## Appendix B Randomised controlled trials: Study details

### Systematic Review of the FLACC scale for assessing pain in infants and children: is it reliable, valid, useful and feasible for use?

Dianne CRELLINa-c, Nick SANTAMARIAa f Franz E BABLb-d, Denise HARRISONa b e

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study** | **Design/Aim** | **Subjects/circumstances/ Setting** | **Intervention/Pain measure** | **Results** | **Quality score** |
| Amin et al, 2014 [[1](#_ENREF_1)] | Double-blind randomized (placebo-controlled) study  To evaluate the role of gabapentin premedication in the management of post-operative pain following adenotonsillectomy in children. | 120 children aged 4 – 6 years  Exc: chronic illness, epilepsy  Postoperative (adenotonsillectomy)  Not stated | 3 groups – participants randomised to:  Group G: - Oral gabapentin 10 mg/kg 2hrs preoperatively  Group D: placebo pre-operatively & dexamethasone 0.15 mg/kg intravenously preoperatively after induction.  Group C: Oral gabapentin 10 mg/kg 2hrs preoperatively & dexamethasone 0.15 mg/kg intravenously preoperatively after induction.  Pain scoring: FLACC  \* Analgesics determined by pain score | FLACC score in Group C and Group  G less at 4 h, 6 h and 8 h post-operatively than in Group D (P < 0.05). At 12h pain score in Group C less than Group G and  Group D (P < 0.05). No difference in FLACC score at 18h post-operatively (p > 0.05). Time to first analgesic longer in Group C than Group G and Group D & time to first analgesic longer in Group G than in Group D (P < 0.05). Total pethidine dose less in Group C & Group G than in Group D (p < 0.05).. | 3 |
| Anand et al, 2011 [[2](#_ENREF_2)] | Randomised double blind parallel group (controlled) trial  To compare the effects of caudal dexmedetomidine combined with ropivacaine to provide postoperative analgesia in children and also to establish its safety in the paediatric population | 60 children aged 6mth – 6 years  Exc: developmental delay  Postoperative (urogenital procedures)  Not stated | 2 groups – participants randomised to:  Group RD - 0.25% ropivacaine 1 ml/kg with dexmedetomidine 2 mμg/kg,  Group R - 0.25% ropivacaine 1 ml/kg + 0.5 ml normal saline  Administer via caudal block following induction of anaesthesia  Pain scoring: FLACC  \* Analgesics determined by pain score | Group RD duration of analgesia longer than Group R (p < 0.001)  Group RD had significantly\* lower FLACC score compared with Group R (0/30 versus 20/30 scored 4 at 6th hour)  Group RD more sedated than Group R (P<0.001) and the emergence behaviour score lower in Group RD (p < 0.001)  \* [p values not reported] | 3 |
| Ashrey et al, 2014[[3](#_ENREF_3)] | Randomised trial  To evaluate the effect of penile block versus caudal block using bupivacaine on the quality of analgesia, and the surgeon’s and parents’ satisfaction after penile paediatric surgery. | 80 children aged 1 – 7 years  Exc: neurological disease  Postoperative (penile surgeries)  Recovery and ward | 2 groups – participants randomised to:  Group P: penile block, 0.25% bupivacaine, 0.5 mg/kg  Group C: caudal block, 0.25% bupivacaine, 0.5 mg/kg  Pain scoring: FLACC  \* Analgesics determined by pain score | FLACC pain scores lower in group P compared with group C (P < 0.05).No decrease in HR & MAP compared with the baseline in Group P. A decrease in HR and MAP in Group C (p < 0.05). Time to first analgesic lower in group P compared with group C (p < 0.05). Total analgesic requirement lower (p < 0.05) in group P than in group C. | 3 |
| Babl et al, 2009 [[4](#_ENREF_4)] | Randomised, double blind placebo controlled trial  To investigate the role of nebulized lidocaine in reducing pain and distress of nasogastric tube insertion in young children. | 36\* children aged 1 – 5 years  Exc: chronic disease, epilepsy, neurological disease, cognitive impairment  Procedural (nasogastric tube insertion)  Emergency department  \* trial concluded early due to concerns re distress associated with administration of trial nebuliser | 2 groups – participants randomised to:  Treatment group - nebulized 2% lidocaine at 4 mg/kg  Placebo group – equivalent volume of normal saline placebo  Administered via nebuliser 10minutes prior to NGT insertion  Pain scoring: FLACC | Nebulization highly distressing (lidocaine median FLACC: 6.3 [IQR:  3.0–8.0]; placebo median: 6.0 [IQR: 1.5–8.0]). FLACC scores during NGT insertion very high in both groups (lidocaine median: 9.8 [IQR: 9.0–10.0]; placebo median: 9.5 [IQR: 9.0–10.0]). Trend in post-NGT insertion period toward lower FLACC scores in the lidocaine group (lidocaine median: 3.5 [IQR: 1.5–6.0]; placebo median: 5.5 [IQR: 3.5–7.0]) | 5 |
| Batra et al, 2009 [[5](#_ENREF_5)] | Randomised controlled trial  To assess spinal anaesthesia (SA) duration provided by four doses of spinal neostigmine added to bupivacaine for lower abdominal and urogenital procedures in infants | 73 infants aged 1 – 12 months  Exc: neurologic, neuromuscular, psychiatric, seizure  Postoperative (lower abdominal and urogenital procedures)  PACU | 5 groups – participants randomised to:  Group B – control group, bupivacaine only  Treatment groups bupivacaine and  Group BN.25 – 0.25 mug/kg neostigmine  Group BN.50 – 0.5 mug/kg neostigmine  Group BN.75 – 0.75mug/kg neostigmine  Group BN1.0 - 1 mug/kg neostigmine  Administered intrathecally  Pain scoring: FLACC  \* Analgesics determined by pain score | Groups BN.75 and BN1.0 had significantly reduced pain scores (p <0.001)  Analgesic requirement lower in neostigmine groups (paracetamol p < 0.01 & fentanyly p < 0.001)  Linear increase in SA duration with IT neostigmine to 65.2 (4.3) min with 0.5 mug/kg (P<0.01), 88.2 (5.1) with 0.75 mug/kg (P<0.001) and 92 (4.3) with 1 mug/kg (P<0.001) from 52.4 (4.3) min with bupivacaine alone | 3 |
| Bharti et al, 2014 [[6](#_ENREF_6)] | Randomized double-blind controlled study  To evaluate the analgesic efficacy and safety of addition of three different doses of dexmedetomidine in caudal ropivacaine compared with plain ropivacaine for postoperative analgesia in paediatric day care patients. | 78 children aged 1 – 8 years  Exc: developmental delay or mental retardation  Postoperative  Day surgery unit | 4 groups – participants randomised to:  Group 1: 0.2% ropivacaine 0.75 ml/kg  Groups 2,3 & 4 receieved 0.2% plain ropivacaine 0.75 ml/kg and:  Group 2: 0.5 µg/kg dexmedetomidine  Group 3: 1.0 dexmedetomidine  Group 4: 1.5 µg/kg dexmedetomidine  Administered as a caudal block  Pain scoring: FLACC  \* Analgesics determined by pain score | Recovery periods longer in Group 3 and 4 but no delayed emergence in any group.  Dexmedetomidine 1.5 g/kg were more sedated compared to the other groups (P < 0.01).  Postoperative analgesia prolonged in all dexmedetomidine groups compared to plain ropivacaine group (P < 0.001) and lower pain scores (p < 0.01). All patients in the plain ropivacaine group required rescue analgesia within first 6 hours, none in Groups 2,3 and 4.  HR lower in Groups 3 and 4 (p < 0.05), no difference in BP. | 5 |
| Boots et al, 2010 [[7](#_ENREF_7)] | Randomised single blind ~~controlled~~ (comparison) trial  To evaluate if discomfort levels are statistically significant when two different topical and intraurethral precatheterisation analgesia strategies are used | 200 children aged 2mth – 8 years  Exc: confounding physical presentation that altered levels of pain perceptions (i.e. spina bifida, prior urethral surgery or trauma)  Procedural (urethral catheterisation)  Radiology department | 2 groups – participants randomised to:  Intervention group - one application of lidocaine five minutes prior to catheterisation.  Control group - two applications, spaced five minutes apart prior to catheterisation.  Pain score: FLACC score | No significant differences (p = 0.779) in the mean FLACC pain score at the time of the catheterisation between the intervention group (mean = 3.30) and the control group (mean = 3.39).  No comparison made between pre and during procedure FLACC scores  No difference in parental perception of child’s discomfort. | 3 |
