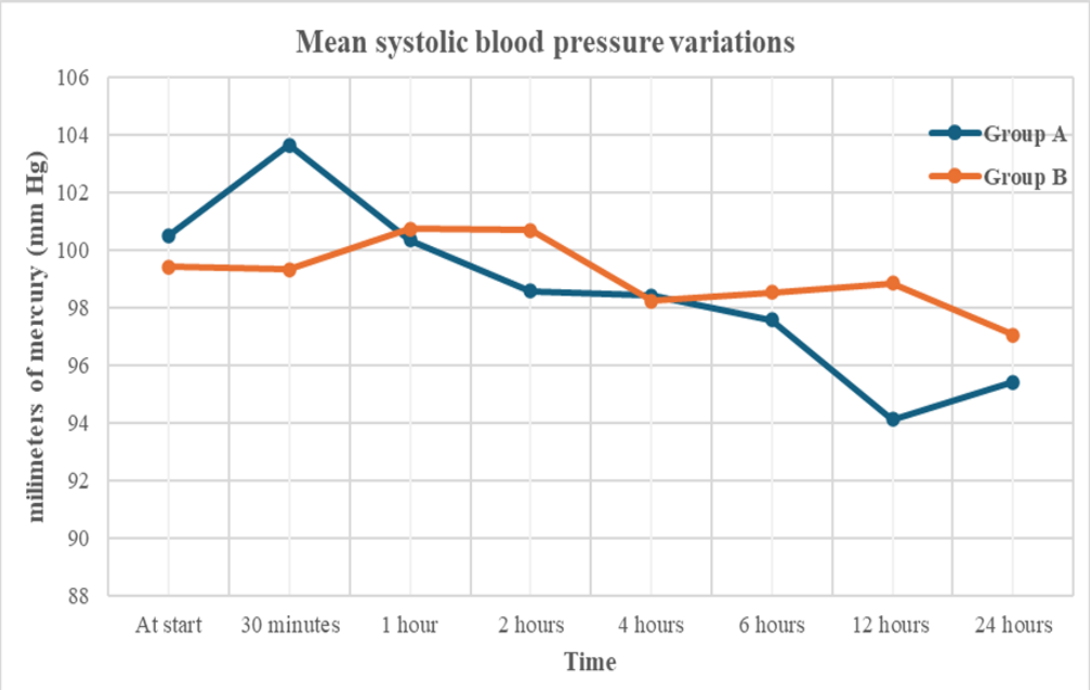
The children in Group A received a significantly higher total dose of Ibuprofen, 298 ± 151 mg (about 17% more) than Group B 53 ± 83 mg . The p-value of 0.00 confirmed that there was a significant association between caudal bupivacaine with dexmedetomidine versus bupivacaine alone and the amount of rescue ibuprofen consumed within 24 hours postoperatively.

4.7. Side effects

4.7.1. Mean systolic blood pressure variations

Overall, the means of the blood pressure at different measurement times within 24 hours of the procedures were not significantly different between groups, $p > 0.05$. Figure 4-3 shows the mean systolic variations.

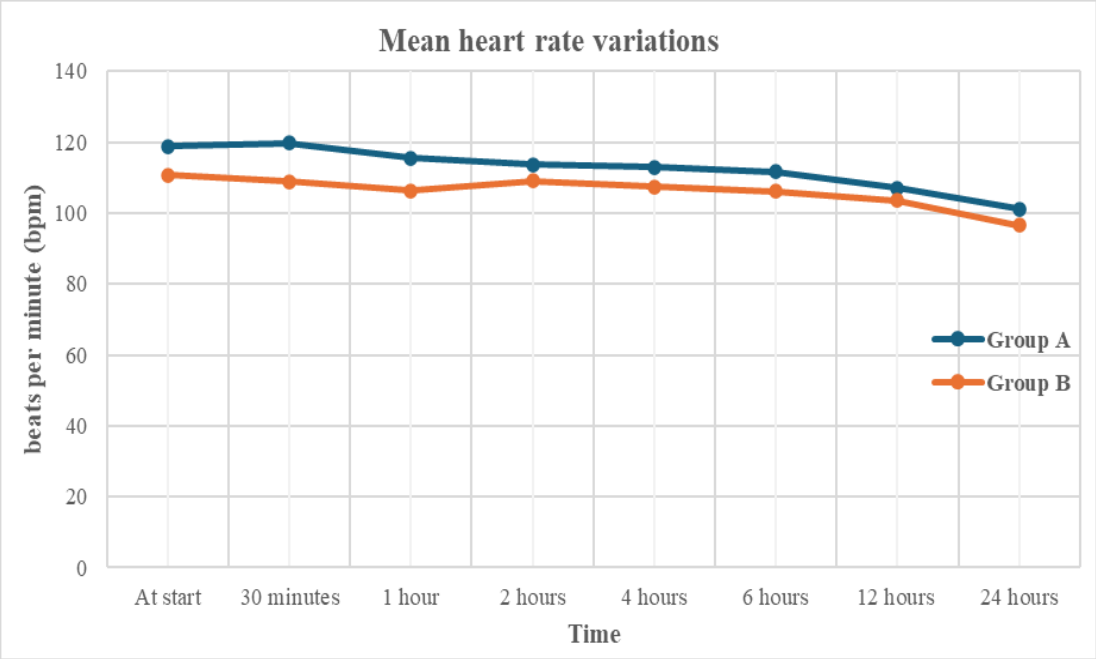
Figure 0-3: Mean systolic variations between the 2 groups



4.7.2. Mean heart rate variation

Heart rates followed a similar pattern to that of blood pressure. The results presented in Figure 4-4 below indicates that there is no statistically significant difference between the two groups.

