A COMPARATIVE STUDY OF RECTAL DICLOFENAC AND RECTAL PARACETAMOL FOR POST OPERATIVE PAIN RELIEF IN PAEDIATRIC ADENOTONSILLECTOMY

Dissertation submitted for M.D. Degree Examination

Branch X - Anaesthesiology

THANJAVUR MEDICAL COLLEGE,
THE TAMILNADU DR MGR MEDICAL UNIVERSITY,
Chennai – Tamilnadu.
MARCH – 2008.

CERTIFICATE

This is to certify that this dissertation entitled

"A COMPARATIVE STUDY OF RECTAL DICLOFENAC AND RECTAL PARACETAMOL FOR POST OPERATIVE PAIN RELIEF IN PAEDIATRIC ADENOTONSILLECTOMY"

is a bonafide record of the work done by Dr.K.Anusha under my supervision and guidance in the department of Anaesthesiology at Government Raja Mirasudhar Hospital of Thanjavur medical college, Thanjavur during the period of her post graduate study from May 2005 to March 2008 for the partial fulfillment of M.D.(Branch X - Anaesthesiolgy) degree.

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INDEX

INTRODUCTION

Pain derived from the latin word " poena" means punishment. The International Association for the Study of Pain (IASP) defined pain as "an unpleasant sensory or emotional experience associated with actual or potential tissue damage or described in terms of such damage "[8].

Understanding of pain is important. It should be viewed as nociception, pain , suffering and pain behaviour. Post operative pain forms one of the categories of acute pain. Acute pain in the postoperative setting is defined as pain that is present in a surgical patient because of pre existing disease, surgical procedure or both.. Surgery activates the stress response. Prolonged insult to the body produces changes in the nervous system which alter the normal physiological response to a noxious stimulus.

Surgery in particular produces biphasic insult. First of all it causes trauma to tissue which produces noxious stimuli. Secondly , after surgery there is inflammatory process at the site. They occur at peripheral level where there is a reduction in threshold of nociceptive afferents and at a central level with an increase in excitation of spinal neurons in pain transmission. Peripheral sensitization refers to events that occur within the

injured tissue itself shortly after injury. Specifically, a complex array of chemical and cellular mediators of inflammation is mobilized from within the tissue and from the circulatory system. Noxious stimuli are transmitted by the peripheral nociceptors and transmitted by the A delta and C fibres from the peripheral visceral and somatic sites to the dorsal horn of the spinal cord, where integration of peripheral nociceptive and descending modulatory input(i.e. encephalins) occurs. Further transmission is determined by complex modulating influences in the spinal cord. Some impulses pass to the anterior and anterolateral horns to initiate segmental reflex responses. Others are transmitted to higher centres through the spinothalamic and spinoreticular tracts, where they produce suprasegmental and cortical responses to ultimately produce the perception of pain.

The inflammatory mediators sensitize nociceptor endings in the skin and deep tissue causing them to generate sensory impulses in response to stimuli that would otherwise be weak . The results are allodynia and hyperalgesia. Central sensitization , another major factor in pain refers to abnormal amplification of incoming sensory signals in the central nervous system particularly the spinal cord. Central sensitization actually causes A beta touch input to be felt as painful.The one condition that consistently

triggers central sensitization is acute painful input, particularly impulses carried along nociceptive sensory C fibres .

A continuous stream of C fibre impulses generated as a result of peripheral sensitization can continuously maintain central sensitization allowing it to persist indefinitely.[9].

Pain inadequately relieved is deleterious. Consequences of unrelieved pain are numerous. First of all, the psychological consequences in the child which includes anxiety, fear, stress and sleep disturbances. The psychological consequences in the parents must also be kept in mind. The developmental consequences include increased behavioural and physiological responses to future painful experiences. Apart from these the cardiovascular , respiratory and metabolic responses also occur. The dominant neuro endocrine responses to pain involve the hypothalamic – pituitary – adrenocortical and sympathoadrenal interactions. Sympathetic activation may decrease myocardial oxygen supply through coronary vasoconstriction. It may also delay return of post operative gastro intestinal motility. Patients with poorly controlled pain may breathe less deeply, have an inadequate cough and may be more likely to develop postoperative pulmonary complications.

An individual who undergoes surgery would probably consider it his right to obtain post operative pain relief. With their knowledge of and familiarity with pharmacology, various regional techniques, and the neurobiology of nociception, anaesthesiologists are continually in the forefront of clinical and research advances in acute post-operative pain management. Anaesthesiologists are leaders in the development of acute post operative pain services. It is therefore the responsibility of the anaesthesiologist who is a perioperative physician to ensure comfort throughout the pre operative , intra operative and post operative period.

Adequate pain relief might translate to better perioperative outcome. Children constitute a special category in pain management. Like that seen in adults, under treatment of acute pain occurs in a substantial percentage of children. In addition to anatomic, physiological, pharmacodynamic differences between children and adults, there are unique barriers to paediatric patients that may hinder effective pain control.

One of the most important barriers to pain control are the myths that children and infants do not feel pain, that pain is not remembered, and that there is no untoward consequence of experiencing pain. Assessment of pain presents problems in the paediatric age group because of developemental,

cognitive and emotional differences. Paediatric patients may have difficulty in conceptualizing and quantifying a subjective experience as pain. Special scales are available to assist young children in self reporting of pain.

Children are often so terrified with the post surgical experience that they suffer pain for fear of something worse being inflicted on them. Children dread injections. Use of intramuscular injections is discouraged. In general, the oral route is preferred for analgesic administration for mild to moderate pain. The fear of needles may inhibit control of postoperative pain because paediatric patients may choose to suffer in silence rather than receive a painful and anxiety provoking intramuscular injection. Use of an intravenous PCA device offers autonomy. Children as young as 4 years have the cognitive ability to use it. Nurse or parent controlled analgesia is also effective, but close monitoring may be needed. Use of nonopioid analgesics such as NSAIDs or acetaminophen may improve overall analgesia, reduce the amount of opioid related side effects

Pain after tonsillectomy is due to trigeminal nerve stimulation, swallowed blood causing gastro intestinal irritation and there is an increased

incidence of post operative nausea and vomiting. Use of opioids may aggravate it. Also oral route may be difficult to administer in such situations.

Hence we chose this study to compare the efficacy of analgesia for post tonsillectomy pain with rectal diclofenac and rectal paracetamol.

AIM OF THE STUDY

To compare the efficacy of analgesia of rectal diclofenac 1mg / kg 8th hourly with that of rectal paracetamol 40mg / kg bolus dose , 20 mg / kg 6th hourly for post operative pain relief in children aged 6 – 13 years posted for elective adenotonsillectomies.

RECTAL ADMINISTRATION

A suppository is a drug delivery system that is inserted either into the rectum , vagina or urethra. The rectal route is useful when the oral ingestion is precluded (anaesthetized, unconscious or vomiting) Rectal route is amenable to both local and systemic delivery .

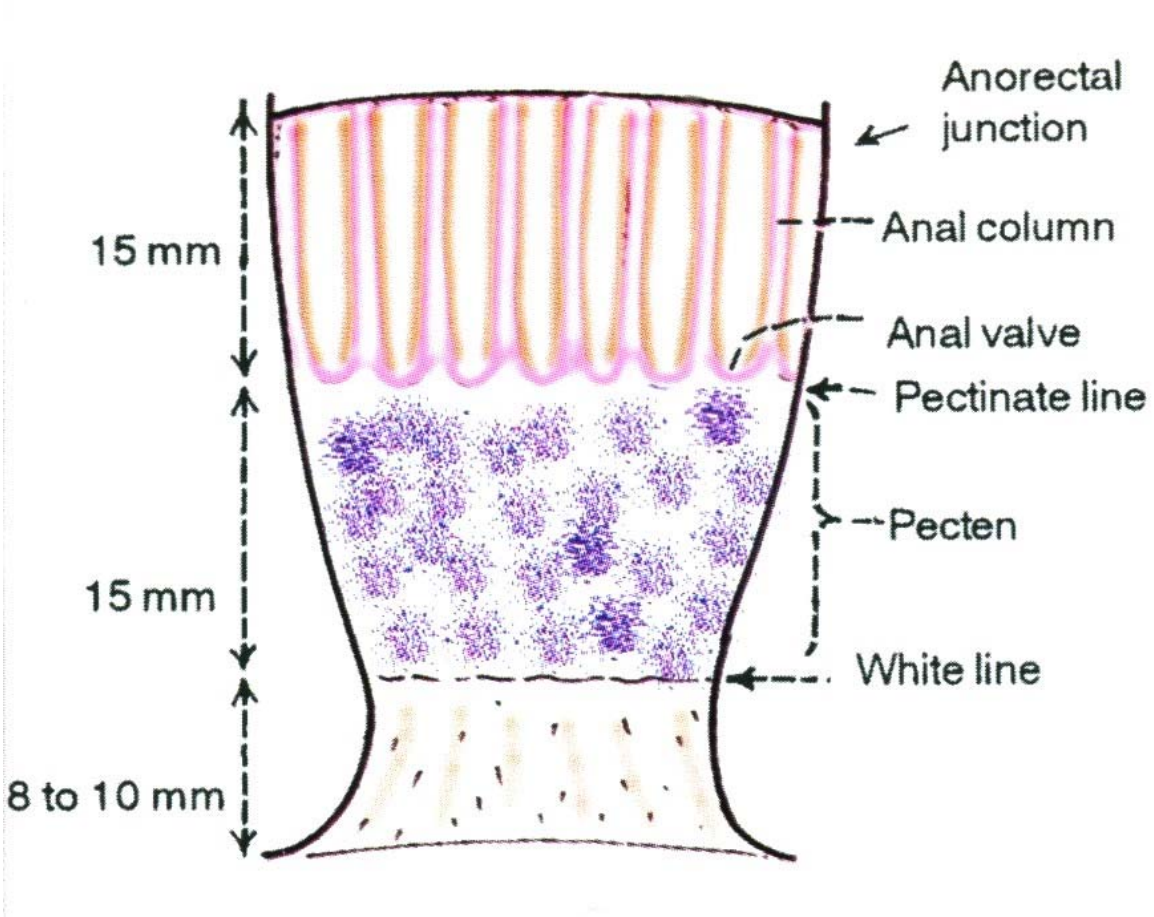
50% of the drug absorbed from the rectum will bypass the liver. So the potential for hepatic first pass metabolism thus is less than that for an oral dose.[1].