| Brown et al, 2014 [[8](#_ENREF_8)] | Parallel-group, superiority,  randomized controlled trial  To investigate the association between  DittoTM use and speed of burn wound re-epithelialization. | 73 children aged 4 – 13 years  Exc: Cognitive, visual & auditory impairment, autistic  Procedural (dressing change)  Burn centre | 2 groups – participants randomised to:  Standard group - standard preparation and standard distraction  Intervention group - DittoTM procedur-  al preparation and DittoTM distraction  Pain scoring: Faces PS revised & FLACC (independent)  \* Analgesics determined by pain score | No difference in FLACC and self-report pain scores, anxiety scores, physiological parameters or salivary cortisol.  No comparison made between pre and during procedure FLACC scores  Wounds in the Ditto intervention group re-epithelialized faster than the standard practice group (-2.12 days (CI: -4.26 to 0.03), p-value = 0.046) adjusted for depth | 3 |
| Chadha et al, 2013 [[9](#_ENREF_9)] | Parallel randomised double blind placebo controlled superiority trial  To compare the degree of pain experienced by children undergoing flexible nasendoscopy after 1 of 3 intranasal sprays: placebo, decongestant with topical local anaesthetic (TLA), or decongestant without TLA | 23 children aged 3 – 12 years  Exc: previous nasendoscopy  Procedural (nasendoscopy)  Otolaryngology ambulatory clinic | 3 groups – participants randomised to:  Group A (control) – 0.9% sodium chloride  Group B - xylometazoline hydrochloride, 0.05%  Group C - lidocaine hydrochloride, 1%, with xylometazoline hydrochloride, 0.05%  0.5ml solution sprayed in nostrils 10 min before procedure  Pain scoring: Wong Baker Faces & FLACC (independent) | Mean child-rated WBFP scale scores were 2.4, 1.8, and 2.2 for the placebo, decongestant, and TLA with decongestant groups, respectively (P=.45)  Statistically non-significant - decongestant had the lowest observer-rated FLACC scale score.  No comparison made between pre and during procedure FLACC scores | 5 |
| Chandler et al, 2013 [[10](#_ENREF_10)] | Randomised, double-blinded, controlled trial  To conduct a randomized-controlled trial comparing the incidence of ED in children following sevoflurane (SEVO) anaesthesia and propofol-remifentanil total intravenous anaesthesia (TIVA) | 112 children aged 2 – 6 years  Exc: developmental delay, neurological injury, psychiatric diagnosis  Postoperative (strabismus repair)  PACU | 2 groups – participants randomised to:  TIVA group - intravenous induction and maintenance of anaesthesia with propofol and remifentanil  SEVO group - inhalational induction and maintenance of anaesthesia with sevoflurane  Pain scoring: FLACC | Incidence of ED was higher with  SEVO (38.3% vs 14.9%, P = 0.018).  Higher FLACC scores seen with SEVO (median 3 vs 1, P = 0.033).  Subjects experiencing ED had higher FLACC scores vs those unaffected by ED (median 7 vs 1, P < 0.0001) | 3 |
| Cho et al 2009 [[11](#_ENREF_11)] | Randomised (controlled) trial  To investigated the efficacy of epidural fentanyl to 1.25 or 1.5 mg/ml ropivacaine for post-operative epidural analgesia in children | 108 children aged 5 – 84 months  Exc: neurological diseases, seizures  Postoperative (hypospadius repair)  Not stated | 4 groups – participants randomised to:  R1.25 group - 1.25 mg/ml ropivacaine  R1.25F group - 1.25 mg/ml ropivacaine with 0.2 mcg/kg/h of fentanyl  R1.5 group - 1.5 mg/ml ropivacaine  R1.5F group - 1.5 mg/ml ropivacaine with 0.2 mcg/kg/h of fentanyl  Pain scoring: FLACC  \* Analgesics determined by pain score | Need for rescue analgesia (FLACC >4) was higher in the R1.25 group compared with other three groups (all P<0.05)  No difference between the groups in the median of the highest FLACC score (p> 0.5)  The FLACC score was higher during 0–6h compared with the other three periods in all groups (p < 0.5), except the R1.25 group, difference was seen only during 6–24 h | 5 |
| Curry et al, 2012 [[12](#_ENREF_12)] | Randomised, double blind placebo controlled trial  To assess the effectiveness of oral sucrose to control infants’ pain during routine immunizations at 2, 4, & 6 months of age | 109 infants, aged 1 – 7 mths  Exc: acute or chronic disease  Procedural (immunisation)  Ambulatory paediatric clinics of two hospitals | 3 groups – participants randomised to:  Placebo group – sterile water  Sucrose group 1 – 50% sucrose  Sucrose group 2 – 75% sucrose  2ml given orally prior to immunisation  Pain scoring: FLACC | No difference in FLACC scores between treatment groups post injection (p = 0.646; F =.439; df = 2).  No difference in crying time by treatment group (p = 0.24; F = 1.43; df = 2)  No difference in crying time (p = 0..35) or FLACC score (p = 0 .697) by age group  No comparison made between pre and during procedure FLACC scores | 3 |
| Curtis et al, 2007 [[13](#_ENREF_13)] | Randomised, double blinded (sucrose), single blinded (dummy) placebo (sucrose) controlled trial.  To determine the effect of sucrose, pacifier or the combination thereof for the procedural pain of venipuncture in infants in the paediatric emergency department population | 84 infants 0 – 6mths  Exc: critically unwell, local anaesthetic at venepuncture site  Procedural (venepuncture)  Emergency department | 4 groups – participants randomised to:  Group 1: sucrose  Group 2: sucrose + dummy  Group 3: water  Group 4: water + dummy    2ml given prior to venepuncture with or without dummy  Pain scoring: FLACC | No significant difference in FLACC scores for sucrose groups (p = 0.66)  No difference in crying time between groups (p = 0.16)  FLACC and crying increased form baseline but no p value reported.  FLACC scores lower with dummy use but not significant (no dummy = 4.3 +/- 4.5 dummy = 2.5 +/- 3.7, p = 0.06) | 3 |
| Dewhirst et al, 2014 [[14](#_ENREF_14)] | Double-blinded, randomized (controlled) clinical trial  To compare the efficacy of intranasal  (IN) dexmedetomidine with IN fentanyl for children undergoing BMT | 100 children aged 1 – 7.7 years  Exc: nil relevant  Postoperative (myringotomy and tympanostomy tube placement)  PACU | 4 groups – participants randomised to:  Group 1 MD: midazolam premedication 0.5 mg/kg & IN dexmedetomidine 1 µg/kg  Group 3 D: IN dexmedetomidine 1 µg/kg  Group 2 MF: Midazolam premedication 0.5 mg/kg & IN fentanyl 2 µg/kg  Group 4 F: IN fentanyl 2 µg/kg  Pain scores: FLACC & OPS (not blinded) | No difference in FLACC scores between Groups: 2, 3 and 4, higher in group MD (p < 0.05) than Group D & F. OPS scores higher in Group MD than Group D and higher for Group MF than Group D  No difference time PACU or time to hospital discharge between 4 groups. The heart rate (HR) lower in group D compared to other groups. No clinically significant difference was noted in blood pressure | 5 |
| Diao et al, 2012 [[15](#_ENREF_15)] | Randomized trial  To assess the need for routine drainage after choledochal cyst excision and Roux-en-Y hepatojejunostomy | 100 children aged < 13 years  Exc: nil relevant  Postoperative (choledochal cyst excision)  Not stated | 2 groups – participants randomised to:  Drainage group  Non-drainage group  Pain scores: FLACC | Time to resume normal activity shorter in non-drainage group (1.04 ± 0.19 vs 4.45 ± 2.51 days and 3.04 ± 0.19 vs 6.14 ±  2.61 days, respectively; P < .001).  FLACC scores decreased in both groups from day 1 to 2 and 3 (p < 0.001). FLACC scores in drainage group higher than non-drainage group (day 1, 4.10 ± 0.73 vs 3.74 ± 0.44, P < 0.01; day 2, 3.10 ± 1.09 vs 1.60 ± 0.72, P < 0.001; day 3, 2.70 ± 1.21 vs 0.62 ± 0.49, P < 0.001). Day 2 & day 3, 7 (14%) and 19  (38%) of non-drainage group pain free vs none of drainage group (P < 0.01 & P <0 .001, respectively) | 3 |
| Elshammaa, 2011 [[17](#_ENREF_17)] | Double blinded randomised (controlled) trial  To evaluate the effect of ketamine, as an adjunct to fentanyl, on postoperative analgesia and duration of Postoperative Care Unit (PACU) stay, in children undergoing tonsillectomy. | 60 children aged 2 – 7 years  Exc: chronic pain  Postoperative (tonsillectomy)  PACU | 4 groups – participants randomised to:  F1 group: fentanyl 1 mcg/kg  F2 group: fentanyl 2 mcg/kg  K group: ketamine 0.5 mg/kg)  FK group: fentanyl 1 mcg/kg & ketamine 0.5 mg/kg  Pain scores: FLACC  \* Analgesics determined by pain score | FLACC scores lower for Groups K (p = 0.02) and FK (p = 0.0048) than F1.  Pain scores increased with surgical time (no p value reported)  Group comparison (adjusted for surgical time) - difference between F1 and K (P = 0.02), and F1 and FK (P = 0.0048) groups.  No difference in additional analgesia required between groups.  F2 and FK group had a shorter PACU stay than F1 (P = 0.05 and 0.04 respectively). | 3 |