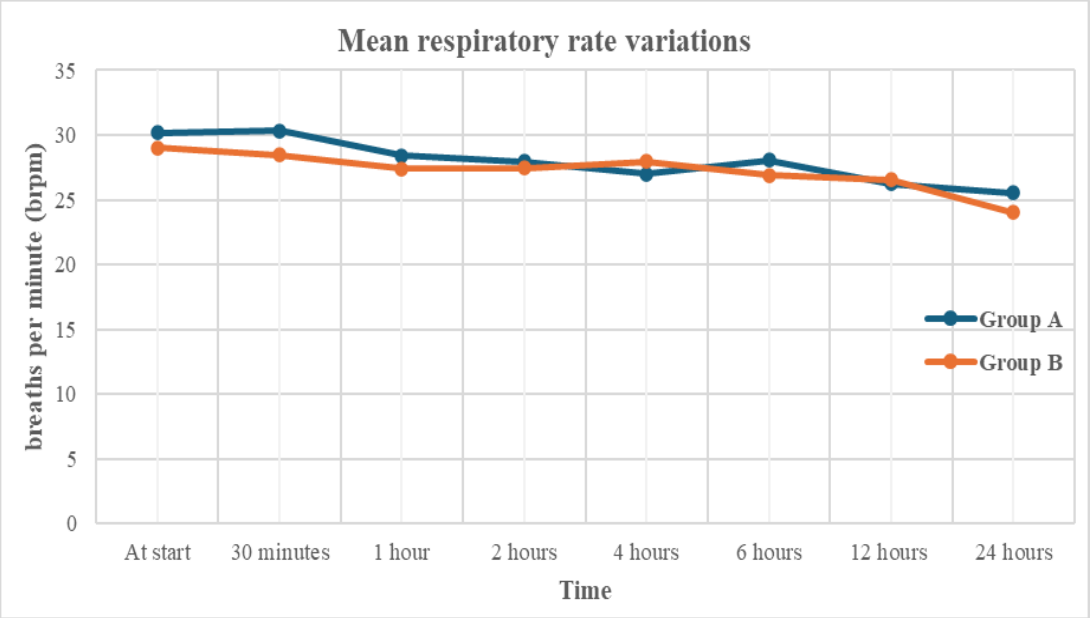
Figure 0-4: Mean heart rate variations between the two groups



4.7.3. Mean respiratory rate variations

There was no significant difference between Group A and Group B regarding the mean respiration rate variations, as shown in Figure 4-5.

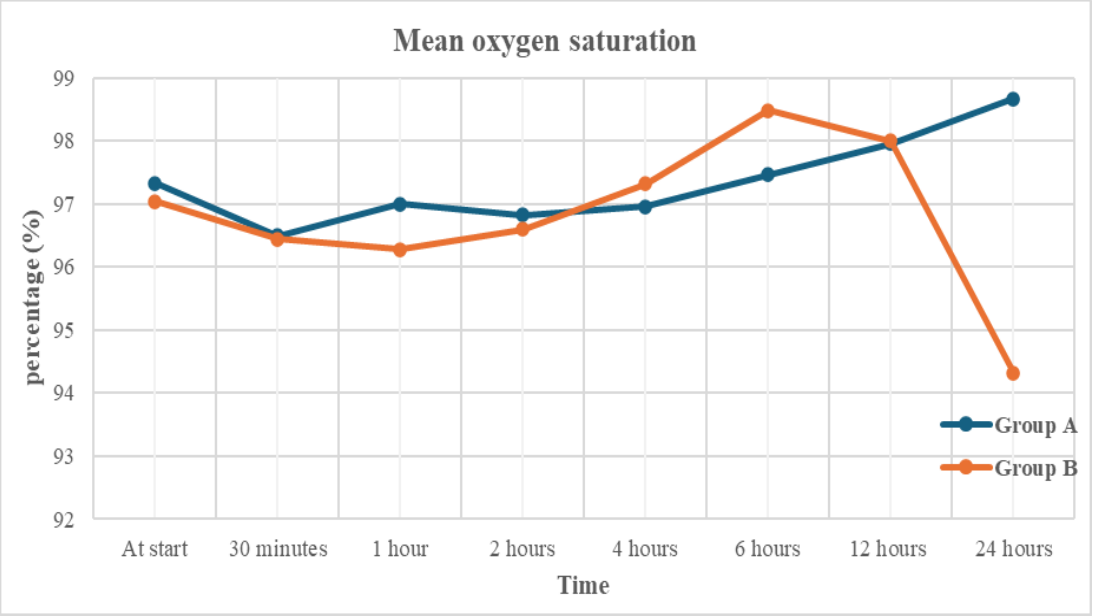
Figure 0-5: Mean respiratory rate variations between the two groups



4.7.4. Mean oxygen saturation variation

Figure 4-6 below shows that six hours after the procedures saturation rates in the two groups were statistically significantly different with a p-value of 0.02. The other measurement points were comparable, as observed in blood pressure, heart rate and respiratory rate.

Figure 0-6: Mean saturation variation between the two groups



4.7.5. Total sedation score

According to Table 4-4, the mean sedation scores were comparable at most intervals of measurement postoperatively. However, at time 0 (zero), time 240 min (4 h) and time 360 min (6 h), the sedation scores were significantly lower in Group A participants than in Group B, $p < 0.05$. Though the sedation score was slightly higher in Group B, it was still below a score of 3.

Table 0-3: Postoperative mean sedation score for the two groups

Time (min)	Group A (n=25)	Group B (n=25)	P value
0 (in PACU)	1.80 ± 1.00	2.60 ± 0.76	0.01*
30	1.68 ± 0.69	2.36 ± 0.70	0.08
60	1.52 ± 0.77	1.88 ± 0.78	0.21
120	1.16 ± 0.55	1.44 ± 0.712	0.45
240	1.20 ± 0.65	1.36 ± 0.57	0.02*

360	1.28 ± 0.79	1.56 ± 0.87	0.00*
720	2.80 ± 0.71	2.92 ± 0.40	0.33
1440	1.04 ± 0.46	1.00 ± 0.00	0.66

Data are mean ± SD, $p < 0.05$ indicates statistical significance

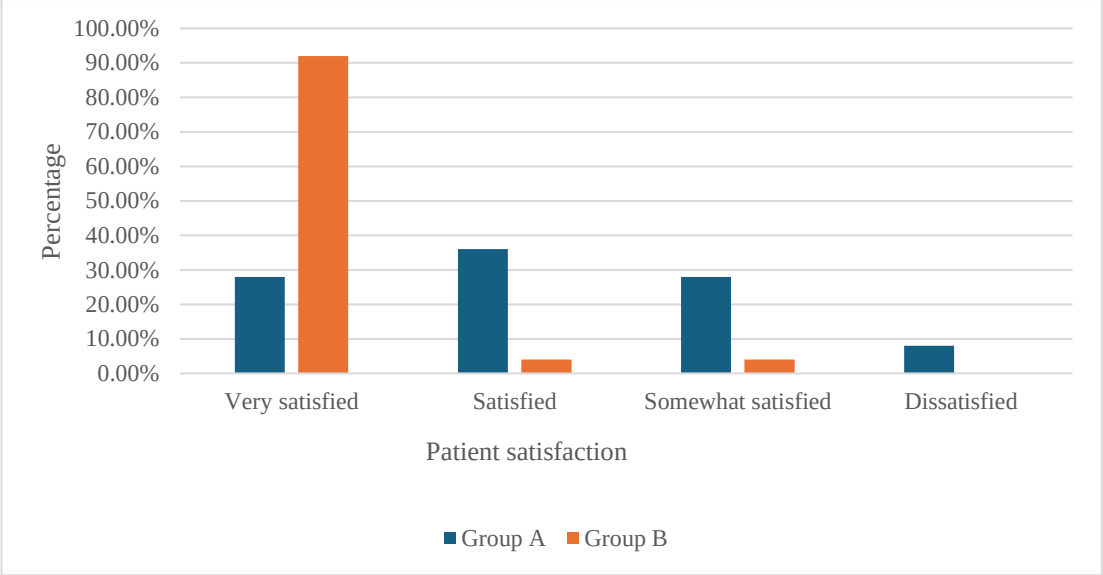
4.7.6. Other side effects

The patients were observed for other side effects, such as nausea and vomiting, pruritus, and urinary retention. None of the 50 patients exhibited any of these side effects.