The surface area available for absorption is not large . Even then absorption can occur owing to extensive vascularity of the rectal mucosa. The rectum is drained by both the superior rectal veins and the inferior rectal veins.

There are two plexuses of veins draining the rectum and anal canal. One of them is the sub mucosal plexus and the other is perimuscular plexus.

Above the Hilton's line these veins are drained by superior rectal veins and thus reach the portal system. Below Hilton's line they drain into

inferior rectal veins and thus into the caval system.[2]. Thus suppositories placed below the Hilton's line have a better bio availability as they bypass the portal system. The Hilton's line is the line between the external and internal sphincters (inter- sphincteric groove or white line). Below this line anal canal is pain sensitive.[2].



Suppositories should not be split as the drug may not be uniformly distributed. Hence dosing may be difficult.

Also absorption from the rectum is irregular and incomplete. It may cause irritation of rectal mucosa. Solid suppositories are the most common form of rectal drug administration. Typically these are torpedo shaped drug preparations composed of fatty bases (low melting) or water soluble bases (dissolving) which vary in weight from 1g to 2.5g. Lipophilic drugs are incorporated into water soluble bases while hydrophilic drugs are formulated into fatty base suppositories. This method maximizes removal of the drug from the suppository base to the immediate environment of the rectal cavity or lower colon.

For suppositories made from fatty bases melting should occur rapidly near body temperature (37^0C) . Ideally the resultant melt would readily flow to provide thin , broad coverage of the rectal tissue thereby minimizing lag time effects due to slow release of the drug from the suppository base. Water soluble suppositories should likewise readily dissolve at 37^oC to facilitate drug release and subsequent absorption . With both fatty base and water soluble base, the potential effects of incorporated drug on melting or dissolution properties need to be evaluated.

Some of the fatty suppository bases are witepsol, cocoa butter , hard butter, estarinum, suppocire, agrasup. These have melting range close to

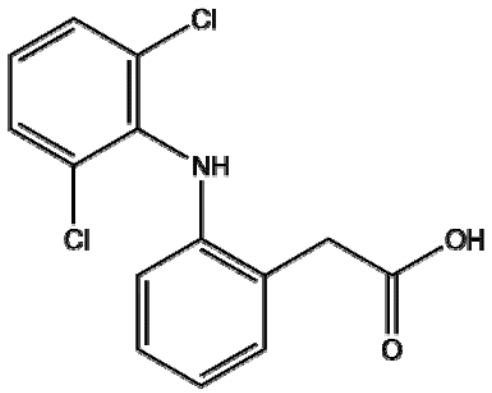
body temperature. Some of the water soluble bases are polyethylene glycol, glycerine sup (glycerol and gelatin),myrj 51 and tween 61. [4].

DICLOFENAC

The chemical name is sodium [2-(2,6- dichloroanilino)phenyl] acetate.

Formula : $C_{14}H_{11}Cl_2NNaO_2$

Structure :



Diclofenac sodium is a NSAID(Non Steroidal anti- inflammatory Drug). It has analgesic and antipyretic properties.[5].

Mechanism of action:

It inhibits prostaglandin synthesis by interfering with the action of prostaglandin synthetase. Although it does not alter the course of the underlying disease it relieves pain, reduces fever, swelling and tenderness.

Routes of administration:

Oral , rectal , Intramuscular, Intravenous.

Dose:

3mg / kg / 24 hours in divided doses by mouth or rectum

Pharmacokinetics:

Rapidly absorbed when given orally or rectally or intramuscular. Suppositories have a more rapid onset but slower rate of absorption than oral enteric coated tablets. Peak blood levels occur in 1 hour. It undergoes 50% first pass metabolism. 99% of the drug is protein bound. Terminal half life is 1 – 2 hours. Metabolites are 4'hydroxy diclofenac, 5- hydroxy diclofenac, 3' – hydroxy diclofenac and 4',5 - dihydroxy diclofenac. Excreted as glucoronides and SO_4 conjugates in urine (60%), bile (35%), <1% unchanged.[5].

Adverse effects:

Hypersensitivity reactions : aspirin sensitive asthmatic patients developed rhinorrhoea, tightness of chest , wheeze and dyspnoea. Anaphylactic shock has been reported.

Blood : reduced platelet aggregation, prolonged bleeding time, aplastic anaemia, hemolytic anaemia, neutropenia, agranulocytosis, thrombocytopenia

GIT : most frequent. Epigastric pain, nausea, vomiting and diarrhoea. Less common with other routes of administration.

Kidney : on chronic use , renal papillary necrosis or Nephrotic syndrome may occur.

Liver :– transaminases are elevated within 6 months of treatment.

Skin : Rash and pruritus may occur. Rectal administration may cause itching, burning and exacerbation of haemorrhoids.

NSAID s and tonsillectomy – they did not increase Post tonsillectomy bleeding [6]

Available Rectal preparations

Suppositories: 12.5 mg, 25 mg, 100mg yellowish white torpedo shaped with glyceride base. To be kept away from excessive heat. [Justin by NEON LABORATORIES]

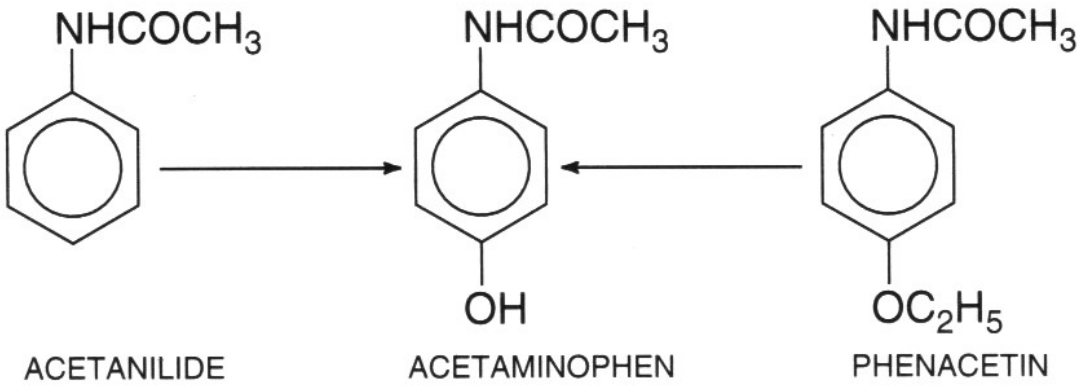
Contra indications:

Peptic ulcer, asthmatics, significant hepatic or renal impairment and known allergy to NSAIDs. Suppositories are contraindicated in patients with lesions in rectum or bleeding PR

PARACETAMOL

The chemical name is N – Acetyl- p- amino phenol. Also known as Acetaminophen or 4'-OH acetanilide.

Structure:



It is a mild analgesic and anti pyretic. Studies have demonstrated opioid sparing effect. It has weak anti inflammatory action.

Mechanism of action:

It reduces the production of prostaglandins in brain and spinal cord. It inhibits COX 3 in the hypothalamus.

Routes of administration:

Oral, rectal, Intramuscular, Intravenous.

An intravenous preparation of paracetamol has become available recently. Initial experience with intravenous paracetamol is that a high effect- site concentration after intravenous administration is associated with high analgesic potency. When administered intravenously, paracetamol should be given as an infusion over 15 minutes.

Peak blood levels are reached in 30-60 minutes after oral administration but peak levels may take 1 – 2hours after rectal administration. There is a wide variation in the bio availability following rectal administration [6].

Bioavailability of suppositories were approximately 80% of that of tablets. Tablets were absorbed faster and higher peak plasma concentrations were obtained than suppositories.[7]

Dose:

Rectal : Loading dose 40 mg/kg followed by 20mg/kg 6^{th} hourly upto a maximum daily dose of 100mg/kg .

Oral : 15 – 20mg/kg 4th hourly.

Pharmacokinetics

Readily absorbed from the GIT. It is distributed into most body tissues , crosses placenta and is present in breast milk. Elimination half life is 2-4 hours. 25% of the drug is protein bound. Metabolized predominantly in the liver and excreted as glucoronide conjugates in urine. Conjugation also occurs with glutathione . < 5% is excreted unchanged.

Adverse effects

When the maximum daily doses are observed it is well tolerated. Hepatotoxicity can occur when the daily dose exceeds 150mg/kg. multiple doses can accumulate in malnourished or dehydrated children. Prolonged use can produce nephropathy. Rarely , hypersensitivity reactions like urticaria, hypotension, rashes can occur. Caution required in liver and renal diseases.

Rectal administration is contraindicated in neutropenic patients (risk of sepsis) and in those with ulcerative or acute inflammatory lesions of rectum or anus.