| El-Sharkawi et al, 2012 [[16](#_ENREF_16)] | Randomised controlled trial  To evaluate the effect of a distraction technique using audio-visual (A/V) glasses on pain perception during administration of local anaesthesia for children | 84 children aged 5 – 7 years  Exc: history of unpleasant experiences in medical settings, experience with local anesthesia injection, and any mental, visual, or auditory impairment  Procedural (dental)  Dentistry clinic | 2 groups – participants randomised to:  Group 1: distraction with AV glasses  Group 2: no distraction  Investigator scored FLACC from video immediately after procedure. 20 recordings rescored 1 week later  Pain scores: FPS and FLACC (independent) | Lower FLACC scores (p = 0.02) and self-report scores (p < 0.001) in distraction group  No comparison made between pre and during procedure FLACC scores  Intra-examiner reliability – kappa = Faces – 1.0, Legs – 0.90, Activity – 1.00, Cry – 0.91, Consolability – 0.89. | 3 |
| Fernandes et al, 2012 [[18](#_ENREF_18)] | Randomised, double-blinded (controlled) trial  To evaluate postoperative analgesia of morphine, or clonidine, or morphine plus clonidine, added to caudal bupivacaine in children undergoing infra-umbilical urological and genital procedures | 80 children aged 1 – 10 years  Exc: neurological disability, history of epilepsy or taking CNS medication  Postoperative (infra-umbilical urological & genital procedures)  PACU | 4 groups – participants randomised to:  Group B – 1.0ml/kg bupivocaine 0.166% with epinephrine 1:600,000  Group BM - 1.0ml/kg bupivocaine 0.166% with epinephrine 1:600,000 + morphine 20mcg/kg  Group BC - 1.0ml/kg bupivocaine 0.166% with epinephrine 1:600,000 + clonidine 1.0mcg/kg  Group BMC - 1.0ml/kg bupivocaine 0.166% with epinephrine 1:600,000 + morphine 20mcg/kg + clonidine 1.0mcg/kg  Pain scores: FLACC  \* Analgesics determined by pain score | FLACC scores higher in Groups B and BC than Groups BM and BMC (p = 0.001) from 6 – 24hours post surgery. No significant difference between groups <6 hours post-surgery (p > 0.5).  No difference in time to 1st analgesia. Number requiring rescue analgesia higher in Group B & BC than BM & BMC (p = 0.018) | 5 |
| Frawley et al, 2006 [[19](#_ENREF_19)] | Randomised double-blinded comparison trial  To determine if there are significant differences in the clinical effectiveness of levobupivacaine compared with racemic bupivacaine for caudal anaesthesia in children having lower abdominal surgery. | 310 children aged 1mth to 10 year  Exc: chronic disease  Postoperative (lower abdominal surgery)  Operating theatre and postoperative recovery room | 2 groups – participants randomised to:  Group 1: bupivacaine 0.25% (2.5 mg/kg)  Group 2: levobupivacaine 0.25% (2.5 mg/kg)  Pain scores: FLACC  \* Analgesics determined by pain score | No significant difference in FLACC scores between groups at 30, 60, 90 and 120minutes post caudal block.  No significant difference between groups in those experiencing satisfactory analgesia (FLACC <6)  No difference in haemodynamic parameters intra-operatively between groups & no difference in motor blockade (extent or duration) between groups | 5 |
| Ghai et al, 2009 [[20](#_ENREF_20)] | Randomised double-blinded controlled trial  To compare the efficacy and safety of subtenon block (SB) versus IV fentanyl for perioperative analgesia in paediatric cataract surgery. | 114 children aged 6 months - 6 years  Exc: nil relevant  Postoperative (cataract surgery)  PACU | 2 groups – participants randomised to:  Group SB: SB with 0.06–0.08 mL/kg of 2%  lidocaine and 0.5% bupivacaine (50:50) mixture and 0.2 mL/kg normal  saline IV  Group F: 1 mg/kg (0.2 mL/kg) of fentanyl IV and subtenon injection with normal saline (0.06–0.08 mL/kg).  Pain scores: FLACC  \* Analgesics determined by pain score | Fewer in Group SB (n=17/58, 29.3%) required rescue analgesia than Group F (n=39/56, 69.6%, P < 0.001). FLACC scores lower in Group SB. Median time to first analgesic requirement longer in Group SB (16 [2–13] vs 4 [0.5–8.5] h in Group F) (P < 0.001).  Sedation scores at 1⁄2h were comparable, afterwards more in Group F anxious or crying than in Group SB (P < 0.05). | 5 |
| Grove et al, 2014 [[21](#_ENREF_21)] | A randomized, grader-blinded, comparative study  To compare the relative gentleness of a silicone tape to a paper tape in healthy infants and children. | 24 infants aged 9 – 47 months  Exc: developmental delay  Procedural (tape removal)  Dermatology research facility | 2 groups – participants randomised to:  Left group: Silicone tape on the left and paper tape on the right side of the back  Right group: Paper tape on the left and silicone tape on the right side of the back  Pain scores: FLACC (assessor blinded to treatment group) | FLACC scores lower for the silicone tape (mean difference from baseline 0.5 vs 3.3, p = .0002). Lower mean ± SEM erythema response for the silicone tape (0.93 ± 0.14 vs 1.35 ± 0.11, P = .0129). No measurable epidermal stripping occurred with the silicone tape compared to a mean ± SEM response of 0.29 ± 0.11 for the paper tape (p = 0.0039). Keratin removal was significantly less with the silicone tape (8.7 ± 0.5 μg/mL vs 15.2 ± 1.3 μg/mL, P < .0001). Few hairs were removed with either tape. No differences in parent tape preferences. | 3 |
| Hall et al, 2009 [[22](#_ENREF_22)] | Double-blinded randomised controlled trial  To compare outcomes after open or laparoscopic pyloromyotomy for the  treatment of pyloric stenosis. | 180 infants aged 11 – 108 days  Exc: nil relevant  Postoperative (pyloromyotomy)  Not stated | 2 groups – participants randomised to:  Controlled: Open pyloromyotomy  Treatment group: Laparoscopic pyloromyotomy | FLACC scores decreased significantly (no p value reported) over time but no difference between groups (p=0.28).  Time to achieve full enteral feeding in the open pyloromyotomy group was (median [IQR]) 23·9 h (16·0–41·0) versus 18·5 h (12·3–24·0; p=0·002) in the laparoscopic group; postoperative length of stay was 43·8 h (25·3–55·6) versus 33·6 h (22·9–48·1; p=0·027). | 5 |
| Hamers et al, 1999 [[23](#_ENREF_23)] | Double-blind, randomized, placebo controlled (2 x 2) factorial design  1. To evaluate the effectiveness of 2 pain protocols used interchangeably to manage early postoperative T&A pain  2. To investigate whether nurses' systematic pain assessments (SPA)improve pain management | 83 children aged 3 - 12 years  Exc: nil relevant  Postoperative (tonsil & adenoid surgery  PACU and ward | 4 groups – participants randomised to:  Group 1: 30-50mg/kg paracetamol suppository & 0.9% saline IM  Group 2: 30-50mg/kg paracetamol suppository, 0.9% saline IM & SPA  Group 3: 30 – 50mg paracetamol suppository & 1microgram/kg fentanyl intramuscularly  Group 4: 30 – 50mg paracetamol suppository & 1microgram/kg fentanyl intramuscularly & SPA  Pain scores: FLACC & CHEOPS (not blinded), VASobs (parent & researcher), Faces Pain Scale & Oucher (independent) | No difference in FLACC, CHEOPS, VAS, Faces or Oucher scores or whether child had drunk between Groups at 1, 2, 3 hours post procedure. | 3 |
| Hippard et al, 2012 [[24](#_ENREF_24)] | Randomised double blinded placebo controlled trial  To compare the immediate postoperative analgesic and behavioural effects of 3 frequently used intra-operative techniques of postoperative pain control for patients undergoing BMT under general anaesthesia | 156 children aged 6 months – 10 years  Exc: nil relevant  Postoperative (myringotomy & placement of ventilating tubes)  PACU | 3 groups – participants randomised to:  Group 1—intranasal fentanyl 2  g/kg (0.04 mL/kg), IV placebo  (0.01 mL/kg), IM placebo (0.01 mL/kg);  Group 2—IV morphine 0.1 mg/kg (0.01 mL/kg), intranasal placebo (0.04 mL/kg), IM placebo (0.01 mL/kg);  Group 3—IM morphine 0.1 mg/kg (0.01 mL/kg), intranasal placebo (0.04 mL/kg), IV placebo (0.01 mL/kg).  Normal saline was used for placebo  Pain scores: FLACC | No significant difference in peak FLACC scores among the 3 groups (mean [95% CI] IN fentanyl - 2.0 [1.2–2.8], IV morphine - 2.7 [1.7–3.6] IM morphine - 2.9 [2.1–3.7] or FLACC scores at specific time points.  Maximum FLACC scores correlated with other outcomes eg PAED score (p = 0.76), time to discharge (p = 0.32) and parental satisfaction with pain Mx (p = 0.35) (P < 0.001) | 5 |
| Hong et al, 2008 [[26](#_ENREF_26)] | Randomized, (controlled), double-blind study  To determine whether caudal midazolam combined with ropivacaine affects anaesthetic requirements, recovery profiles, and post-operative analgesia compared with ropivacaine alone in paediatric day-case hernioplasty. | 60 boys aged 2–5 years old  Exc: pre-existing neurological disease  Postoperative - hernioplasty  Not explicitly stated | 2 groups – participants randomised to:  RM group: 0.2% ropivacaine 1ml/kg and epinephrine 1 : 200,000 with 50 mg/kg  midazolam.  R group: 0.2% ropivacaine 1ml/kg and epinephrine 1 : 200,000  Given via caudal injection  Pain scores: FLACC | Pain scores lower in the R group lower than the RM group (p = 0.011).  No difference between groups in effect on MAP and HR. No difference between groups in ETsevo% prior to or following surgical stimuli. No difference between groups in time to extubation, emergence, drinking or discharge.  No difference in sedation scores 1hr post-surgery. | 3 |