4.8. Comparison of patient satisfaction between the two groups

Figure 4-7 shows that 92% of patients' parents in group B were very satisfied, 4% were satisfied and another 4% were somewhat satisfied. None of the patients' parents were dissatisfied. In Group A, only 28% of the parents were very satisfied and 36%, 28% and 8% were satisfied, somewhat satisfied and dissatisfied, respectively.

Figure 0-7: Patient satisfaction between the two groups


100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
Percentage
Very satisfied
Satisfied
Somewhat satisfied
Dissatisfied
Patient satisfaction
Group A
Group B

CHAPTER 5: DISCUSSION

The objectives of this study aimed to comprehensively assess the duration of analgesic coverage and safety of caudal bupivacaine with dexmedetomidine compared to bupivacaine alone in providing postoperative analgesia after infraumbilical surgery and to determine patient satisfaction with pain management strategies.

5.1. Post-operative pain scores

The results of the study show that a higher percentage of patients in Group B experienced lower pain scores compared to Group A, indicating better pain relief with the addition of dexmedetomidine to bupivacaine in Group B. However, statistical tests reveal that these differences in pain scores between the two groups are not significant. This implies that overall pain scores among patients were similar regardless of the group they were assigned to.

It is important to note that the pain scores were assessed by doctors at fixed time intervals, sometimes after the administration of rescue analgesics, which could introduce variability in the scoring. Additionally, the pain scores were observational and not self-reported by the patients, which may have limitations, especially with older children. Although the pain scores were similar between the two groups, it appears that patients in Group B experienced less pain, compared to those in Group A. This suggests that plain bupivacaine can still be effective in providing pain relief, albeit with potentially slightly higher pain scores compared to bupivacaine with dexmedetomidine. Furthermore, the trend of decreasing mean pain scores over time in both groups may suggest that baseline analgesic drugs administered as standard multimodal therapy may have also contributed to pain relief. However, it is essential

to consider other factors beyond pain scores alone when evaluating the efficacy of different analgesic regimens.

The pain scores at time 0 minutes in the PACU, 240 and 360 minutes show that a higher percentage of patients in Group B experienced lower pain scores compared to Group A, at $p < 0.05$ indicating potentially better pain relief with the addition of dexmedetomidine to bupivacaine. However, both groups showed significant improvement in pain scores over time, with 75% of patients in both groups reporting minimal to no pain 24 hours after surgery.

5.2. Time to first-time request for rescue ibuprofen syrup

The comparison of the time intervals to the first request for rescue ibuprofen between Group A and Group B reveals significant differences in analgesic duration. Group A patients exhibited a much shorter time to the first request, with a mean of 470.72 ± 230.79 minutes. In contrast, Group B patients had a substantially longer time interval, with a mean of 1339.08 ± 210.56. These differences were statistically significant, $p < 0.05$ indicating superior analgesic efficacy in Group B.

Further analysis of percentiles demonstrates the magnitude of these differences. For instance, 40% of Group A patients had requested rescue ibuprofen within 407 minutes and it took 1430 minutes for a similar proportion of Group B patients to do so. Besides, a notable proportion of Group B patients (68%) did not require rescue ibuprofen at all, compared to only 4% of Group A patients. The variation in time intervals and the lower proportion of patients requiring rescue ibuprofen in Group B underscore the enhanced analgesic effect of caudal bupivacaine with dexmedetomidine compared to bupivacaine alone. These findings highlight the clinical relevance of incorporating

dexmedetomidine as an adjuvant in caudal blocks for paediatric patients undergoing infraumbilical surgeries.

The consistency of findings across various studies underscores the robustness of the evidence supporting the efficacy of dexmedetomidine as an adjuvant to caudal bupivacaine in prolonging analgesia duration compared to bupivacaine alone. While there may be slight variations in the duration of analgesic effect observed in different studies, the overall trend remains consistent.

Saadway et al. in a cohort study of 30 patients in each group, showed that the time to first rescue analgesic request was 18.5 ± 2.8 hours in the group that received 0.25% bupivacaine with dexmedetomidine 1mcg/kg and 6.2 ± 2.8 for the group that received 0.25% plain bupivacaine alone ($P < 0.001$).[37]

Karuppiah et al. observed in a cohort study of 30 patients in each group, that time to first rescue analgesic request was 964.2 ± 309 min (16.07 ± 5.15 hours) in the group that received 0.25% bupivacaine with dexmedetomidine 1mcg/kg and 444.6 ± 179.4 min (7.41 ± 2.99 hours) for the group that received 0.25% plain bupivacaine alone $P<0.001$).[38]

Al-Zaben et al. observed in a cohort study of 25 patients in each group, that the time to first rescue analgesic request was 14.4 ±7.5 hours in the group that received 0.25% bupivacaine with dexmedetomidine 1mcg/kg and 6.6 ± 2.5 hours for the group that received 0.25% plain bupivacaine alone ($P < .05$)[39]

Goyal et al. observed in a cohort study of 50 in each group, that time to first rescue analgesic request was 9.88 ± 0.90 hours in the group that received 0.25% bupivacaine

with dexmedetomidine 1mcg/kg and 4.33 ± 0.98 hours for the group that received 0.25% plain bupivacaine alone ($P < .0001$).[40]

The mechanism of action of α2-adrenergic agonists like dexmedetomidine involves the modulation of pain pathways at multiple levels, including the brain, spinal cord, and peripheral tissues.[37] By activating descending inhibitory pathways and reducing sympathetic outflow, α2 agonists exert potent analgesic effects.[37] Moreover, it is important to note that there is an interaction between opioids and, α2 agonists at the spinal cord level which further enhances their analgesic efficacy.

The inclusion of pre-emptive analgesic agents such as fentanyl and intravenous paracetamol as part of a multimodal analgesic regimen intra-operatively could indeed have influenced the results of the study. All patients also received oral paracetamol 6 hourly. These agents may have provided additional pain relief and could potentially mask differences in analgesic duration between the groups receiving caudal bupivacaine with or without dexmedetomidine.