Available rectal preparations:

80mg, 170 mg and 250 mg soluble base added To be stored in a cool, dry place protected from light.

[Anamol by Elders pharmaceuticals – 80mg , 170 mg]

[Neomol – 250 By NEON LABORATORIES]

METHODS OF PAIN ASSESSMENT

1. Self report techniques
2. Behavioural assessment
3. Physiological measurements

1. Self Report Techniques:

a) Visual analogue scale : It is a measurement that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot be directly measured easily. Operationally a VAS is usually a horizontal line 100mm in length, anchored by word descriptors at each end. The patient marks on the line the point that they feel represents their perception of their current state. The VAS score is determined by measuring in mm from the left hand side of the line to the point where the patient marks.

b) Numerical rating: Same as VAS scoring. But it has numbers 1to 10 for those 100mm. 1 indicates no pain, 5 indicates moderate pain and 10 worst ever experienced pain.

c) **Wong baker faces pain scale:** It is recommended for persons of age three and more. It contains six different faces of expression varying from a happy to sad mood. The patient has to be explained that each face is for a person who feels happy because he has no pain (hurt) or sad because he has some or a lot of pain. Ask the patient to choose the face that best describes how he is feeling. The child needs to have a cognitive developmental understanding of the term ‘pain’ or ‘hurt’.

d) **Poker – chip tools:** Aligning chips horizontally in front of the child and categorizing the chips as ‘least hurt’ to ‘ most hurt’ , ask the child to choose a chip that corresponds to his pain. No option of zero hurt. Record the number of chips.

e) **Oucher scale:** Variant of faces scale. It is designed to measure pain Intensity from 3 – 12 years. 6 photographs of children in varying degrees of pain are positioned vertically to the right and a numerical scale on the left.

All self reporting tests are highly subjective. They are more important when looking at a change within individuals and are of less value for comparing across a group of individuals at one point of time.

2) <u>Behavioural assessment:</u>

Behaviour is one of the first indicator that alerts a caregiver to the presence of pain. They score the behaviour which represent the reaction to pain and scores are allotted accordingly. Different scales have been developed concentrating on the different behaviours including crying, facial expression, motor responses , body posturing , activity and appearance. These tools may require pre assessment of behaviour that indicate whether pain is present or not.

a) FLACC scale:

This scale is appropriate for children >3years. It considers Facial expression, Leg movements , Activity , Cry and Consolability. Each category carries points from 0 – 2. A score > 4 indicates pain. (Refer Annexure,Fig 1).

b) CHEOPS scoring

(Children's Hospital Eastern Ontario Pain Scale)

It is recommended for children 1-7 years old . A score greater than 4 indicates pain. The parameters in this scale include cry, facial expression, verbal complaints, torso movements leg movements and localizing pain. (Refer Annexure Fig 2)

c) Objective pain scale

This measures pain as a physiological variable, blood pressure along with behavioural changes. This has been shown to be a sensitive and reliable tool in evaluating postoperative pain in children who are not able to verbally comment upon their pain experience. This takes into account the systolic blood pressure, cry and it's response to love and care, movement, agitation and verbal evaluation as described by **Hanallah RS .**

3) <u>Physiological measurements:</u>

Presence of pain is indicated through changes in physiological variables that can be associated with pain.These include heart rate, respiratory rate, BP, O_2 saturation metabolic and endocrine variables.

These measurements do not require child’s co operation. When other forms of assessment are impossible (intubated and ventilated) , this serves to be useful.

But most physiological measures of pain focus on the presence or absence of pain rather than the intensity or severity or magnitude of pain. These are best in combination with other forms of pain assessment.

MATERIALS AND METHODS

The study population consisted of 100 ASA grade I / II Children in the age group of 6 – 13 years admitted to undergo elective adenotonsillectomy at Government Raja Mirasudhar Hospital of Thanjavur Medical college.

The patients were randomly allocated into two groups

Group D : Receiving rectal Diclofenac 1mg/kg x 8th hourly

Group P : Receiving rectal Paracetamol

40mg/kg loading dose

20mg/kg 6th hourly

As the suppositories could not be split, the approximate per kg dose that was closest was selected.

Exclusion criteria consisted of bleeding diathesis, Bronchial asthma, inflammatory lesions of the rectum and anal canal, use of NSAID's within 10 days prior to the surgery and those with history of allergy to any of the NSAIDs.

The study was approved by the institutional ethical committee. A written consent was obtained from the parents. The children were assessed for anaesthetic fitness as out patients. ASA grade I/II children were selected.

Hb%, Total count, Differential count , Bleeding time, Clotting time and urine for albumin and sugar were done as pre operative investigations. For all children, pre operative starvation was for a period of 6 hours. Baseline BP, PR and SpO_2 were recorded.

All the children received Inj. Glycopyrrolate 0.01mg/kg and Inj. Midazolam 0.1mg/kg Intramuscularly 45 minutes prior to surgery as pre medication.

After shifting to the operating room, a 22G IV cannula was inserted on the right upper limb and a DNS infusion started.

Monitors (NIBP , ECG and Pulse oximetry) were connected. Then inj Fentanyl 2microgram/kg was given IV. Preoxygenation was done with 100% O_2 for 5 minutes.

Inj Thiopentone sodium 2.5% 5mg/kg was used for induction. Intubation was facilitated with Inj. Suxamethonium 2mg/kg .

All patients were intubated using an appropriate size endotracheal tube nasotracheally.

The rectal suppositories were placed after securing the airway.Anaesthesia was maintained with N_2O and O_2 at 66: 33%

Atracurium was the muscle relaxant used. Intermittent Positive Pressure Ventilation was employed.

After obtaining surgical homeostasis patients were reversed from neuromuscular blockade with Inj Neostigmine 0.05mg/kg and Inj Glycopyrrolate 0.02mg/kg..

The total duration of the surgical procedure and the blood loss were noted. Intra operative fluid therapy was done according to holiday and segar 4-2-1 formula.

Patients were extubated after oropharyngeal toileting.Post operative suppositories were kept 6th hourly for Paracetamol group and 8th hourly for Diclofenac group.

Postoperative pain assessment was done with Objective pain scoring system every 2 hours for a period of 24 hours.

If the pain scoring was more than 5, we had planned to give Inj Tramadol 1mg/kg as rescue analgesic.

Post operative pain assessment was done by an observer blinded to the study.

Objective pain scale:

OBSERVATION	CRITERIA	SCORING
Systolic blood pressure	± 10 % of Pre-op value	0
	>20% of Pre-op value	1
	>30% of Pre-op value	2
Crying	Not crying	0
	Crying but responds to TLC *	1
	Crying not responds to TLC*	2
Movement	None	0
	Restless	1
	Thrashing around	2
Agitation	Asleep or calm	0
	Mild agitation	1
	Hysterical	2
Verbalization of Pain	Asleep, States no pain	0
	Vague, Can't localize	1
	Localize pain	2

* Touch , Love and Care

OBSERVATIONS AND ANALYSIS

Hundred ASA grade I or II patients were taken up for our study. Among them, 50 belonged to Group D, diclofenac group and 50 belonged to Group P, Paracetamol group. All children were in the age group of 6 – 13 years.

In the postoperative period they were monitored by an observer blinded to the study.

AGE AND SEX DISTRIBUTION

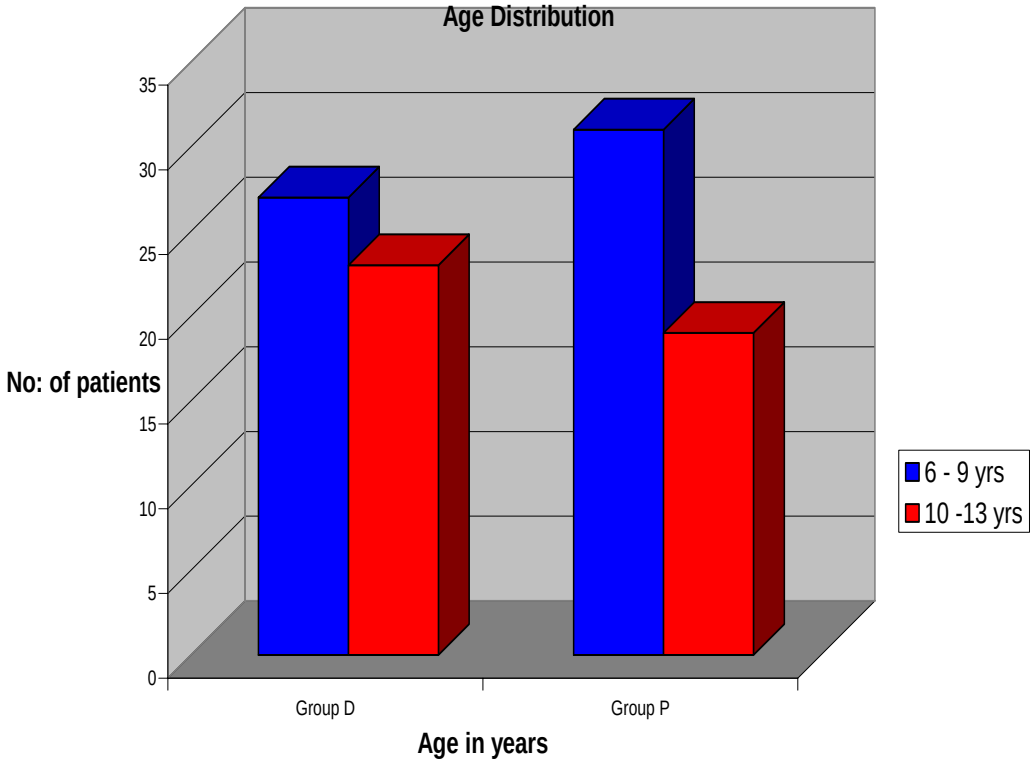
The age distribution in both the groups ranged from 6 – 13 years. The age and sex distribution are as follows

Age in years	**No: of Patients in Group D**	**No: of patients in Group P**
6 – 9 years	27	31
10 – 13 years	23	19

From this table it is clear that the number of children in 6 – 9 years and in the 10 – 13 years are not much different. This shows that the age was not a confounding factor. This can be seen better in the bar diagram that follows.