| Hong et al, 2010 [[25](#_ENREF_25)] | Randomised double-blinded (controlled) study  To examine the effects of a single I.V. dose of dexamethasone in combination with caudal block on postoperative analgesia in children. | 77 children aged 1 – 5 years  Exc: pre-existing neurological disease-  Postoperative - orchiopexy  PACU | 2 groups – participants randomised to:  Treatment group: dexamethasone 0.5 mg/kg (max 10 mg)  Control group: same volume of saline  Administered intravenously  Pain scores: FLACC, CHEOPS, VASobs (not blinded)  \* Fentanyl determined by FLACC/CHEOPS  Acetaminophen determined by VASobs | FLACC & CHEOPS scores significantly lower in the treatment group (no p value reported).  Fewer in the treatment group required fentanyl (7.9% vs 38.5%, p < 0.01) in PACU or acetaminophen (23.7% vs 64.1%, p < 0.001) after discharge. Time to first acetaminophen longer in the treatment group (646 vs 430 min, p = 0.012). | 5 |
| Hughes et al, 2013 [[27](#_ENREF_27)] | Pilot study (randomised trial)  To determine the effect of nasogastric (NG) feeding compared with oral feeding on morphine requirements after primary cleft palate repair, and  secondarily on enteral intake. | 50 children aged 5 – 10 months  Exc: nil relevant  Postoperative - cleft palate repair  Ward | 2 groups – participants randomised to:  O group: oral postoperative feeding  NG group: NGT postoperative feeding  Pain scores: FLACC | No difference in morphine consumption or painful episodes (FLACC ≥ 4) between groups.  NG group received three times more feed over 24 hours than O group (Diff of means = -0.88, CI -114.9 to -61.3) | 3 |
| Jindal et al, 2011 [[28](#_ENREF_28)] | Prospective randomised double blind controlled trial  To evaluate the efficacy of adding clonidine to bupivacaine in bilateral infraorbital blocks | 50 children aged less than 24 months  Exc: systemic disease that compromises neurological function  Postoperative - cleft lip repair  Not stated | 2 groups – participants randomised to:  Group A: 1 ml solution of clonidine 1microgram/kg & 0.25% bupivacaine  Group B: 1ml 0.25% bupivacaine  Administered as an infraorbital block  Pain scores: FLACC  \* Analgesics determined by pain scores | FLACC scores in group A slightly lower than in Group B (no p value reported). Time to rescue analgesia longer for Group A compared with Group B (p,0.05) | 5 |
| Jonnavithula et al, 2007 [[29](#_ENREF_29)] | Randomised double blinded (controlled) study  To compared the efficacy of pethidine as an adjuvant to bupivacaine with the efficacy of bupivacaine alone for infra-orbital nerve block in alleviating postoperative pain in children undergoing cleft lip repair | 40 children aged 5 – 60 months  Exc: major systemic illness  Postoperative - cleft lip repair  Not stated | 2 groups – participants randomised to:  Group B - 1 ml of 0.25% bupivacaine  Group P - 1 ml of 0.25% bupivacaine +  0.25 mg.kg)1 body weight pethidine  Pain scores: FLACC | No difference in the highest FLACC scores achieved between the two groups p = 0.15, (χ2 = 2.66, df = 1)  No difference in UMSS scores between the two groups p = 0.274 (χ2 = 2.59, df = 2) | 3 |
| Jonnavithula et al, 2010 [[30](#_ENREF_30)] | Randomised controlled trial  To evaluate the efficacy of palatal block in children with cleft palate undergoing palatoplasty by evaluating its effects on intraoperative anaesthetic requirement, postoperative analgesia and parental satisfaction. | 45 children aged 8 – 62 months  Exc: major illness, associated congenital anomalies  Postoperative - cleft lip repair  Postoperative recovery room | 3 groups – participants randomised to:  Group NB - no block for control,  Group S - 0.5 ml of normal saline  Group B - 0.5 ml of 0.25% bupivacaine  Pain scores: FLACC  \* Analgesics determined by pain scores | The mean FLACC scores in group NB were higher than those in groups S and B.  The Area Under Curve (AUC) of FLACC scores of group NB were greater than group B and S but no difference between group B and group S (p ~0.000)  Time to rescue analgesic was less and the number of doses greater in the NB group (p ~0.000)  Parental satisfaction with pain relief lowest in NB group (p ~0.000) | 3 |
| Kil et al, 2012 [[31](#_ENREF_31)] | Prospective, randomized, observer-blinded (placebo controlled) study  To evaluate the effects of oral chloral hydrate on perioperative psychological and behavioural phenomena in children. | 100 children aged 1 – 5 years  Exc: Behavioural disorders and use of psychiatric medications  Postoperative: orchiopexy  Day surgery unit | 2 groups – participants randomised to:  CH group: 40mg/kg chloral hydrate  Placebo group: placebo in appropriate volume  Pain scores: FLACC, CHEOPS (not blinded)  \* Analgesics determined by pain scores | FLACC and CHEOPS scores lower in the CH group (p < 0.05). Fewer participants in CH group required rescue analgesic (p = 0.01)  Anxiety scores lower in the CH group (45.7 vs 28.8, p < 0.001). Induction compliance of CH group better than control group (3.2 vs 4.8). Postoperative sedation was more frequent (62.7% vs 20.4%) in CH group. Postoperative emergence delirium and maladaptive behaviour changes similar between groups. | 5 |
| Kim et al, 2014 [[33](#_ENREF_33)] | Randomised double-blind (placebo controlled) study  To assess the effect of dexme-  detomidine infusion on sevoflurane requirements, recovery profiles, and emergence agitation in children undergoing ambulatory surgery | 40 children aged 1 – 5 years  Exc: mental retardation, develop-  mental delay, neurological or psychiatric illnesses  Postoperative - ambulatory surgery  PACU | 2 groups – participants randomised to:  D group: dexmedetomidine 1 μg/kg, followed by 0.1 μg/kg/h until the end of surgery  S group: volume matched saline  Pain scores: FLACC, CHEOPS  \* Analgesics determined by pain scores | ET-sevo reduced in Group D (23.8-67%, p < 0.05). The incidence of emergence agitation lower in Group D than in Group S (5% vs. 55%, p=0.001). Sedation scores higher at 0min and 30min in Group D (p < 0.05)  No difference in pain scores except at 30min CHEOPS and FLACC lower in D group (p < 0.05).  No difference in discharge time between groups. Mean arterial pressure & HR lower in Group D during surgery (p < 0.05) | 5 |
| Kim et al 2012 [[32](#_ENREF_32)] | Randomised double blinded placebo controlled triage  To determine the availability of a 5% lidocaine patch used prophylactically for venipuncture or injection-related pain during induction of anaesthesia | 72 children aged 4 – 15 years  Exc:use of prescription strength analgesic in previous 24 hours  Procedural - venipuncture  Operating room | 2 groups – participants randomised to:  Group A – 5% lidocaine patch (Lidoderm()  Group B – pre-treatment with a placebo patch  Pain scores: FLACC | FLACC score during venipuncture was significantly lower for treatment group (median – 0) than placebo group (median = 4) p<0.001. | 5 |
| Kundu et al, 2014 [[34](#_ENREF_34)] | Randomised double-blinded controlled study  To examine the effects of Reiki as an adjuvant therapy to opioid therapy for postoperative pain control in paediatric patients. | 38 children aged 9 months – 4 years  Exc: regional blocks  Postoperative - dental work  PACU | 2 groups – participants randomised to:  Treatment group: Reiki therapy  Control group: ‘sham’ Reiki therapy  Pain scores: FLACC  \* Unclear how analgesia requirement determined | No difference in FLACC scores between groups and no difference in opioid requirements between groups. | 5 |