In studies where patients did not receive additional analgesic agents until the time of the first request for rescue analgesia, the analgesic effect observed would likely be more attributable to the drugs administered in the caudal block alone. Therefore, the results of studies utilising different analgesic regimens may not be directly comparable, and the impact of pre-emptive analgesia on the duration of analgesic effect should be considered when interpreting the findings.

Future studies could explore the specific contribution of pre-emptive analgesia to the overall analgesic efficacy of different regional anaesthesia techniques, including

caudal blocks with or without adjuncts like dexmedetomidine. This could help optimise perioperative pain management strategies and improve patient outcomes.

Factors such as variations in technique, patient demographics, volume administered, and type of surgery may contribute to the observed differences in analgesic duration among studies. Further research is warranted to elucidate the impact of these factors and optimise the use of dexmedetomidine in caudal analgesia for pediatric patients undergoing infraumbilical surgeries

5.3. Total ibuprofen syrup

The significant reduction in the requirement for rescue ibuprofen and the lower total ibuprofen consumption in Group B compared to Group A suggests that the addition of caudal dexmedetomidine to bupivacaine may have contributed to enhanced analgesia and reduced postoperative pain in paediatric patients undergoing infraumbilical surgeries. However, the administration of oral paracetamol as part of a multimodal analgesic approach could have also influenced these findings. Previous similar studies also demonstrated a decrease in rescue analgesic necessity among patients receiving caudal bupivacaine with dexmedetomidine, albeit with the utilisation of paracetamol as the primary rescue analgesic, contrasting with the use of ibuprofen syrup in the current study.

In this study, paracetamol was given to all patients intraoperatively and continued postoperatively, hence ibuprofen was used as a rescue analgesic drug. The inclusion of paracetamol as a standardised intraoperative and postoperative analgesic regimen underscores the multifaceted nature of pain management strategies, seeking to optimise patient comfort and mitigate pain burden across different modalities. This

approach aligns with contemporary principles of multimodal analgesia, which emphasise the synergistic effects of combining diverse analgesic agents to achieve superior pain relief while minimising adverse effects and opioid consumption.

By administering ibuprofen syrup as a rescue analgesic drug, the study not only expanded the analgesic options but also provided a comparative perspective on the efficacy of dexmedetomidine in conjunction with bupivacaine within the context of a multimodal analgesic regimen. This approach to pain management underscores the importance of tailoring analgesic strategies to individual patient needs and optimising outcomes through comprehensive multimodal interventions.

It is essential to consider the synergistic effects of different analgesic agents and their impact on postoperative pain management. While dexmedetomidine has demonstrated analgesic properties in various studies, the combination of paracetamol and caudal bupivacaine with dexmedetomidine may have contributed to the overall reduction in pain intensity and the need for rescue analgesia observed in Group B. Therefore, it is crucial to interpret these results within the context of multimodal analgesic strategies and the comprehensive management of postoperative pain in paediatric patients.

Further research may be warranted to elucidate the specific contributions of dexmedetomidine and other analgesic agents in multimodal approaches to paediatric pain management, considering factors such as dosing regimens, patient characteristics, and surgical procedures.

5.4. Side effects

5.4.1. Mean vitals variations (systolic blood pressure, heart rate, respiratory rate and oxygen saturation)

In this study, the utilisation of mean vital signs alongside the modified Hannallah pain scale with a score of ≥ 4 provided a comprehensive approach to pain assessment in paediatric patients who were recruited for the study. The absence of substantial differences in vital signs between Group A and Group B throughout the 24-hour post-procedure period suggests that the administered drugs had minimal impact on these parameters. This aligns with findings from previous studies using similar drug regimens, Saadawy et al.[37], Karuppiah et al[38], Al-Zaben et al[39] and Goyal et al[40].

While some studies reported bradycardia and hypotension in patients receiving dexmedetomidine in conjunction with bupivacaine, particularly at higher doses 2mcg/kg[38] or when dexmedetomidine was administered intravenously at 1mcg/kg[39], these adverse events were not observed in the current study. This indicates that the dosage and route of administration of dexmedetomidine may influence its hemodynamic effects. The consistent findings across multiple studies reinforce the safety profile of the studied drug combinations, particularly when administered via the caudal route. Overall, the incorporation of both pain scales and vital sign monitoring provides a comprehensive approach to pain assessment and management in paediatric patients, allowing for a more nuanced understanding of pain relief efficacy and potential adverse effects of analgesic interventions.

Changes in vital signs, such as blood pressure, heart rate, respiratory rate and saturation, can sometimes indicate pain in infants but are not consistently reliable

indicators of pain in older children.[41] It is important to note that the absence of changes in vital signs does not necessarily mean the absence of pain in children.[41]

5.4.2. Total sedation score

The study shows a statistically significant difference in sedation scores between Group A and Group B, particularly noted at time 0 in PACU and 30 minutes after the procedure, suggests that the addition of dexmedetomidine to caudal bupivacaine influenced the level of sedation experienced by the patients. The higher proportion of patients in Group A with sedation scores of 2 or less compared to Group B indicates that patients who received bupivacaine alone were less sedated initially. As time went on, the patients in Group B were not sedated, however, more tranquil and calmer than the patients in Group A.

Indeed, maintaining an appropriate balance of sedation is crucial in perioperative care, ensuring patient comfort without compromising safety. The observed increase in sedation levels associated with dexmedetomidine supplementation in caudal bupivacaine could offer benefits in terms of reducing perioperative anxiety and improving overall patient experience. Importantly, as evidenced in this study and corroborated by similar findings in other studies, the sedative effects of dexmedetomidine did not interfere with patient recovery or postoperative monitoring, indicating its potential as a valuable adjunct in paediatric anaesthesia.

However, it is essential for clinicians to exercise caution and individualise sedation management based on patient characteristics, surgical procedures, and monitoring requirements. Close monitoring of sedation levels, respiratory function, and vital signs is necessary to prevent oversedation and ensure patient safety throughout the

perioperative period. With proper attention to dosing, monitoring, and patient assessment, dexmedetomidine can be a valuable tool in enhancing perioperative care for paediatric patients undergoing infraumbilical surgeries.

Overall, the results suggest that dexmedetomidine as an adjuvant to caudal bupivacaine may influence sedation levels in paediatric patients undergoing infraumbilical surgeries, potentially offering additional benefits in terms of perioperative comfort and patient experience.

5.4.3. Other side effects

The absence of side effects such as nausea, vomiting, pruritus, and urinary retention in both groups of patients in your study is noteworthy. It suggests that the use of dexmedetomidine as an adjuvant to caudal bupivacaine did not increase the incidence of these side effects compared to bupivacaine alone. This does not align with the findings of some other studies such as Saadawy et al.[37] where similar side effects were observed, particularly urinary retention, with the use of dexmedetomidine.