AGE DISTRIBUTION

Although there are more children in the 6 – 9 age group, the distribution among the two study groups is almost the same. In this bar diagram, the horizontal axis represents age in years and the vertical axis represents the number of patients. The blue colour represents the 6 – 9 age group and the red colour represents 10 – 13 age group. Group D is first in the series followed by group P



SEX DISTRIBUTION

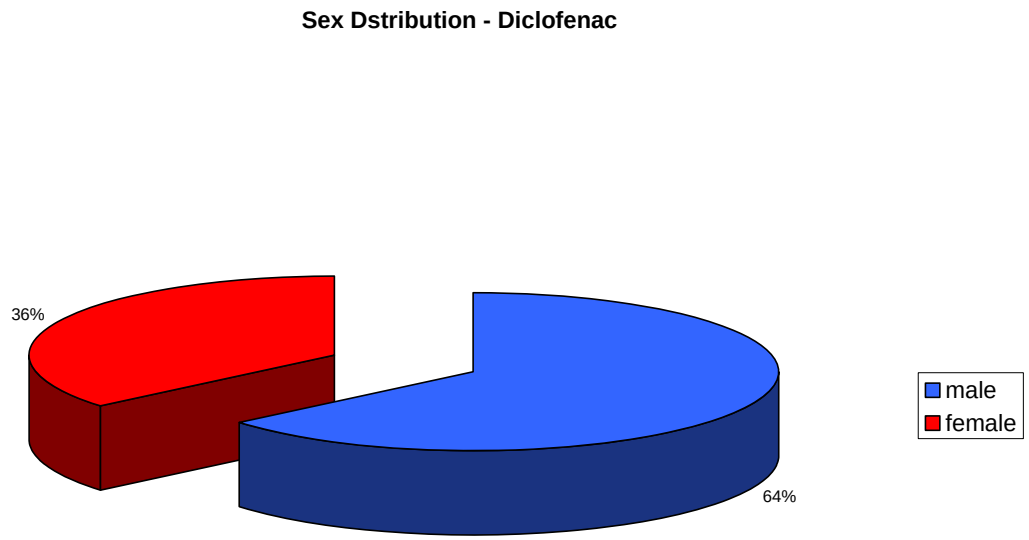
The sex distribution in both the groups are as follows

Sex	No: of patients in Group D	No: of patients in Group P
Male	32	29
Female	18	21

The sex distribution in both the groups is also not much different. This is evidenced by the pie diagram that follows.

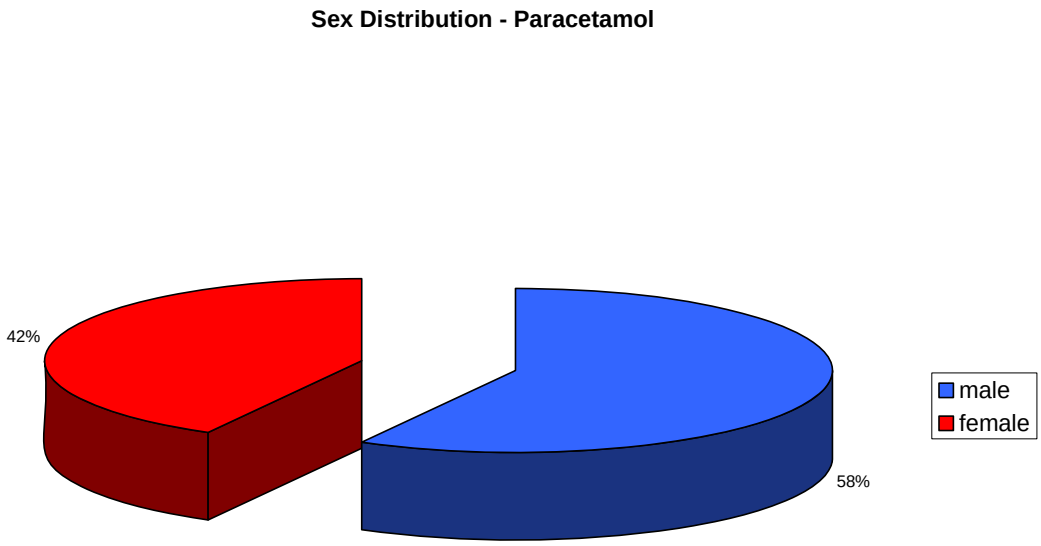
SEX DISTRIBUTION – GROUP D

The red colour represents female sex and the blue colour represents male sex.



In the group D, the percentage of males is 64 % and that of females is 26%.

SEX DISTRIBUTION – GROUP P



Similarly in Group P the male percentage is 58% and that of females is 42%.

Hence there is no bias in the age and sex distribution.

The mean weight among both the groups is as follows.

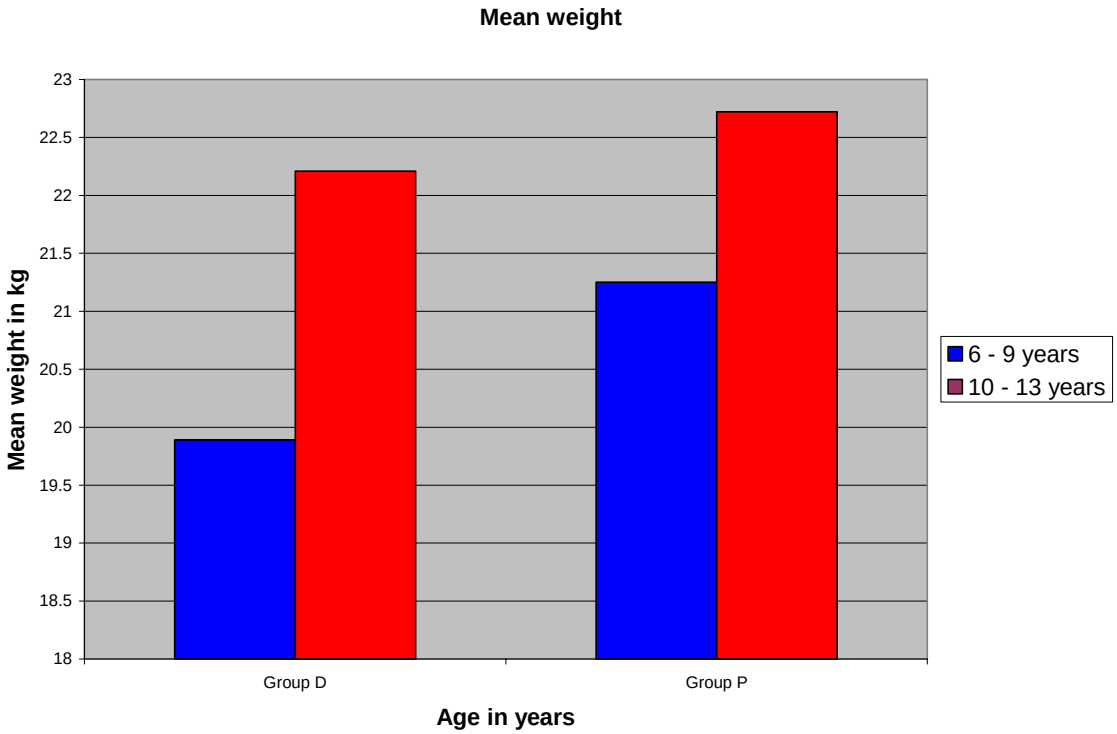
STATISTICS – GROUP D

		AGE D	WEIGHT D
N	Valid	50	50
	Missing	0	0
Mean		9.22	21.32
Median		9.00	21.00
Std. Deviation		1.57	2.19

STATISTICS – GROUP P

		AGE P	WEIGHT P
N	Valid	50	50
	Missing	0	0
Mean		9.10	21.6600
Median		9.00	20.5000
Std. Deviation		1.74	2.2003

The weight range is almost the same in both the groups in both the age groups. Hence there is no bias in the weight in both the groups.



The mean duration of surgery in both the groups is as follows. Both values are almost the same. This means that there was no differernce in the duration of surgery in both the groups.

All the surgeries were done by surgeons of equal experience in the field and they followed the same technique. None of the surgeries involved the use of cautery and none of the surgeries were unusually prolonged for the reason of bleeding. There was no increased blood loss in any of the cases in group D.