| Loetwiriyakul et al, 2011 [[35](#_ENREF_35)] | Randomised, double-blinded (controlled) clinical trial  To compare the effectiveness of 3 mg/Kg bupivacaine administered as 1.2 mL/Kg 0.25% bupivacaine and 1.5 mL/Kg 0.2% bupivacaine for caudal block in paediatric patients undergoing intra-abdominal surgery | 74 children aged 6 months – 7 years  Exc: neurological disease  Postoperative intra-abdominal surgery  Theatre and recovery room | 2 groups – participants randomised to:  Group A: 1.2 mL/Kg 0.25% bupivacaine  Group B: 1.5 mL/Kg 0.2% bupivacaine with morphine 50 µg/Kg  Administered as a caudal block  Pain scores: FLACC  \* Postop analgesics determined by FLACC score. Intra-operatively anaesthetists judgement | Intra-operatively, no difference in numbers requiring rescue analgesic (group A = 67% & group B = 63%). No difference in numbers requiring muscle relaxant (group A = 49% & group B = 57%).  Time to extubation shorter in Group B (9.5±1.1 min) than group A (14.3±0.9 minutes), p < 0.01. Time to first analgesic required in recovery longer in Group B (202±45 minutes) than in group A (149±27 minutes), p < 0.05. Time to first analgesic required in ward longer in Group B (10.4±3.1 hours) than in group A (8.2±2.0 hours) p < 0.05. No difference in fentanyl requirements between groups, Group A = 52.5±2.0 µg & Group B = 49.5±3.0 µg. FLACC scores lower in Group B at 8 (2 v 3) and 12 hours (2 v 3) p < 0.05.  No difference in HR or MAP between groups. | 5 |
| Lorenzo et al, 2014 [[36](#_ENREF_36)] | Parallel group, randomized, ~~controlled~~ (comparison) trial  To evaluate ultrasound guided transversus abdominis plane block superiority over surgeon delivered regional field infiltration for children undergoing open pyeloplasty at a tertiary referral centre | 32 children aged 0 – 6 years  Exc: history chronic pain  Postoperative - pyeloplasty  Tertiary referral centre | 2 groups – participants randomised to:  TAP Group: ultrasound guided TAP block  FRI Group: wound infiltration with 0.4 ml/kg bupivacaine 0.25% with 1:200,000 epinephrine before incision  Pain scores: FLACC  \* Analgesics determined by pain scores | Mean FLACC scores lower in the RFI group (5, SD +/- 5 vs 2, SD +/- 3, p = 0.043) in the recovery room. Fewer in RFI group required rescue morphine administration (13 of 16 receiving transversus abdominis plane block and 6 of 16 receiving regional field infiltration, p = 0.011).  Mean +/- SD morphine consumption lower in RFI group (0.066 +/- 0.051 vs 0.028 +/- 0.040 mg/kg, p = 0.021). No local anaesthetic specific adverse events | 5 |
| Miller et al, 2011 [[38](#_ENREF_38)] | Randomised (controlled) trial  To determine if a combined MMD  protocol (preparation and distraction) will reduce the pain and distress of 3–10 year olds undergoing burn care procedures as outpatients when compared with children provided with  Standard Distraction (SD) (current typical treatment). | 40 children aged 3 – 10 years  Exc: cognitive impairment, sedation and anxiolytics  Procedural - burn care procedure  Burns Outpatient Centre | 2 groups – participants randomised to:  Group SD: standard distraction  Group MMD: Multimodal distraction  Pain scores: FLACC, Wong and Baker Faces, VASobserver (not blinded) | Pain scores (p < 0.001) and distress scores ( p < 0.001) lower in MMD group when compared to SD (except FLACC pre removal of dressing). HR lower in MMD group (p = 0.04)  Length of treatment (p < 0.05), days to healing and the number of pain adverse events were also reduced (p < 0.05) with the use of the MMD protocol. | 3 |
| Miller et al, 2010 [[37](#_ENREF_37)] | Randomised controlled trial  To investigate if either MMD procedural preparation (MMD-PP) or distraction (MMD-D) has a greater impact on child pain reduction compared to standard distraction (SD) or hand held video game distraction (VG), (2) to understand the impact of MMD-PP and MMD-D on clinic efficiency by measuring length of treatment across groups, and lastly, (3) to assess the efficacy of distraction techniques over three dressing change procedures | 80 children aged mean 6.2 years (SD ± 2.3)  Exc: cognitive impairment, sedation and anxiolytics  Procedural (burn care procedure)  Burns Outpatient Centre | 4 groups – participants randomised to:  SD group: standard distraction  VG group: video game distraction  MMD-PP group: MMD procedural preparation  MMD group: MMD distraction  Pain scores: FLACC, Wong and Baker Faces Scale, VAS observer | MMD groups had consistent reductions in pain levels over the three procedures compared to the SD and VG groups for child reported pain (p < 0.001), parent observed VAS (p < 0.001) and FLACC scores (p < 0.01). No difference between MMD-PP and MMD groups for child report, parent VAS or FLACC. No difference in physiological measures | 3 |
| Natarajan Surendar et al, 2014 [[39](#_ENREF_39)] | Randomised triple blind comparative study  To evaluate & compare the efficacy & safety of intranasal (IN) dexmedetomidine, midazolam & ketamine in producing moderate sedation among uncooperative pediatric dental patients. | 84 children aged 4 – 14 years  Exc: nil relevant  Procedural (dental) | 4 groups – participants randomised to:  D1 group: dexmedetomidine 1µg/kg  D2 group: dexmedetomidine 1.5µg/kg  M group: Midazolam 0.2mg/kg  K group: Ketamine 5mg/kg (K1)  Pain scores: | Intra & post-operative FLACC scores differed between D1 (3.81 ± 0.81 & 1.29 ± 0.90), D2 (3.67 ± 0.91 & 1.14 ± 0.65) and K1 (3.52 ± 0.68 & 1.10 ± 0.89) compared to M (5.62 ± 1.12 & 2.81 ± 0.60).  Procedural success rate and sedation level not statistically different  No significant difference in HR, RR, BP and SpO2 between groups. | 3 |
| Newbury et al, 2009 [[40](#_ENREF_40)] | Parallel randomised double-blind ~~controlled~~ (comparison) study  To determine if amethocaine improves the success of cannulation compared with EMLA and whether it is a more effective topical anaesthetic | 65 children aged 3months – 15 years  Exc: nil  Procedural (intravenous cannula insertion)  Emergency department | 2 groups – participants randomised to:  Group A: amethocaine  Group E: EMLA  Cream applied to two vein sites  Pain scores: FLACC & VASobserver (not blinded) | No difference between success rates for Groups A or E  No difference in FLACC or VAS (observer) scores between groups A and E  Inter-rater reliability for FLACC – 0.86 (p<0.0001) | 3 |
| Nilsson et al, 2013 [[41](#_ENREF_41)] | Non-blinded randomised (controlled) clinical trial  To test if serious gaming and lollipops influence pain, distress and anxiety in conjunction with a wound care session. | 62 children aged 5 – 12 years  Exc: cognitive impairment & non-Swedish speaking  Procedural (wound care)  Day care unit | 3 groups – participants randomised to:  Serious gaming group  Lollipop group  Control group  Pain scores: FLACC, self-report (CAS) | FLACC scores lower in serious gaming group than in other groups - effect size (d) for serious gaming was 0.72 (95% CI, 0.07–1.35) compared with lollipops and 0.80 (95% CI, 0.14–1.42) compared with the control group. Self-reported pain (CAS), did not differ between groups  Distress (FAS) lower in serious gaming group than in lollipop group but not compared to control group. The effect size (d) for serious gaming was 0.72 (95% CI, 0.06–1.34) compared with lollipops and 0.29 (95% CI, −0.34 to 0.91) compared with the control group.  Serious gaming & lollipop groups reported lower anxiety (short STAI) scores after they underwent the wound dressing than control group. The effect size (d) for changes of the short STAI before and after serious gaming was 0.44 (95% CI, −0.2 to 1.06) compared with lollipops and 0.26 (95% CI, −0.37 to 0.88) compared with control group.  Individual pain intensity (CAS & FLACC) increased significantly from before to during the procedure | 3 |
| Nilsson et al, 2009 [[42](#_ENREF_42)] | Randomised controlled trial  To test whether postoperative music listening reduces morphine consumption and influence pain, distress, and anxiety after day surgery and to describe the experience of postoperative music listening | 80 children aged 7 – 16 years  Exc: cognitive impairment, non-Swedish speaking  Postoperative (minor procedure)  PACU | 2 groups – participants randomised to:  Intervention group – music for 45min from arrival in post anaesthetic care unit  Control – no music  Pain score: FLACC, FAS & CAS (? Not blinded)  \* Analgesics determined by pain score | No significant difference in FLACC, FAS, CAS or anxiety scores between groups.  Morphine consumption lower in music group (p < 0.05)  No p value reported | 3 |
| Nord et al, 2009 [[43](#_ENREF_43)] | Randomized, controlled, single-blinded study  To examine the effectiveness of  an aromatherapy intervention on the reduction of children’s distress in  a perianaesthesia setting | 94 children aged 1 – 21 years  Inc: with/without cognitive impairment  Postoperative  PACU | 2 groups – participants randomised to:  Group LG – Lavender and ginger oil  Group J – Jojoba oil  Applied topically and inhaled  Pain scores: parent applied FLACC | No difference in mean FLACC score (p = 0.55) between groups.  No difference in parental satisfaction with aromatherapy between groups | 3 |