The study done by Karuppiah et al**.**[38] highlighted the observation that the incidence of urinary retention increased with higher doses of caudal bupivacaine with dexmedetomidine further emphasising the importance of careful dose selection and risk assessment when using this combination. It highlights the need for individualised patient management and consideration of potential side effects when determining the optimal dose of adjuvants in regional anaesthesia techniques.

Overall, the absence of side effects in this study adds to the safety profile of caudal bupivacaine with dexmedetomidine and supports its use as a viable option for

perioperative pain management in paediatric patients undergoing infraumbilical surgeries.

5.4.4. Patient satisfaction

The study illustrates notable disparities in parental satisfaction levels between Group A and Group B. In Group B, an overwhelming majority of 92% of parents expressed high levels of satisfaction, with 4% indicating satisfaction and another 4% expressing moderate satisfaction. Conversely, in Group A, parental satisfaction was more varied, with 28% reporting very high satisfaction, followed by 36% expressing satisfaction, 28% indicating moderate satisfaction, and 8% reporting dissatisfaction.

These findings highlight the potential benefits of incorporating dexmedetomidine into caudal bupivacaine anaesthesia for infra-umbilical surgeries, as evidenced by the significantly higher satisfaction rates among parents whose children received this adjunct. The robust satisfaction reported by most parents in Group B suggests a positive overall experience with the analgesic regimen, likely attributable to the extended duration of analgesia and improved perioperative comfort afforded by dexmedetomidine.

Conversely, the more heterogeneous pattern of satisfaction in Group A highlights the variability in pain management outcomes associated with bupivacaine alone, potentially reflecting a shorter duration of analgesia and less consistent pain relief. The presence of parental dissatisfaction in this group further underscores the limitations of relying solely on bupivacaine for paediatric pain management, underscoring the importance of exploring adjunctive strategies such as dexmedetomidine to optimise postoperative outcomes and enhance patient and parental satisfaction.

The findings of this study align with similar investigations in which parental satisfaction was notably higher among patients who received caudal bupivacaine with dexmedetomidine. Consistency in parental satisfaction across these studies underscores the potential benefits associated with incorporating dexmedetomidine into caudal anaesthesia for paediatric patients undergoing infraumbilical surgeries. The observed pattern of increased satisfaction in the dexmedetomidine group suggests that the addition of this adjunctive agent may contribute to enhanced perioperative comfort and improved pain management outcomes. Factors such as prolonged analgesic duration, reduced rescue analgesic requirements, and possibly lower incidence of adverse effects may collectively contribute to higher levels of parental satisfaction in this group.

These findings underscore the importance of considering adjunctive pharmacological agents, such as dexmedetomidine, as part of multimodal analgesic strategies for paediatric patients. By optimising pain management and enhancing patient and parental satisfaction, these approaches have the potential to improve overall perioperative experiences and postoperative outcomes for paediatric surgical populations. Further research and clinical exploration are warranted to validate these findings and elucidate the precise mechanisms underlying the observed benefits of dexmedetomidine in paediatric caudal anaesthesia

CHAPTER 6: CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS

5.1. Conclusions

The results of the study indicate that there is a difference in the duration of analgesic effect between caudal with bupivacaine alone versus bupivacaine with dexmedetomidine in paediatric infraumbilical surgeries, thus supporting the alternative hypothesis resulting in the rejection of the null hypothesis.

In conclusion, the addition of dexmedetomidine to caudal bupivacaine demonstrates several favourable outcomes in paediatric patients undergoing infraumbilical surgeries. This adjunctive therapy effectively prolongs the duration of analgesia while exhibiting minimal side effects. Furthermore, it significantly reduces the need for rescue analgesics, indicating enhanced pain management efficacy. Equally important, parental satisfaction is notably increased when dexmedetomidine is incorporated into the anaesthetic regimen.

These findings underscore the potential of dexmedetomidine as a valuable adjunct in paediatric caudal anaesthesia, offering improved perioperative pain control and overall patient satisfaction. Further research is warranted to elucidate its precise mechanisms of action and optimise its clinical utility in paediatric surgical settings.

The findings from this study suggest that incorporating caudal dexmedetomidine into the anaesthesia regimen for day-case surgeries is feasible and beneficial. With prolonged analgesia and reduced postoperative pain, patients can potentially be managed effectively with simple oral analgesics, minimising the need for opioids and their associated side effects. However, the implementation of such a strategy in day-

case surgery should be carefully evaluated, considering factors such as patient selection, perioperative monitoring protocols, and resource availability. Indeed, further research may be necessary to fully assess the long-term outcomes and cost-effectiveness of this approach for these types of operations to be done as day cases.

5.2. Recommendations

Indeed, the availability and cost of dexmedetomidine are important considerations for its widespread use in clinical practice. Further research into the storage stability of dexmedetomidine after use, including optimal storage conditions and duration, is crucial to ensure its efficacy and safety. Additionally, exploring alternative or complementary analgesic strategies that may be more cost-effective could be beneficial.

Regarding observational pain scores, while they have limitations, they remain valuable tools for assessing pain in certain patient populations, particularly those who are unable to self-report. However, continued research into the development of more reliable and valid pain assessment tools is necessary to improve pain management practices and outcomes.

Healthcare providers must remain vigilant in assessing and addressing pain in podiatric patients, particularly in those who are non-verbal or have cognitive impairments. Not all healthcare providers receive specialised training in paediatric pain management, leading to variations in the quality of care provided to children in pain.

Ensuring that healthcare professionals receive education and training in paediatric pain management is crucial. Parents and caregivers also play a pivotal role in paediatric pain management, especially in the home setting.

Many parents lack the education and resources to effectively manage their children's pain, resulting in unnecessary suffering and inadequate pain control. Children often experience fear and anxiety related to pain and medical procedures, which can exacerbate the perception of pain and make interventions more challenging. Addressing the emotional aspect of pain is thus a vital component of paediatric pain management. Children's pain perception can vary widely based on developmental stage, cultural background, and individual differences. Healthcare providers must take these factors into account when assessing and managing pain. Moreover, the development of pain medications for children lags behind that of adults. Many medications are not approved for paediatric use, and dosing guidelines may not be well-established. Therefore, research into safe and effective paediatric pain medications is imperative.

Continued research into paediatric pain medications is imperative. This encompasses not only the development of new drugs but also the refinement of existing medications' formulations and dosages to render them more appropriate for children. Telemedicine holds promise in broadening access to paediatric pain management services, particularly for families residing in remote or underserved areas. Telehealth consultations can offer guidance on pain management strategies and extend support to parents and caregivers.