	Mean duration of surgeries in minutes with standard deviation
Group D	40.7+/-8.050
Group P	40.34+/-7.179

COMPARISON OF MEAN PAIN SCORES FOR BOTH THE GROUPS

T-TEST

(D – Diclofenac, P- Paracetamol, numbers represent hours)

STATISTICS – GROUP D

		MEAN D4	**MEAN D8**	**MEAN D12**	**MEAN D16**	**MEAN D20**	**MEAN D24**
N	Valid	50	50	50	50	50	50
	Missing	0	0	0	0	0	0
Mean		1.0700	1.3300	1.3400	1.2300	1.3300	1.3200
Median		1.0000	1.5000	1.5000	1.0000	1.5000	1.0000
Std. Deviation		.3196	.4803	.5194	.3228	.4908	.5322

STATISTICS – GROUP P

		MEAN D4	MEAN D8	MEAN D12	MEAN D16	MEAN D20	MEAN D24
N	Valid	50	50	50	50	50	50
	Missing	0	0	0	0	0	0
Mean		1.1900	1.4400	1.5500	1.3900	1.4100	1.2800
Median		20.5000	1.2500	1.5000	1.5000	1.5000	1.0000
Std. Deviation		.4151	.6197	.5912	.5080	.5411	.5639

GROUP P

Paired Samples Statistics A

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	MEAN D 4	1.0700	50	.3196	0.045
	MEAN P 4	1.1900	50	.4151	0.058
Pair 2	MEAN D 8	1.3300	50	.4803	0.067
	MEAN P 8	1.4400	50	.6197	0.087
Pair 3	MEAN D 12	1.3400	50	.5194	0.073
	MEAN P 12	1.5500	50	.5912	0.083
Pair 4	MEAN D 16	1.2300	50	.3228	0.045
	MEAN P 16	1.3900	50	.5080	0.071
Pair 5	MEAN D 20	1.3300	50	.4908	0.069
	MEAN P 20	1.4100	50	.5411	0.076
Pair 6	MEAN 24	1.3200	50	.5322	0.075
	MEAN P 24	1.2800	50	.5639	0.079

Paired Samples Test

		Paired Differences					t	df	P VALUE Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	MEAN D 4 - MEAN P 4	-.1200	.5398	0.076	-.2734	0.033	-1.572	49	.122
Pair 2	MEAN D 8 - MEAN P 8	-.1100	.8707	.1231	-.3574	.1374	-.893	49	.376
Pair 3	MEAN D 12 - MEAN P 12	-.2100	.7149	.1011	-.4132	-0.006	-2.077	49	.043
Pair 4	MEAN D 16 - MEAN P 16	-.1600	.5664	0.0801	-.3210	0.00097	-1.997	49	.051
Pair 5	MEAN D 20 - MEAN P 20	-0.08	.6496	0.091	-.2646	.1046	-.871	49	.388
Pair 6	MEAN 24 - MEAN P 24	-0.04	.7879	.1114	-.1839	.2639	.359	49	.721

The Paired-Samples T Test procedure compares the means of two variables that represent the same group at different times . The mean values

for the two variables are displayed in the Paired Samples Statistics table.A low significance value for the t test (typically less than 0.05) indicates that there is a significant difference between the two variables. If the confidence interval for the mean difference does not contain zero, this also indicates that the difference is significant.

If the significance value is high and the confidence interval for the mean difference contains zero, then it cannot be concluded that there is a significant difference between the means for the two variables.

In this sample only the 3rd Pair i.e at 12th hour the pain score is higher for Para group(1.55) when compared to Diclo Group(1.34) which is statistically significant marginally (P=0.043 of < 5).

The mean fourth hourly pain scoring in both the groups is represented as a line diagram. The horizontal axis is time in fourth hourly intervals. The vertical axis is mean pain scores. Red line represents Diclofenac and the blue line represents Paracetamol. Both the lines are almost close to each other demonstrating that there is no significant difference in pain scores in both the groups. The pain scoring was done once every 2 hours by an observer blinded to the study for 24 hours using the objective pain scale.

REVIEW OF LITERATURE

Dommerby et al (1984)

The efficacy of Diclofenac suppositories was estimated in a two centre, double blinded placebo controlled study comparing 97 patients. Post operative patients received immediately 100mg of diclofenac followed by 50 mg in the morning after operation or placebo suppositories.

The efficacy was assessed by both patients and by staff by marking on a visual analogue scale. Statistical analysis showed that diclofenac had a significant effect on pain associated with swallowing and on the general condition of the patient.[11]

Baer et al (1992)

They compared the effects of rectally administered diclofenac (12.5mg) with paracetamol (125mg) and post operative behaviour and the need for supplementary analgesia in 44 children scheduled for adenoidectomy. The study drugs were given in combination with diazepam (0.5mg/kg) about 20 minutes before the children were taken to the operating room.

Their observations were that children who had received diclofenac were significantly quieter (0.05), easier to handle ($p<0.01$) and cried less (0.05) than those in the paracetamol group. During recovery , children in the diclofenac group needed fewer supplementary doses of IV Pethidine than those receiving Paracetamol ($p<0.01$). There were no obvious differences between the groups in intraoperative bleeding.

They concluded saying pre operative rectal diclofenac for pain relief after adenoidectomy is safe and effective. [12].

A.Swanepoel et al (1999)

They compared the post operative analgesic effect of oral diclofenac with the rectal route. They studied 80 children between 2 and 14 years of age presenting for adenotonsillectomy. Rectal paracetamol 20mg/kg was given to all patients after induction of anaesthesia. One group of patients received rectal diclofenac (1mg/kg) following induction and another group received the same dose as oral suspension 2 hours prior to surgery. Post operatively all patients received oral diclofenac 1 mg/kg 8th hourly and oral paracetamol 12.5 mg/kg 6th hourly.

They concluded that pre operative oral administration of diclofenac is safe and more effective than if given PR. [13].

Tawalbeh et al

They did a comparative study of diclofenac sodium suppositories and paracetamol syrup for post tonsillectomy pain relief in 80 children aged 3 - 14 years. 41 children received diclofenac (1-3mg/kg) post operatively whereas 39 children received only paracetamol syrup (10 - 15mg/kg) in 4 divided doses.

They concluded that diclofenac sodium has a significant effect on decreasing pain associated with swallowing post operatively and on the general condition of the patient.[14].

Watters et al

Diclofenac sodium was assessed as an analgesic for post operative pain following paediatric tonsillectomy comparing it with pethidine. There were no significant differences between the two drugs in respect to time to awaken from anaesthesia or incidence of post operative vomiting.[15]

Bone et al

They conducted a study in 60 children between 3 and 13 years of age to compare the effectiveness of Diclofenac and papaveretum in prevention of pain and restlessness after tonsillectomy in children.

The consumption of paracetamol on the day of operation was significantly less in the diclofenac group. They concluded saying diclofenac offered advantages of safety and convenient to use over papaveretum.[16]

Romsing et al

They conducted a randomized double blind study of 48 children 5 - 15 years of age who underwent tonsillectomy to compare the analgesic efficacy of oral diclofenac and high dose acetaminophen. 24 children were assigned to receive either diclofenac 2-3mg/kg/24 hours or acetaminophen 90mg/kg/24 hours for first 3 days after surgery. Post operative pain was assessed by self report each day before scheduled medication at 7th hour, 12th hour, 18th hour and 23rd hour.

They concluded that diclofenac was no more effective than high dose acetaminophen (90mg vs 60mg/kg/24 hours) for analgesia, but resulted in a

lower incidence of nausea and vomiting in patients following tonsillectomy.[17].

A.Schmidt et al

They conducted a study in 90 patients (adults) who underwent tonsillectomy. They compared the effects of rectal diclofenac 1mg/kg given 20 - 30 minutes before tonsillectomy with that of rectal paracetamol 20 mg/kg a dose twice than that studied by Baer et al. The anaesthetic or surgical management did not differ between the groups but a significantly longer period of surgery was found in the diclofenac group. Pain scores or pethidine consumption was not significantly different. Intra operative blood loss was significantly larger in the diclofenac group.

They concluded that pre operative rectal diclofenac offers no advantage over paracetamol with respect to post operative analgesia in tonsillectomy patients but increases intra operative blood loss.[18].

B.N. Ewah et al

They conducted a prospective study examining the incidence of complications in 100 children admitted for routine elective day care tonsillectomy. They suggested a protocol which includes propofol 4mg/kg,

ondansetron 0.1mg/kg , maintenance with sevoflurane in air or O2, reinforced LMA, spontaneous respiration, dexamethasone 0.25mg/kg, rectal diclofenac 1mg/kg, rectal paracetamol 20mg/kg and IM codeine phosphate 1 mg/kg.

Post operative pain was well controlled with 85% of the children having minimal pain on the day of surgery reporting a pain score of 0 - 2 (wong baker faces pain scale).

They concluded that modifications to the anaesthetic technique can improve the outcome of pain and post operative nausea and vomiting in children undergoing day care. tonsillectomy.[19].

P M. Robinson et al

They did a retrospective review of case notes of patients having tonsillectomy done. The review revealed that 4 of the 73 patients (5.5%) receiving diclofenac at induction of anaesthesia suffered reactionary haemorrhage requiring operative control as compared to 2 of 293 (0.7%) receiving other analgesics.[20].

Steen Meiniche et al

They analysed 25 studies with data from 970 patients receiving a NSAID and 883 receiving a non NSAID treatment or a placebo. Data were combined using a fixed effect model.

They concluded that the evidence for NSAIDs to increase the incidence of bleeding after tonsillectomy remains ambiguous. The cautious clinical message must be that there is some evidence from randomized , controlled trials that NSAIDs may increase the likelihood of re operation because of bleeding particularly when NSAIDs are given in the post operative period. However, there is a lack of evidence for NSAIDs to increase intra operative blood loss or to increase the likelihood of post operative bleeding or re admission because of bleeding. Compared with opioids NSAIDs seem to be equianalgesic for this type of surgery and decrease the risk of PONV to some extent. [21].