| Saha et al, [[44](#_ENREF_44)] | Prospective comparative study  To evaluate a short comparison between laparoscopic and open appendicectomy in children in regards to postoperative morbidity. | 60 children aged 4 - 12 years  Exc: nil relevant  Postoperative (appendicetomy)  Department of surgery | 2 groups – participants randomised to:  Group A: Laparoscopic appendicectomy  Group B: Open appendicectomy  Pain scores: FLACC  \* Analgesics determined by pain score | FLACC score lower in group A at 6, 24 and 48hours (p < 0.001). Group A analgesic requirements were lower (p = 0.0001). Complication rates were higher in Group B (p < 0.05) | 3 |
| Sethi et al, 2013 [[45](#_ENREF_45)] | Randomised double blinded study  To compare the use of desflurane and sevoflurane to determine the postoperative emergence delirium in children undergoing cataract surgery | 88 children aged 2 – 6 years  Exc: cognitive impairment  Postoperative (cataract surgery)  PACU | 2 groups – participants randomised to:  Group S: desflurane  Group D: sevoflurane  Both administered with 50% nitrous oxide to maintain anaesthesia  Pain score: FLACC | Emergence from anaesthesia faster in desflurane group (p=0.001).  PAED scores FLACC scores, m-YPAS anxiety scores, length of PACU stay and anaesthetic duration did not differ between groups. | 5 |
| Singh et al, 2012 [[46](#_ENREF_46)] | Randomised controlled trial  To compare the analgesic quality and duration of ropivacaine 0.2% with the addition of fentanyl with that of ropivacaine 0.2% and the addition of ketamine | 90 children aged 1 – 10 years  Exc: active CNS disorders  Postoperative (sub-umbilical procedures) | 3 groups – participants randomised to:  Group R: 0.75ml/kg ropivacaine 0.2% in normal saline  Group: RK: 0.75ml/kg ropivacaine 0.2% & 0.5mg/kg ketamine  Group RF: 0.75ml/kg ropivacaine 0.2% & 1microgram/kg fentanyl  Pain score: FLACC  \* Analgesics determined by FLACC score or patient complaint of pain | FLACC scores lower in the Group RK (p < 0.05)  Mean duration of analgesia longer in Group RK (p < 0.05)  No difference in physiological parameters. | 1 |
| Stuth et al, 2011 [[47](#_ENREF_47)] | Randomised double-blinded trial  To determine whether single-shot caudal epidural with high-dose morphine (100 µg/kg) diluted in  0.25% bupivacaine with 1 : 200 000 epinephrine) after induction would lead to a higher rate of successful ex-  tubation in the operating room (OR) and to delayed and lower postoperative analgesic requirements than IV morphine given after CPB but before the end of surgery. | 63 children aged 75 – 1167 days (2 – 37 months)  Exc: severe preoperative neurological impairment  Postoperative (stage 2 & 3 cardiac palliation procedures)  CICU | 2 groups – participants randomised to:  Group C: pre-incisional caudal morphine–bupivacaine (100 µg/kg morphine with 0.25% bupivacaine with 1 : 200 000 epinephrine, total 1 ml/kg) and post cardiopulmonary bypass (CPB) intravenous (IV) droperidol (75 µg/kg)  Group IV: pre-incisional caudal saline (1 ml/kg) and post-CPB IV morphine (150 µg/kg) with droperidol (75 µg/kg) .  Pain scores: FLACC or NIPS  \* Unclear how analgesics determined | No difference in pain scores between groups.  Group IV required earlier rescue morphine in stage 3 patients (P = 0.02) but not in stage 2 patients (P = 0.189). No difference at 12h in morphine consumption (P = 0.085). Morphine requirements higher for stage 2 compared with stage 3 patients (P < 0.001). | 3 |
| Takmaz et al, 2009 [[48](#_ENREF_48)] | Randomised double blind ~~controlled~~ (comparison) trial  To evaluate the effectiveness of bilateral extraoral infraorbital nerve block with 0.25% bupivacaine administered at the end of surgery in postoperative pain relief after cleft lip repair | 40 children aged < 2 years  Exc: neurologic, or neuromuscular disease  Postoperative (cleft lip repair)  Recovery and ward | 2 groups – participants randomised to:  Group I - 1.5 mL 0.25% bupivacaine  Group II - 1.5 mL saline and 20 mg/kg rectal paracetamol  Pain score: FLACC  \* Analgesics determined by FLACC score | FLACC scores of the patients in recovery room in group I (2.0 ± 0.6) lower than group II (8.1 ± 0.9) (p <0.001). FLACC scores in the first 4 hours lower in group I compared with group II (p < 0.001)  Time to paracetamol longer & amount less in Grp 1 (p=0.001). Tramadol requirement Grp 1 (0/20 pts) versus 20/20 in Grp II (p=0.001).  Parent satisfaction scores higher in Grp 1 (p=0.001)  No difference in physiological parameters | 4 |
| Townsend et al, 2009 [[49](#_ENREF_49)] | Randomised, prospective, double blind study  To evaluate the effects of the combination of local anaesthetics and an intravenous nonsteroidal anti-inflammatory drug (NSAID) vs NSAID alone on quality of recovery following dental rehabilitation under general anaesthesia (GA) | 27 children aged 3 – 5.5 years  Exc:  Postoperative (Dental rehabilitation)  PACU  Not stated | 2 groups – participants randomised to:  Control group - 1 mg/kg ketorolac intravenously within 15 minutes of case completion  Experimental group - 1 mg/kg ketorolac within 15 minutes of case completion as well as local anaesthetic infiltration.  Pain score: FLACC | Mean FLACC score at PACU discharge did not differ between the experimental or control groups (L, 2.47 ± 2.69 vs C,  2.58 ± 2.54; P < 0.88). No difference between groups for highest FLACC score (P < 0.84).  FACES scores at home similar between groups (L, 0.30 ± 0.21 vs C, 0.60 ± 1.35; P < 0.92).  No difference in analgesic use at home between groups (L, 2 of 11 vs C, 4 of 12; P < 0.70) | 5 |
| Vaughan et al, 2005 [[50](#_ENREF_50)] | Randomised double blind placebo controlled trial  To evaluate the use of 2% lignocaine gel to alleviate the pain associated with BC in young children (<2 years) in the ED. | 115 children aged < 2 years  Exc: altered mental status  Procedural (urinary catheterisation)  Emergency Department | 2 groups – participants randomised to:  Experimental group – 1- 2ml 2% lignocaine lubricant gel  Control group – 1 – 2 ml non-anaesthetic lubricant gel  Applied to genital mucosa 2 - 3 min before catherisation and used to lubricate catheter  Pain score: FLACC | Mean FLACC scores between the control (7.55 +/- 2.56) & study groups (7.37 +/- 2.87) during catherisation did not differ.  Increase in FLACC scores from pre-procedure to during procedure (p < 0.01) (Not blinded to circumstances)  Pre-study - Interrater reliability, ICC (95% CI: 0.93–0.99 during time 1, 0.95–0.99 during time 2, and 0.92–0.99 at time 3) | 5 |
| Voepel-Lewis et al, 1998 [[51](#_ENREF_51)] | Randomised double blind placebo controlled trial  To determine whether abdominal discomfort is a cause for distress symptoms in infants following administration of inhalational anaesthesia, and to evaluate the effectiveness of simethicone in treating this discomfort. | 175 children aged < 28 months  Exc: mental impairment  Postoperative (minor non-invasive procedure under inhalational anaesthetic)  PACU | 2 groups – participants randomised to:  Experimental group - 0.3 ml of simethicone  Control group - 0.3ml placebo  Pain score: FLACC  \* analgesic determined by clinician – unclear whether aware of/measuring FLACC scores | Both groups improved over time but simethicone group had significantly less discomfort at 20 & 30 min post treatment (p < 0.05) than that control group.  Rescue analgesia given 2 (12%) simethicone grp and 9 (47%) control grp | 3 |
| Zier et al, 2008 [[52](#_ENREF_52)] | Randomised double blind placebo controlled trial  To compare the efficacy of inhaled nitrous oxide (N2O) with enteral midazolam for sedation of children with cerebral palsy (CP) undergoing botulinum toxin A (BoNT-A) injections | 50 children aged from 1 – 16 years.  Exc: nil relevant  Procedural (botulinum toxin A injections)  Outpatient clinic sedation area | 2 groups – participants randomised to:  Midazolam group - 0.35 to 0.5mg⁄kg to a max of 10mg (orally or rectally) and 100% O2 via mask  N2O group – 70% N2O via mask, titrated by clinician and equivalent volume of saline (orally or rectally)  Pain scores: FLACC & VASobserver (blinded) | FLACC scores were lower for the N2O grp (4, 0 – 10) than midazolam grp (6, 0 – 10) (p=0.010). VASobs nurse and parent lower for N2O grp (p = 0.007 and p = 0.009 respectively).  No difference in maximum sedation (UMSS) score between groups (0.661), sedation higher at discharge in midazolam grp (p < 0.001)  No difference in parent satisfaction between groups | 5 |