Education plays a pivotal role in enhancing paediatric pain management. Healthcare providers should receive specialised training in paediatric pain assessment and treatment, while parents and caregivers should have access to educational resources to effectively manage their children's pain at home. Routine pain assessment and screening should be integrated as standard practice in paediatric healthcare settings,

employing age-appropriate tools and considering the emotional and psychological dimensions of pain.

Transdisciplinary pain teams, comprising healthcare professionals from diverse disciplines, can deliver holistic care for children with complex pain conditions. This approach ensures that the physical, emotional, and psychological facets of pain are comprehensively addressed. Moreover, ongoing research in paediatric pain management, including the exploration of non-pharmacological interventions, targeted pain treatments, and innovative approaches, will propel advancements in the field.

5.3. Limitations

1. The study recruited only 50 patients.
2. The infra-umbilical surgeries included in the study comprised Circumcisions, Inguinal Hernia Repairs, Hydrocelectomies, and Orchidopexies, each with distinct operating times and incisional sites.
3. The operations were performed by different surgeons.
4. Cases with an increase in systolic blood pressure and/or heart rate exceeding 15% were excluded from the study.
5. Pain scores were based on observations rather than self-reporting.
6. Different surgical procedures involved varying volumes of local anaesthetic drugs administered, and some patients underwent two procedures simultaneously.

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Appendix i: Ethical Clearance

UNAM
UNIVERSITY OF NAMIBIA

ETHICAL CLEARANCE CERTIFICATE

Ethical Clearance Reference Number: HREC-H 2/8/2023 SOM **Date: 18/08/2023**

This Ethical Clearance Certificate is issued by the University of Namibia Research Ethics Committee (UREC) in accordance with the University of Namibia's Research Ethics Policy and Guidelines. Ethical approval is given in respect of undertakings contained in the Research Project outlined below. This Certificate is issued on the recommendations of the ethical evaluation done by the Faculty/Centre/Campus Research & Publications Committee sitting with the Postgraduate Studies Committee.

Title of Project: COMPARATIVE STUDY OF ANALGESIC EFFECT OF CAUDAL BUPIVACAINE WITH DEXMEDETOMIDINE VERSUS BUPIVACAINE ALONE FOR INFRAUMBILICAL SURGERIES IN CHILDREN IN WINDHOEK CENTRAL AND KATUTURA STATE HOSPITALS

Nature/Level of Project: MASTER OF MEDICINE (ANEASTHESIOLOGY, CRITICAL CARE AND PAIN MANAGEMENT)

Researcher: NIITA AMAAMBO

Student Number: 200409603

Faculty: Health Sciences and Veterinary Medicine

Supervisor: Prof. T. Roche

Take note of the following:

(a) Any significant changes in the conditions or undertakings outlined in the approved Proposal must be communicated to the HREC-H. An application to make amendments may be necessary.
(b) Any breaches of ethical undertakings or practices that have an impact on ethical conduct of the research must be reported to the HREC-H.
(c) The Principal Researcher must report issues of ethical compliance to the HREC-H (through the Chairperson of the Faculty/Centre/Campus Research & Publications Committee) at the end of the Project or as may be requested by HREC-H.
(d) The HREC-H retains the right to:
  (i) Withdraw or amend this Ethical Clearance if any unethical practices (as outlined in the Research Ethics Policy) have been detected or suspected,
  (ii) Request for an ethical compliance report at any point during the course of the research.

HREC-H wishes you the best in your research.

HREC-H Chairperson

Prof CJ Wilders

Appendix ii: Ministry of Health and Social Services Approval

REPUBLIC OF NAMIBIA

MINISTRY OF HEALTH AND SOCIAL SERVICES

Ministerial Building
Harvey Street
Private Bag 13198, Windhoek

OFFICE OF THE EXECUTIVE DIRECTOR

Tel: No: 061 -203 2507
Fax No: 061-222 558
Andreas.Shipanga@mhss.gov.na

Ref: 22/4/2/3
Enquiries: Mr. A. Haufiku

Date: 27 September 2023

Dr. Niita Amaambo
PO Box 8976
Bachbrecht
Windhoek

Dear Dr. Amaambo

Re: Comparative study of analgesic effect of caudal bupivacaine with dexmedetomidine versus bupivacaine alone for infraumbilical surgeries in children in Windhoek Central and Katutura State Hospitals.

1. Reference is made to your application to conduct the above-mentioned study.
2. The proposal has been evaluated and found to have merit.
3. **Kindly be informed that permission to conduct the study has been granted under the following conditions:**
   - 3.1 The data to be collected must only be used for academic purpose;
   - 3.2 No other data should be collected other than the data stated in the proposal;
   - 3.3 Stipulated ethical considerations in the protocol related to the protection of Human Subjects should be observed and adhered to, any violation thereof will lead to termination of the study at any stage;
   - 3.4 A quarterly report to be submitted to the Ministry's Research Unit;
   - 3.5 Preliminary findings to be submitted upon completion of the study;
   - 3.6 Final report to be submitted upon completion of the study;
   - 3.7 Separate permission should be sought from the Ministry for the publication of the findings.
4. All the cost implications that will result from this study will be the responsibility of the applicant and **not** of the MoHSS.

Yours sincerely,

EXECUTIVE DIRECTOR
29 SEP 2023
Republic of Namibia
HEALTH AND SOCIAL SERVICES

BEN NANGOMBE
EXECUTIVE DIRECTOR

All official correspondence must be addressed to the Executive Director

My NAMIBIA

Appendix iii: Windhoek Central Hospital Approval

REPUBLIC OF NAMIBIA

MINISTRY OF HEALTH AND SOCIAL SERVICES

Private Bag 13215
Windhoek
Namibia
Enquiries: Ms. S.Iipinge

Harvey Street
Windhoek Central Hospital
Ref: 22/3/1/2 NA

Tel. No: (061) 2033024
Fax No: (061) 222886
Email: Selma.Iipinge@mhss.gov.na
Date: 09 October 2023

OFFICE OF THE SENIOR MEDICAL SUPERINTENDENT

Dr.Niita Amaambo
P.O.BOX 8976
Windhoek

Dear Dr.Amaambo

SUBJECT: PERMISSION TO CONDUCT A RESEARCH STUDY ON THE COMPARATIVE STUDY OF ANALGESIC EFFECT OF CAUDAL BUPIVACAINE WITH DEXMEDETOMIDINE VERSUS BUPIVACAINE ALONE FOR INRAUMBILICAL SURGERIES IN CHILDREN IN WINDHOEK CENTRAL AND KATUTURA HOSPITAL.

Reference is made to the above mentioned subject:

Kindly be informed that permission has been granted to conduct the research study on the above mentioned subject under the following conditions:

1. Patient client information should be kept confidential at all times
2. The purpose for research is only for your study purposes as you have requested and does not include any remuneration.
3. **Preliminary findings to be submitted to Customer care office, Windhoek Central Hospital upon completion of the study.**

Thank you for your kind cooperation.