Lau H et al

They conducted a prospective randomized trial of pre - emptive analgesics following ambulatory inguinal hernia repair. They compared

intravenous ketorolac 30mg immediately prior to induction with rectal diclofenac 50 mg in 108 patients who underwent ambulatory inguinal hernia repair under GA.

They concluded that diclofenac suppository is an economical alternative to intravenous ketorolac.[22].

Moores MA, Wanders JG, Fell D

43 children for day care inguinal herniotomy under GA were randomly assigned to receive either 1ml/kg caudal bupivacaine 0.25% or rectal diclofenac 0.25mg/kg intra operatively to provide postoperative analgesia.

They concluded that caudal bupivacaine provided more pain free patients at first 24 hours but later the incidence of pain was similar in both the groups. Rectal diclofenac is a useful alternative to caudal blockade in this group of patients.[23]

Emine ozyuvaci et al

They conducted a study in 60 boys aged 3 - 12 years who were operated for surgical repair of hypospadias. The patients were randomized into 3 groups. Patients in group I received rectal paracetamol 20-25mg/kg just before operation. Group II received only caudal bupivacaine. Group III received rectal paracetamol (20 - 25mg/kg) at the end of the operation. Pain was assessed by CHEOPS scoring.

These found that the duration of surgery and anaesthesia, pain scores and sedation scores of the groups were not significantly different.

They concluded that addition of pre operative or post operative rectal paracetamol in the doses used did not show an effect on the duration and intensity of post operative analgesia obtained by caudal bupivacaine.[24].

RESULTS AND DISCUSSION

This study was a randomized single blinded trial. It was conducted to compare the analgesic efficacy of diclofenac and paracetamol for post tonsillectomy pain.

There were 50 patients in each group. Group D received 1mg/kg of rectal Diclofenac 8th hourly and group P received rectal paracetamol 40 mg/kg loading dose and 20mg/kg 6th hourly. The pain scores were evaluated 2 hourly by the objective pain scale. The 4th hourly mean of the pain scores were almost the same. There was no difference in the pain scores in both the groups as is evident from the statistical analysis using the student's t test and paired sample test.

This means that rectal diclofenac offered no special advantage over rectal paracetamol and the analgesic efficacy of both the drugs were equal. These results correlated well with study results obtained by A.Schmidt et al.[18].

But in our study none of the the patients had increased blood loss as assessed by the surgeons and the duration of the surgery. None of the patients were taken up for post tonsillectomy bleed. All the surgeries were performed by surgeons of similar experience in the field.

Also none of the patients had a pain score of more than 5 and hence none of them received rescue analgesics.

These results also correlate well with the study results obtained by Romsing et al[17]. They reported that diclofenac was no more effective than high dose acetaminophen for analgesia but diclofenac resulted in a lower incidence of nausea and vomiting in patients following tonsillectomy. But they compared oral preparations which may have some practical difficulty in administering as these patients have pain on swallowing.

The study by Baer et al [12] and another study by Tawalbeh et al[14] suggested that diclofenac was better than paracetamol. But in the Baer et al group, they used a lower dose of acetaminophen than in our study group (125mg). and in the study by Tawalbeh et al they had compared an oral preparation with rectal diclofenac. As the surgery will be associated with

pain on swallowing in the post operative period, comparing rectal diclofenac with an oral paracetamol seems to have a bias.

Regarding blood loss and NSAIDs the study by A.schmidt et al [18] has stated that there is increased blood loss with diclofenac as pre operative analgesic. This was also supported by P.M. Robinson et al[20]. But a comprehensive analysis done by Steen meinche et al from 25 studies suggest that there is no evidence supporting increased intra operative blood loss or increased post operative bleeding or re admission because of bleeding.

In our study also there were no cases of reactionary haemorrhage and none of the patients required surgical control for bleeding post operatively.

SUMMARY

A randomized, single blind study was conducted in 100 ASA grade I / II patients aged 6 - 13 years posted for elective adenotonsillectomy. Post operative pain relief was compared between rectal diclofenac 1 mg / kg given eighth hourly and rectal paracetamol with a loading dose of 40 mg / kg followed by 20 mg / kg sixth hourly. The patients were divided into two groups of 50 in each group. The post operative pain scores were observed in both the groups for a period of 24 hours. Objective pain scale was used. The post operative pain scores were equal in both the groups which has been proved statistically using the student's t test and paired t test.

There was no excessive bleeding in the Diclofenac group as evidenced by an equal duration of surgery in both the groups. None of the patients had post tonsillectomy bleeding. All the surgeries were done by surgeons of equal experience in the field and they used the same technique.

Hence we concluded that rectal diclofenac and rectal paracetamol are equally effective in relieving post tonsillectomy pain in children and there was no increase in blood loss in diclofenac group.

CONCLUSION

We conclude that both rectal diclofenac and rectal paracetamol are equally effective on the analgesic efficacy of post tonsillectomy pain in children undergoing elective adenotonsillectomies. There was no significant increase in bleeding with the rectal diclofenac group.

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PROFORMA

Name : **Age :** **Sex:** **Weight :**

Assessment no: **ASA grade:** **I.P.No:**

History:

Starvation:

Pre operative examination:

PR: **BP:** **CVS:** **RS:**

Airway:

Others:

Investigations:

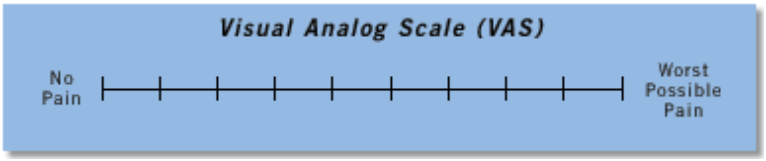
Hb% : **Urine :** **TC:** **DC:**

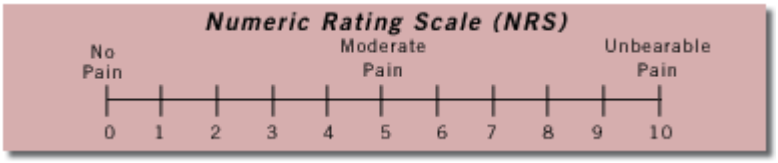
ESR : **Blood grouping:** **BT:** **CT:**

Rectal Suppository : **Drug :** **Dose :**

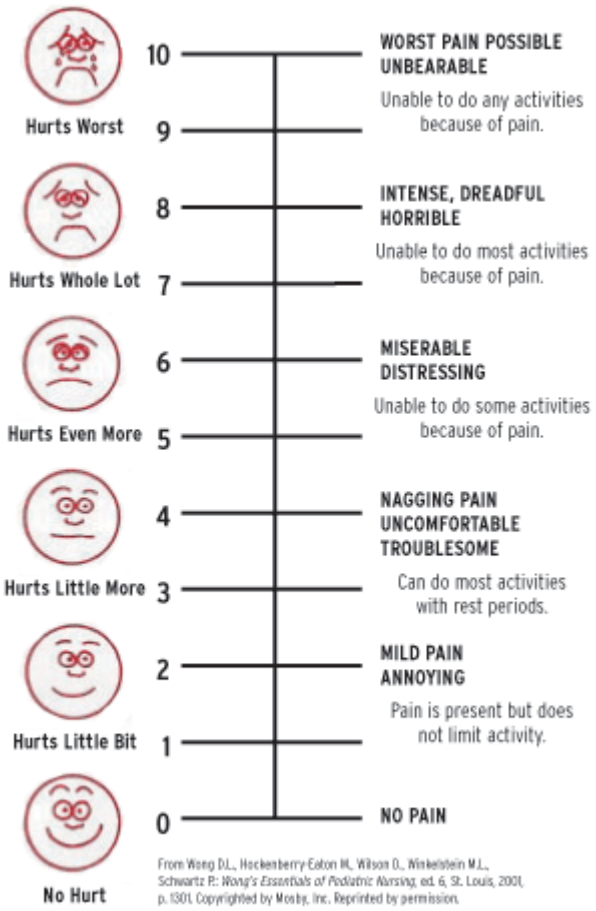
Duration of Surgery :

Pain Scoring	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**18**	**20**	**22**	**24**
Group D												
Group P												


Visual Analog Scale (VAS)
No Pain
Worst Possible Pain


Numeric Rating Scale (NRS)
No Pain
Moderate Pain
Unbearable Pain
0 1 2 3 4 5 6 7 8 9 10