**Note:**

**BMT –** myringotomy and tympanostomy tube placement**, CHEOPS – Children’s Hospital Eastern Ontario Pain Scale, CICU – cardiac intensive care unit, ED – emergency department, FLACC – Face, Legs, Activity, Consolability, Cry, ICC – intraclass coefficient, OPS – Objective Pain Scale, OR – operating room, PACU – postoperative acute care unit, PAED – Paediatric Assessment of Emergence Delirium, VAS – Visual Analogue Scale, VASobs – VAS observer**

## References

[1] Amin SM. Evaluation of gabapentin and dexamethasone alone or in combination for pain control after adenotonsillectomy in children. Saudi journal of anaesthesia 2014;8(3):317.

[2] Anand VG, Kannan M, Thavamani A, Bridgit MJ. Effects of dexmedetomidine added to caudal ropivacaine in paediatric lower abdominal surgeries. Indian journal of anaesthesia 2011;55(4):340-346.

[3] Ashrey E, Bosat B. Single-injection penile block versus caudal block in penile pediatric surgery. Ain-Shams Journal of Anaesthesiology 2014;7(3):428.

[4] Babl FE, Goldfinch C, Mandrawa C, Crellin D, O'Sullivan R, Donath S. Does nebulized lidocaine reduce the pain and distress of nasogastric tube insertion in young children? A randomized, double-blind, placebo-controlled trial. Pediatrics 2009;123(6):1548-1555.

[5] Batra YK, Rajeev S, Panda NB, Lokesh VC, Rao KLN. Intrathecal neostigmine with bupivacaine for infants undergoing lower abdominal and urogenital procedures: Dose response. Acta Anaesthesiologica Scandinavica 2009;53(4):470-475.

[6] Bharti N, Praveen R, Bala I. A dose-response study of caudal dexmedetomidine with ropivacaine in pediatric day care patients undergoing lower abdominal and perineal surgeries: a randomized controlled trial. Paediatr Anaesth 2014.

[7] Boots BK, Edmundson EE. A controlled, randomised trial comparing single to multiple application lidocaine analgesia in paediatric patients undergoing urethral catheterisation procedures. Journal of Clinical Nursing 2010;19(5-6):744-748.

[8] Brown NJ, Kimble RM, Rodger S, Ware RS, Cuttle L. Play and heal: Randomized controlled trial of Ditto intervention efficacy on improving re-epithelialization in pediatric burns. Burns 2014;40(2):204-213.

[9] Chadha NK, Lam GOA, Ludemann JP, Kozak FK. Intranasal topical local anesthetic and decongestant for flexible nasendoscopy in children: a randomized, double-blind, placebo-controlled trial. JAMA Otolaryngol Head Neck Surg 2013;139(12):1301-1305.

[10] Chandler JR, Myers D, Mehta D, Whyte E, Groberman MK, Montgomery CJ, Ansermino JM. Emergence delirium in children: a randomized trial to compare total intravenous anesthesia with propofol and remifentanil to inhalational sevoflurane anesthesia. Paediatric Anaesthesia 2013;23(4):309-315.

[11] Cho JE, Kim JY, Hong JY, Kil HK. The addition of fentanyl to 1.5 mg/ml ropivacaine has no advantage for paediatric epidural analgesia. Acta Anaesthesiologica Scandinavica 2009;53(8):1084-1087.

[12] Curry DM, Brown C, Wrona S. Effectiveness of oral sucrose for pain management in infants during immunizations. Pain Management Nursing 2012;13(3):139-149.

[13] Curtis SJ, Jou H, Ali S, Vandermeer B, Klassen T. A randomized controlled trial of sucrose and/or pacifier as analgesia for infants receiving venipuncture in a pediatric emergency department. BMC Pediatrics 2007;7:27.

[14] Dewhirst E, Fedel G, Raman V, Rice J, Barry ND, Jatana KR, Elmaraghy C, Merz M, Tobias JD. Pain management following myringotomy and tube placement: Intranasal dexmedetomidine versus intranasal fentanyl. International Journal of Pediatric Otorhinolaryngology 2014;78(7):1090-1094.

[15] Diao M, Li L, Cheng W. To drain or not to drain in Roux-en-Y hepatojejunostomy for children with choledochal cysts in the laparoscopic era: a prospective randomized study. J Pediatr Surg 2012;47(8):1485-1489.