Yours faithfully

.....

DR.S SHALONGO

SENIOR MEDICAL SUPERINTENDENT

MINISTRY OF HEALTH AND SOCIAL SERVICES
Private Bag 13215
10 OCT 2023
Windhoek, Namibia
WINDHOEK CENTRAL HOSPITAL

Appendix iv: Research Ethics

The researcher will obtain the necessary official ethical clearance from the University of Namibia and the Ministry of Health to proceed with the research. The clearance is crucial as it will also act as a proxy to ensure respondents that data will be purely for academic purposes.

A1: Informed consent

Informed consent was obtained from the patient's parents or legal caregivers. Details regarding the purpose of the research, all the steps of the procedure and possible complications was explained and was provided in written form. The patients' parents or caregivers signed the written form.

A2: Voluntary participation

Participation or withdrawal from the study was voluntary. No benefits were tacit or implied to the participants.

A3: Confidentiality of data

All information for patients was treated as confidential. The collected data was stored in a lockable safe and will be destroyed by shredding and burning when no longer required.

A4: Anonymity

The researcher also made an intentional effort to protect the rights of participants and ensure anonymity. The serial numbers were used to identify the patients. Any complications observed in any patient during the study were to promptly and

appropriately managed and reported to the ethics and research committee. The guardians were also to be informed. Fortunately no complications or side effects were observed in the study.

A5: Beneficence to participants

All patients participating in the study were treated in accordance with the ethical guidelines of the Ministry of Health and Social Services and the Health Professions Council of Namibia. All patients received required post-operative analgesia to control post-operative pain, no patient was refused necessary treatment for the sake of the study.

A6: Non-maleficence to participants

All safety and precautionary measures were observed throughout the study. The caudal block was performed under an aseptic technique and the procedure was aborted after the third attempt of being unsuccessful. Safe anaesthesia was also provided to all patients. Emergency airway trolleys, emergency drugs, and resuscitative equipment were all be readily available in theatres and wards in case of complications and adverse effects. The anaesthetic consultant covering the theatre suite was also informed before the procedure was started to assist should a need arise. Any complications observed in any patient during the study were to be promptly, appropriately managed and reported to the ethics and research committee. The guardians were also to be informed.

A7: Dissemination of results

The results of the study will be presented and published locally in the necessary departments and may be published in Anaesthesia or scientific journals.

Appendix v: Research Questionnaire

COMPARATIVE STUDY OF ANALGESIC EFFECT OF CAUDAL BUPIVACAINE WITH DEXMEDETOMIDINE VERSUS BUPIVACAINE ALONE FOR INFRAUMBILICAL SURGERIES IN CHILDREN IN WINDHOEK CENTRAL AND KATUTURA STATE HOSPITALS

1. Serial number_____
2. Hospital number_____
3. Diagnosis_____
4. Date of procedure_____
5. Name of procedure_____
6. Sex: M/F (circle)
7. Age_____
8. Weight_____
9. Time caudal block was performed (time zero) H
10. Postoperative pain assessment – Modified Hannallah score/Visual Analogue score

a) 2 hours_____

b) 4 hours_____

c) 6 hours_____

d) 12 hours_____

e) 24 hours_____

11. Postoperative sedation score - Ramsay score

a) 2 hours_____

b) 4 hours_____

c) 6 hours_____

d) 12 hours_____

e) 24 hours_____

12

	Blood pressure	**Heart rate**	**Respiratory rate**	**Saturation**
2 hours				
4 hours				
6 hours				
12 hours				
24 hours				

13. Postoperative time to first request for rescue opioid analgesia H

14. Total ibuprofen syrup doses given in 24 hours

15. Side effects

a) Nausea and vomiting Yes No

b) Pruritus Yes No

c) Other …….. Yes No

16. Patient satisfaction with the effect of the treatment of postoperative pain

a) Very satisfied 0

b) Satisfied 1

c) Somewhat satisfied 2

d) Dissatisfied 3

Appendix vi: Modified Hanallah Pain Scale Form

Serial number:

Hospital number:

MODIFIED HANALLAH PAIN SCALE

OBSERVATION	CRITERIA	SCORE
Crying	No crying	0
	Crying responding to tender loving care	1
	Crying not responding to tender loving care	2
Movement	None	0
	Restless	1
	Thrashing (aggressive)	2
Agitation	Asleep/calm	0
	Mild	1
	Hysterical	2
Swallowing of secretions	Normal	0
	Uncomfortable	1
	Unable	2
Verbalization of pain	Asleep/ states no pain	0
	Vague/can't localize	1
	Can localize pain	2

Note: Total score of 4 or more, give rescue analgesic agent (ibuprofen syrup)

PATIENT SCORE CHART

Time interval	Time	Crying	Movement	Agitation	Swallowing of secretions	Verbalization Of pain	Total pain score
30 minutes							
1 hour							
2 hours							
4 hours							
6 hours							
12 hours							
24 hours							

Time rescue analgesic agent give (ibuprofen syrup): _____

Appendix vii: Ramsay Sedation Score Form

Serial number:

Hospital number:

RAMSAY SEDATION SCORE

Score	Definition
1	Awake and alert, minimal or no cognitive impairment
2	Awake but tranquil, purposeful responses to verbal commands at conversation level
3	Appears asleep, purposeful responses to verbal commands at conversation level.
4	Appears asleep, purposeful responses to verbal commands, but at louder than usual conversation level or requiring light glabellar tap
5	Asleep, sluggish purposeful responses only to loud verbal commands or strong glabellar tap
6	Asleep, sluggish purposeful responses only to painful stimuli
7	Asleep, reflex withdrawal to painful stimuli only (no purposeful response)
8	Unresponsive to external stimuli, including pain

PATIENT SCORE CHART

Time interval	Time	Total sedation score
30 minutes		
1 hour		
2 hours		
4 hours		
6 hours		
12 hours		
24 hours		

Appendix viii: Informed Consent Form (English)

INFORMED CONSENT FORM

COMPARATIVE STUDY OF ANALGESIC EFFECT OF CAUDAL BUPIVACAINE WITH DEXMEDETOMIDINE VERSUS BUPIVACAINE ALONE FOR INFRAUMBILICAL SURGERIES IN CHILDREN IN WINDHOEK CENTRAL AND KATUTURA STATE HOSPITALS

I, Dr. Niita Nelago Tangi Amaambo, a student in the Master of Medicine in Anaesthesia, Critical Care and Pain Management at the University of Namibia am conducting a study designed to evaluate postoperative pain scores at rest, two hours, four hours, six hours, twelve hours, and twenty-four hours for patients receiving caudal bupivacaine with dexmedetomidine and caudal bupivacaine alone in paediatric patients after infra-umbilical surgery. Side effects will also be evaluated.