WONG BAKER FACES PAIN SCALE



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S.No.	Name	Age	Sex	Weight	Duration of Surgery	Baseline Bp mmHg	Diclofenac 8th hourly	Pain Scoring - 2 hourly												Rescue Analysis
								2	4	6	8	10	12	14	16	18	20	22	24	
1	Manikandan	11	M	20kg	40min	100/70	25mg	1	1	1	1	2	2	1	1	2	1	1	2	–
2	Venkatesan	11	M	25kg	45min	98/72	25mg	1	0	0	1	2	1	1	2	0	1	2	1	–
3	Dhinesh	8	M	20kg	48min	104/68	25mg	1	1	1	2	2	1	1	1	1	1	2	0	–
4	Muthamizhselvi	8	F	22kg	60min	97/60	25mg	1	1	2	1	2	1	1	2	1	2	2	0	–
5	Chandran	12	M	22kg	42min	113/72	25mg	1	2	2	1	2	2	1	1	2	1	1	1	–
6	Deepan	12	M	23kg	44min	119/79	25mg	1	1	2	1	1	1	1	1	1	2	1	1	–
7	Rasnali	10	M	22kg	46min	109/84	25mg	1	1	1	1	1	1	1	1	1	1	2	1	–
8	Shanmuga Priya	11	F	23kg	48min	98/60	25mg	1	1	1	1	1	0	1	2	0	1	2	1	–
9	Saranya	12	F	20kg	50min	96/66	25mg	1	1	2	1	1	1	1	1	1	1	2	1	–
10	Praveena	10	F	20kg	52min	92/64	25mg	1	2	2	1	1	1	1	1	1	1	2	1	–
11	Vichithra	9	F	22kg	28min	120/74	25mg	1	2	3	1	2	2	1	2	1	1	3	1	–
12	Cholarajan	11	M	25kg	36min	110/68	25mg	1	1	1	1	1	1	1	1	2	1	2	1	–
13	Shyamala	9	F	20kg	38min	100/72	25mg	1	1	1	0	1	1	1	1	0	1	1	0	–
14	Hariharan	10	M	20kg	40min	102/60	25mg	1	1	2	1	1	1	1	1	0	1	2	0	–
15	Appuraj	12	M	24kg	32min	100/70	25mg	1	1	2	1	1	1	1	2	1	1	2	0	–
16	Navrose Banu	8	F	18kg	30min	98/60	25mg	1	0	1	1	1	2	1	2	1	2	2	1	–
17	Ashika Parveen	6	F	19kg	34min	92/70	25mg	1	1	0	1	1	1	1	2	2	2	2	1	–
18	Vikram	8	M	23kg	36min	116/74	25mg	1	1	2	1	1	1	1	1	2	2	2	2	–
19	Subhashini	7	F	18kg	38min	113/77	25mg	1	1	1	1	1	0	1	2	1	2	1	1	–
20	Jamila	7	F	20kg	44min	107/69	25mg	1	1	1	1	1	1	1	2	2	2	1	1	–
21	Gowtham	7	M	20kg	46min	112/69	25mg	1	1	1	1	0	1	1	1	1	1	2	1	–
22	Azhauddin	8	M	20kg	48min	101/58	25mg	1	1	2	1	1	1	1	2	1	2	1	1	–
23	Thanga Thamilan	9	M	22kg	26min	104/59	25mg	1	1	1	1	1	2	1	2	1	1	2	2	–
24	Maheshwari	10	F	20kg	30min	106/60	25mg	1	0	1	1	0	1	2	1	0	1	1	0	–
25	Maheshwaran	7	M	20kg	34min	118/04	25mg	1	1	2	1	1	0	1	1	0	1	1	1	–

S.No.	Name	Age	Sex	Weight	Duration of Surgery	Baseline Bp mmHg	Diclofenac 8th hourly	Pain Scoring - 2 hourly												Rescue Analysis
								2	4	6	8	10	12	14	16	18	20	22	24	
26	Chandran	9	M	22kg	44min	98/70	25mg	1	0	1	2	1	1	1	2	2	1	1	0	–
27	Solainathan	10	M	24kg	48min	94/68	25mg	1	1	2	1	2	1	1	1	1	1	2	2	–
28	Lakshmi Priya	8	F	20kg	50min	108/74	25mg	1	2	1	1	1	1	1	2	1	2	2	0	–
29	Nivetha	7	F	18kg	54min	118/68	25mg	1	2	3	2	2	3	1	1	4	1	2	4	–
30	Saravanan	9	M	25kg	25min	107/70	25mg	1	1	3	1	2	2	1	2	1	2	1	1	–
31	Sumathy	10	F	20kg	30min	106/60	25mg	1	2	2	1	2	1	1	2	2	2	2	1	–
32	Dhanalakshmi	8	F	21kg	34min	102/58	25mg	1	1	2	1	1	1	1	1	1	2	3	1	–
33	Senthil Kumar	9	M	23kg	35min	109/62	25mg	1	2	1	1	2	1	1	2	1	1	1	0	–
34	Santhosh	10	M	24kg	32min	94/60	25mg	1	1	1	1	1	1	2	1	1	1	2	0	–
35	Pandiyan	9	M	23kg	38min	98/62	25mg	1	2	1	1	1	1	1	1	1	1	1	1	–
36	Veeramuthu	10	M	24kg	44min	116/42	25mg	1	1	2	1	2	2	2	2	2	2	1	1	–
37	Vandhana	9	F	23kg	46min	103/59	25mg	1	0	2	1	1	2	1	0	2	2	1	2	–
38	Paulraj	10	M	25kg	48min	106/70	25mg	1	1	3	2	1	2	1	1	2	1	2	2	–
39	Bhoopathy	11	M	25kg	50min	98/66	25mg	1	1	2	1	1	2	1	1	2	1	1	1	–
40	Devi Priya	9	F	20kg	52min	117/80	25mg	1	2	3	1	2	4	1	2	3	2	2	3	–
41	Farooq	11	M	25kg	40min	113/80	25mg	1	3	4	1	2	1	1	1	1	2	1	0	–
42	Madhan Kumar	10	M	20kg	42min	119/82	25mg	1	2	1	2	2	1	1	0	1	1	2	2	–
43	Manikandan	10	M	21kg	44min	92/60	25mg	1	1	2	1	2	1	1	1	1	1	2	1	–
44	Suresh Kumar	9	M	23kg	46min	116/80	25mg	1	2	1	1	2	1	2	2	2	1	1	1	–
45	Balaji	10	M	22kg	47min	94/66	25mg	1	1	1	1	2	2	1	1	1	2	2	2	–
46	Krishnan	9	M	20kg	38min	107/68	25mg	1	1	1	1	1	2	1	1	1	1	2	1	–
47	Ramesh	8	M	18kg	36min	113/56	25mg	1	0	0	1	1	1	2	1	1	2	1	1	–
48	Diwakar	7	M	17kg	40min	105/60	25mg	1	1	1	1	2	2	1	1	1	1	2	1	–
49	Bhama	6	F	18kg	28min	97/56	25mg	1	1	1	1	2	1	1	1	1	2	1	1	–
50	Podhene Ponnu	10	F	20kg	29min	108/64	25mg	1	2	1	2	2	2	1	1	1	2	2	0	–

S.No.	Name	Age	Sex	Weight	Duration of Surgery	Baseline Bp mmHg	Paracetamol 6th hourly		Pain Scoring - 2 hourly														Rescue Analysis
							L	T	2	4	6	8	10	12	14	16	18	20	22	24			
1	Sugan	7	M	20kg	45min	104/60	750/500		1	2	3	1	2	2	2	2	2	2	1	1	–
2	Vignesh	10	M	25kg	38min	92/58	1000/500		1	2	2	2	2	2	1	3	2	2	1	2	–
3	Dhivya	7	F	20kg	40min	116/77	750/500		0	1	1	1	1	1	1	2	1	2	1	1	–
4	Natarajan	9	M	18kg	42min	117/62	750/500		1	2	4	3	2	3	3	1	3	2	1	4	–
5	Pasamalar	12	F	22kg	34min	108/58	750/500		1	1	0	1	1	0	0	2	2	2	2	1	–
6	Dhivya	9	F	20kg	26min	98/70	750/500		1	0	1	1	2	0	0	1	1	1	1	0	–
7	Nivedha	10	F	20kg	28min	113/63	750/500		1	2	2	1	1	1	1	2	2	1	1	1	–
8	Kateswaran	13	M	23kg	40min	107/59	750/500		1	1	1	2	1	0	0	1	1	2	2	0	–
9	Ranjith Kumar	13	M	25kg	45min	116/62	1000/500		1	2	2	2	1	1	1	2	1	1	1	1	–
10	Kamal Raj	6	M	20kg	46min	93/64	750/500		1	1	2	1	2	2	2	1	2	1	2	2	–
11	Devi	8	F	23kg	48min	99/70	750/500		1	2	1	1	2	1	1	1	0	1	1	1	–
12	Nandhini	10	F	20kg	60min	112/70	750/500		1	1	2	1	2	1	1	3	2	2	1	1	–
13	Soundar	7	M	20kg	42min	99/60	750/500		1	2	2	1	1	2	1	1	2	2	2	1	–
14	Tamil Selvi	8	F	23kg	44min	92/58	750/500		1	2	2	1	2	0	1	1	1	1	1	1	–
15	Venilla	9	F	18kg	45min	111/62	750/500		1	1	2	2	1	1	2	1	1	1	1	1	–
16	Mohamined Aran	7	M	20kg	40min	96/70	750/500		1	2	1	1	1	2	1	1	2	1	1	1	–
17	Yousuf	9	M	24kg	35min	119/63	1000/500		1	2	3	2	1	2	2	2	1	2	2	1	–
18	Prabavathy	7	F	20kg	36min	104/60	750/500		1	1	3	1	1	3	1	1	3	1	1	3	–
19	Hariharan	7	M	25kg	38min	121/74	1000/500		1	2	2	2	1	1	1	2	1	2	1	2	–
20	Devibala	9	F	25kg	40min	96/66	1000/500		1	2	2	1	2	1	2	1	2	1	1	2	–
21	Mahamined Ansari	7	M	25kg	42min	104/64	1000/500		1	1	1	1	3	2	2	1	1	1	1	1	–
22	Sarath Kumar	8	M	23kg	44min	109/70	750/500		1	2	3	1	1	2	2	2	2	2	2	2	–
23	Priyadharshini	11	F	24kg	46min	119/68	1000/500		1	3	4	1	2	3	1	1	1	1	1	2	–
24	Poovarasan	7	M	20kg	48min	106/70	750/500		1	1	0	1	0	1	2	2	1	1	0	1	–
25	Poovendhan	7	M	20kg	40min	101/64	750/500		1	2	1	1	1	2	1	1	0	1	0	1	–

S.No.	Name	Age	Sex	Weight	Duration of Surgery	Baseline Bp mmHg	Paracetamol 6th hourly		Pain Scoring - 2 hourly														Rescue Analysis
							L	T	2	4	6	8	10	12	14	16	18	20	22	24			
26	Dhinesh	8	M	20kg	40min	108/72	750/500		1	1	1	1	2	1	1	2	2	1	1	1	–
27	Kavitha	9	F	22kg	35min	118/60	750/500		2	1	2	1	1	2	2	2	2	1	2	2	–
28	Vikram	8	M	24kg	20min	119/74	1000/500		1	1	1	2	1	0	1	1	1	2	1	1	–
29	Devarajan	10	M	20kg	35min	98/62	750/500		1	2	1	1	1	1	1	2	1	1	2	1	–
30	Vidhya	11	F	25kg	44min	100/72	1000/500		1	2	3	2	2	4	3	2	4	1	2	3	–
31	Muthusamy	9	M	25kg	25min	104/63	1000/500		1	1	1	2	1	2	1	0	2	1	2	2	–
32	Bhanupriya	9	F	20kg	40min	116/70	750/500		1	1	0	1	2	1	1	1	2	1	2	1	–
33	Sasi Kumar	8	M	23kg	36min	97/60	750/500		1	1	2	1	2	3	2	2	2	1	1	1	–
34	Selvaraj	10	M	24kg	42min	117/68	1000/500		1	2	1	1	1	2	2	2	1	1	2	1	–
35	Senthil Kumar	8	M	20kg	40min	107/58	750/500		1	2	3	1	2	2	1	1	1	2	2	1	–
36	Rajalakshmi	7	F	20kg	38min	117/60	750/500		1	2	3	1	1	2	2	2	2	1	1	1	–
37	Sangeetha	9	M	19kg	32min	120/58	750/500		1	2	2	1	2	1	1	2	2	1	0	0	–
38	Bharath	9	M	20kg	46min	106/64	750/500		1	1	1	1	3	2	1	2	0	1	1	0	–
39	Rajan	10	M	22kg	28min	104/62	750/500		1	1	0	2	1	1	1	2	0	1	1	0	–
40	Paulraj	11	M	24kg	48min	108/70	1000/500		1	2	0	1	1	1	1	0	2	1	1	1	–
41	Veerapandi	13	M	25kg	44min	118/68	1000/500		1	1	1	1	1	2	1	1	1	1	2	1	–
42	Sathya Priya	12	F	24kg	38min	104/62	1000/500		1	1	0	1	1	1	2	1	1	1	1	1	–
43	Sasikala	10	F	20kg	47min	100/64	750/500		1	1	1	2	1	2	1	1	1	1	1	1	–
44	Kalavathy	10	F	18kg	50min	96/70	750/500		2	1	1	1	2	2	1	1	1	1	1	1	–
45	Dharmaraj	9	M	20kg	48min	92/68	750/500		2	1	1	1	0	2	1	1	1	2	1	0	–
46	Suganthi	10	F	22kg	33min	116/71	750/500		1	3	0	1	2	2	1	3	0	1	2	1	–
47	Palanisamy	8	M	20kg	37min	99/73	750/500		0	1	1	2	2	2	2	2	2	1	2	2	–
48	Pandiyan	9	M	22kg	40min	106/64	750/500		0	1	3	1	1	4	1	1	2	4	1	1	–
49	Prema	10	F	20kg	46min	116/72	750/500		0	1	2	0	1	3	1	1	2	2	1	3	–
50	Lakshmi	11	F	21kg	48min	101/64	750/500		0	0	2	1	2	2	1	0	1	1	1	4	–

ANNEXURES

FLACC Behavioural pain scale:

FLACC Behavioral Pain Assessment			
Categories	**Scoring**		
	0	**1**	**2**
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position moves easilyl	Squirming, shifting back and forth, tense	Arched, rigid or jerking
Cry	No cry, (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching hugging or being talked to, distractable	Difficulty to console or comfort

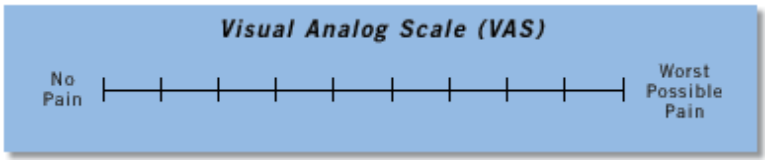
Each of the five categories is scored from 0-2, resulting in a total score between 0 and 10.
The FLACC scale was developed by Sandra Merkel, MS, RN, Terri Voepel-Lewis, MS, RN, and Shobha Malviya, MD, at C. S. Mott Children's Hospital, University of Michigan Health System, Ann Arbor, MI.

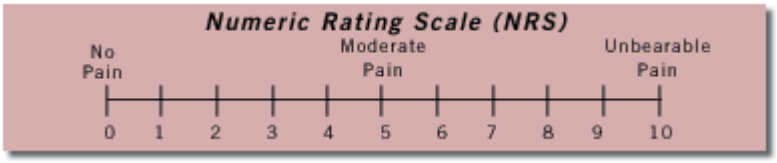
Fig 1

Children's Hospital Eastern Ontario Pain Scale (CHEOPS)

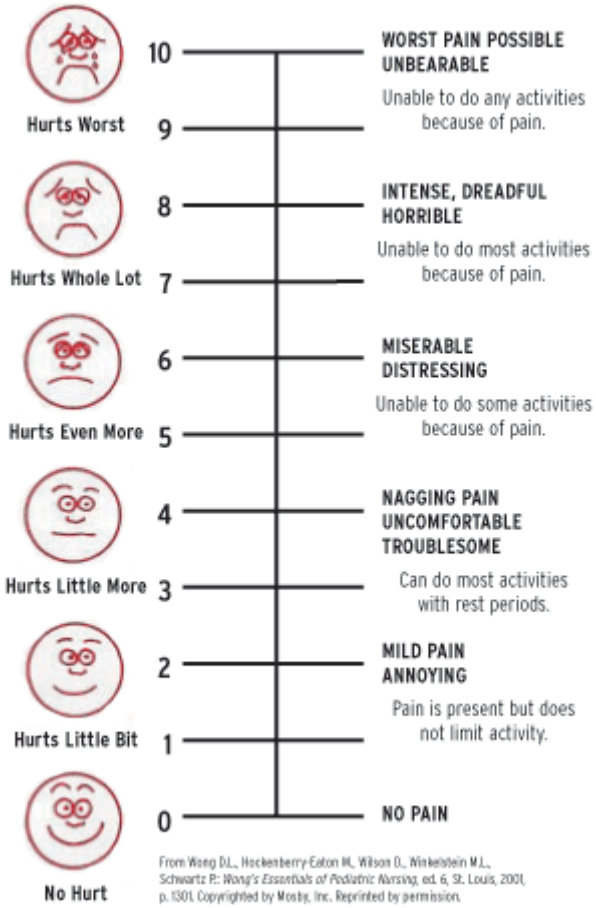
(Recommended for children 1-7 years old) - A score greater than 4 indicates pain.

Item	Behavioral		Definition	Score
Cry	No cry	1	Child is not crying.	
	Moaning	2	Child is moaning or quietly vocalizing silent cry.	
	Crying	2	Child is crying, but the cry is gentle or whimpering.	
	Scream	3	Child is in a full-lunged cry; sobbing; may be scored with complaint or without complaint.	
Facial	Composed	1	Neutral facial expression.	
	Grimace	2	Score only if definite negative facial expression.	
	Smiling	0	Score only if definite positive facial expression.	
Child Verbal	None	1	Child not talking.	
	Other complaints	1	Child complains, but not about pain, e.g., “I want to see mommy” of “I am thirsty”.	
	Pain complaints	2	Child complains about pain.	
	Both complaints	2	Child complains about pain and about other things, e.g., “It hurts; I want my mommy”.	
	Positive	0	Child makes any positive statement or talks about others things without complaint.	
Torso	Neutral	1	Body (not limbs) is at rest; torso is inactive.	
	Shifting	2	Body is in motion in a shifting or serpentine fashion.	
	Tense	2	Body is arched or rigid.	
	Shivering	2	Body is shuddering or shaking involuntarily.	
	Upright	2	Child is in a vertical or upright position.	
	Restrained	2	Body is restrained.	
Touch	Not touching	1	Child is not touching or grabbing at wound.	
	Reach	2	Child is reaching for but not touching wound.	
	Touch	2	Child is gently touching wound or wound area.	
	Grab	2	Child is grabbing vigorously at wound.	
	Restrained	2	Child's arms are restrained.	
Legs	Neutral	1	Legs may be in any position but are relaxed; includes gentle swimming or separate-like movements.	
	Squirm/kicking	2	Definitive uneasy or restless movements in the legs and/or striking out with foot or feet.	
	Drawn up/tensed	2	Legs tensed and/or pulled up tightly to body and kept there.	
	Standing	2	Standing, crouching or kneeling.	
	Restrained	2	Child's legs are being held down.	


Visual Analog Scale (VAS)
No Pain
Worst Possible Pain


Numeric Rating Scale (NRS)
No Pain
Moderate Pain
Unbearable Pain
0 1 2 3 4 5 6 7 8 9 10

WONG BAKER FACES PAIN SCALE



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OUCHER FACES PAIN SCALE