The study drug is expected to enhance pain relief during and after infra-umbilical surgery. The pain will be quantified using the modified Hannallah pain score for children aged 1 to 5 years and the visual analogue pain score for children over five years to eight years. The level of sedation will be measured using the Ramsay sedation score. The procedure will be done after the patient is under general anaesthesia. Additionally, vitals namely, blood pressure, pulse rate, oxygen saturation and respiratory rate will be measured at the same intervals as the pain scores. The patient will be assigned a number and their name will not be written on the form to ensure confidentiality. The findings in this study will help in recommendations to Hospital Management with respect to the usefulness of dexmedetomidine as an adjuvant to caudal bupivacaine.

As a parent/ legal guardian to the patient, you are free to decline participation in this study, but we will greatly appreciate your help in taking part. The study is the first of its kind both in this centre and in Namibia. You have a right to withdraw at any given time if you choose to.

Consent:

I, _____in my full sense hereby give my complete consent for _____ performed on my son/daughter_____ age _____ The nature and risk involved in the procedure have been explained to me to my satisfaction.

I will be willing for my child to take part in the survey.

_____ _____

Signature/Thumbprint of participant / Date Signature of Investigator / Date

Appendix ix: Translator Confidential Agreement Form

CONFIDENTIAL AGREEMENT FORM FOR TRANSLATOR

Consent:

I, _____, ID number: _____in my full sense hereby confirm that I was a translator between the patient's parent/legal guardian of patient_____ and Dr _____. I confirm that the information I was asked to explain is correct. I will keep this information confidential.

---------- ------- -------- ----------

Signature/Thumbprint of translator date Signature of Investigator/Date

Appendix x: Patient Information Leaflet

PATIENT INFORMATION LEAFLET

CAUDAL BLOCKS

We have given you this leaflet because your child will be taking part in the study that looks at how much pain relief children have after operations that are done below the bellybutton. We will compare two groups; one group will receive an injection of a combination of medicine for pain in the lower back (bupivacaine and dexmedetomidine) and the second group will receive an injection bupivacaine only in the lower back. Your child will be randomly selected to be in one of these groups. We will be measuring the pain levels at different times, and we will also be looking out for any side effects. If there are side effects, the child will be treated immediately. In the case of an emergency, the child will be treated but will no longer take part in the study, but the incident will be reported.

Caudal blocks are routinely done in Windhoek Central and Katutura State Hospitals as one of the options the anaesthetist may suggest for pain relief.

What is a caudal block?

When the anaesthetist gives your child the general anaesthetic, they also try to ensure that your child does not feel pain. There are a few ways to manage pain.

1. pain relief medicine that goes into a vein and affects the whole body.
2. There are other pain relief medicines that are given before or after the operation, which can be given as tablets, or occasionally other injections not in the vein. However, these medicines may have side effects which can make your child feel unwell.

A caudal block is an injection of local anaesthetic given to your child after they are anaesthetised and it numbs the lower half of the body, from the belly button downwards. The anaesthetist injects the caudal block right at the bottom of the back. It contains local anaesthetic which 'blocks' (numbs) the nerves in the area being operated on.

To ensure that pain relief lasts longer, additional medicines are given together with the local aneasthetic agent (Bupivacaine). In this study we will be looking at how long is pain relief when using bupivacaine and dexmedetomidine versus bupivacaine alone. All these medicines are proven to be safe for caudal blocks and in some countries, they are standard of practice. It is not essential that your child has a caudal block, but it is an additional type of pain relief that can help make sure your child is very comfortable without the side-effects of some strong pain relief medicines.

What are the benefits of a caudal block?

Your child is more likely to wake up without significant pain, and free of the side-effects of the stronger pain relief medicines (such as morphine) and of the general anaesthetic itself. This means that your child is likely to eat and drink sooner and can get back to normal quicker.

Are there any alternatives?

Yes. The surgeon can place local anaesthetic close to the area of the operation. This will give a smaller area of numbness which can be effective but may not cover all the necessary areas.

Alternatively, we can give your child stronger pain relief medicines into a vein and try to prevent sickness or side effects with other medicines. Nowadays the standard of practice is moving away giving strong medicines that are called opioids such as morphine because of many side effects. That is why caudal blocks are now becoming standard of practice in most centers as they are associated with fewer side effects and are effective.

Risks and side-effects

A caudal block is a very common procedure for children having an operation below the bellybutton. It has been shown in large studies to be extremely safe. However, as with all procedures, there are some risks and side effects to be aware of when deciding

about whether you would like your child to have a caudal block.

Common risks:

Numb, weak or heavy legs for a short amount of time

This is due to the local anaesthetic that is used for the caudal block. It will wear off after two to 12 hours. You must supervise your child when walking or crawling and keep them away from hot objects like radiators or hot baths.

Inadequate pain relief

Sometimes the local anaesthetic does not numb the whole area of the operation. The anaesthetist can usually tell if this has happened before your child wakes up. They will give them extra pain relief so that they wake up comfortably.

Rare risks:

Difficulty passing urine

The numbness may mean that it is difficult for your child to pass urine. A nurse may need to insert a small tube (catheter) into the bladder, but this is rare.

Infection

As with any injection, it is possible that the area can become infected. This is extremely rare, and great care is taken to make sure the skin and equipment used is sterile.

Bruising or bleeding

Sometimes, the skin around the injection site may bruise, this will soon settle. Very rarely a deeper blood clot may form, which may need further treatment to avoid nerve damage.

Reactions to local anaesthetic

These are extremely rare. Like any medicine, local anaesthetic can cause an allergic reaction. It can also enter the bloodstream or spinal fluid, which can cause a serious or life-threatening reaction. The anaesthetist will take precautions against this, and monitor your child carefully during and after the injection so that any problems can be treated.

Nerve damage

A caudal block is similar to an epidural, so nerve damage such as numbness or weakness is possible but extremely rare.

How rare are these risks?

The serious risks from a caudal block, as listed above, are all extremely rare. In a national survey of over 18,000 caudal blocks performed in the UK, no child suffered permanent harm or death.

However, it is important for you to be aware of all the possibilities when thinking about what is best for your child.

When your child leaves hospital

As the caudal block wears off, your child will start to feel more discomfort from the operation. You should give them simple pain relief medicine. We will give you advice about this before you leave.

Remember to keep your child away from hot or sharp objects until the day after their operation.

If there are any concerns do not hesitate to bring your child back to hospital for review.

Useful links

www.gosh.nhs.uk/medical-information/proceduresand-treatments/caudal-blocks

Contact the hospital at:

Telephone: **+264 612039111**