[16] El-Sharkawi HFA, El-Housseiny AA, Aly AM. Effectiveness of new distraction technique on pain associated with injection of local anesthesia for children. Pediatric Dentistry 2012;34(2):e35-38.

[17] Elshammaa N, Chidambaran V, Housny W, Thomas J, Zhang X, Michael R. Ketamine as an adjunct to fentanyl improves postoperative analgesia and hastens discharge in children following tonsillectomy - a prospective, double-blinded, randomized study. Paediatr Anaesth 2011;21(10):1009-1014.

[18] Fernandes ML, Pires KCC, Tiburcio MA, Gomez RS. Caudal bupivacaine supplemented with morphine or clonidine, or supplemented with morphine plus clonidine in children undergoing infra-umbilical urological and genital procedures: a prospective, randomized and double-blind study. Journal of Anesthesia 2012;26(2):213-218.

[19] Frawley GP, Downie S, Huang GH. Levobupivacaine caudal anesthesia in children: a randomized double-blind comparison with bupivacaine. Paediatric Anaesthesia 2006;16(7):754-760.

[20] Ghai B, Ram J, Makkar JK, Wig J, Kaushik S. Subtenon block compared to intravenous fentanyl for perioperative analgesia in pediatric cataract surgery. Anesthesia & Analgesia 2009;108(4):1132-1138.

[21] Grove GL, Zerweck CR, Ekholm BP, Smith GE, Koski NI. Randomized Comparison of a Silicone Tape and a Paper Tape for Gentleness in Healthy Children. Journal of Wound Ostomy & Continence Nursing 2014;41(1):40-48.

[22] Hall NJ, Pacilli M, Eaton S, Reblock K, Gaines BA, Pastor A, Langer JC, Koivusalo AI, Pakarinen MP, Stroedter L, Beyerlein S, Haddad M, Clarke S, Ford H, Pierro A. Recovery after open versus laparoscopic pyloromyotomy for pyloric stenosis: a double-blind multicentre randomised controlled trial. Lancet 2009;373(9661):390-398.

[23] Hamers JP, Huijer Abu-Saad H, Geisler FE, van den Hout MA, Schouten HJ, Halfens RJ, van Suijlekom HA. The effect of paracetamol, fentanyl, and systematic assessments on children's pain after tonsillectomy and adenoidectomy. Journal of PeriAnesthesia Nursing 1999;14(6):357-366.

[24] Hippard HK, Govindan K, Friedman EM, Sulek M, Giannoni C, Larrier D, Minard CG, Watcha MF. Postoperative analgesic and behavioral effects of intranasal fentanyl, intravenous morphine, and intramuscular morphine in pediatric patients undergoing bilateral myringotomy and placement of ventilating tubes. Anesthesia & Analgesia 2012;115(2):356-363.

[25] Hong J-Y, Han S, Kim W, Kim E, Kil H. Effect of dexamethasone in combination with caudal analgesia on postoperative pain control in day-case paediatric orchiopexy. British journal of anaesthesia 2010;105(4):506-510.

[26] Hong JY, Lee I, Shin S, Park E, Ban S, Cho J, Kil H. Caudal midazolam does not affect sevoflurane requirements and recovery in pediatric day‐case hernioplasty. Acta Anaesthesiologica Scandinavica 2008;52(10):1411-1414.

[27] Hughes J, Lindup M, Wright S, Naik M, Dhesi R, Howard R, Sommerlad B, Kangesu L, Sury M. Does nasogastric feeding reduce distress after cleft palate repair in infants? . Nursing children and young people 2013;25(9):26-30.

[28] Jindal P, Khurana G, Dvivedi S, Sharma JP. Intra and postoperative outcome of adding clonidine to bupivacaine in infraorbital nerve block for young children undergoing cleft lip surgery. Saudi Journal of Anaesthesia 2011;5(3):289-294.

[29] Jonnavithula N, Durga P, Kulkarni DK, Ramachandran G. Bilateral intra-oral, infra-orbital nerve block for postoperative analgesia following cleft lip repair in paediatric patients: comparison of bupivacaine vs bupivacaine-pethidine combination. Anaesthesia 2007;62(6):581-585.

[30] Jonnavithula N, Durga P, Madduri V, Ramachandran G, Nuvvula R, Srikanth R, Damalcheruvu MR. Efficacy of palatal block for analgesia following palatoplasty in children with cleft palate. Paediatric Anaesthesia 2010;20(8):727-733.

[31] Kil HK, Kim WO, Han SW, Kwon Y, Lee A, Hong J-Y. Psychological and behavioral effects of chloral hydrate in day-case pediatric surgery: a randomized, observer-blinded study. Journal of Pediatric Surgery 2012;47(8):1592-1599.

[32] Kim C-H, Yoon J-U, Lee H-J, Shin S-W, Yoon J-Y, Byeon G-J. Availability of a 5% lidocaine patch used prophylactically for venipuncture- or injection-related pain in children. Journal of Anesthesia 2012;26(4):552-555.

[33] Kim NY, Kim SY, Yoon HJ, Kil HK. Effect of Dexmedetomidine on Sevoflurane Requirements and Emergence Agitation in Children Undergoing Ambulatory Surgery. Yonsei medical journal 2014;55(1):209-215.

[34] Kundu A, Lin Y, Oron AP, Doorenbos AZ. Reiki therapy for postoperative oral pain in pediatric patients: Pilot data from a double-blind, randomized clinical trial. Complementary therapies in clinical practice 2014;20(1):21-25.

[35] Loetwiriyakul W, Asampinwat T. Caudal block with 3 mg/Kg Bupivacaine for intraabdominal surgery in pediatric patients: a randomized study. Asian Biomedicine 2011;5(1):93-99.

[36] Lorenzo AJ, Lynch J, Matava C, El-Beheiry H, Hayes J. Ultrasound Guided Transversus Abdominis Plane vs Surgeon Administered Intraoperative Regional Field Infiltration with Bupivacaine for Early Postoperative Pain Control in Children Undergoing Open Pyeloplasty. The Journal of urology 2014.

[37] Miller K, Rodger S, Bucolo S, Greer R, Kimble RM. Multi-modal distraction. Using technology to combat pain in young children with burn injuries. Burns 2010;36(5):647-658.

[38] Miller K, Rodger S, Kipping B, Kimble R. A novel technology approach to pain management in children with burns: A prospective randomized controlled trial. Burns 2011;37(3):395-405.

[39] Natarajan Surendar M, Kumar Pandey R, Kumar Saksena A, Kumar R, Chandra G. A Comparative evaluation of Intranasal Dexmedetomidine, Midazolam and Ketamine for their sedative and analgesic properties: A Triple Blind Randomized Study. Journal of Clinical Pediatric Dentistry 2014;38(3):255-261.

[40] Newbury C, Herd DW. Amethocaine versus EMLA for successful intravenous cannulation in a children's emergency department: a randomised controlled study. Emergency Medicine Journal 2009;26(7):487-491.

[41] Nilsson S, Enskär K, Hallqvist C, Kokinsky E. Active and passive distraction in children undergoing wound dressings. Journal of pediatric nursing 2013;28(2):158-166.

[42] Nilsson S, Kokinsky E, Nilsson U, Sidenvall B, Enskar K. School-aged children's experiences of postoperative music medicine on pain, distress, and anxiety. Paediatric Anaesthesia 2009;19(12):1184-1190.

[43] Nord D, Belew J. Effectiveness of the essential oils lavender and ginger in promoting children's comfort in a perianesthesia setting. Journal of PeriAnesthesia Nursing 2009;24(5):307-312.

[44] Saha N, Saha DK, Rahman MA, Islam MK, Aziz MA. Comparison of post operative morbidity between laparoscopic and open appendectomy in children. Mymensingh Med J 2010;19(3):348-352.

[45] Sethi S, Ghai B, Ram J, Wig J. Postoperative emergence delirium in pediatric patients undergoing cataract surgery - A comparison of desflurane and sevoflurane. Paediatric Anaesthesia 2013;23(12):1131-1137.

[46] Singh R, Kharbanda M, Sood N, Mahajan V, Chatterji C. Comparative evaluation of incidence of emergence agitation and post-operative recovery profile in paediatric patients after isoflurane, sevoflurane and desflurane anaesthesia. Indian journal of anaesthesia 2012;56(2):156-161.

[47] Stuth EA, Berens RJ, Staudt S, Robertson FA, Scott JP, Stucke AG, Hoffman GM, Troshynski TJ, Tweddell JS, Zuperku EJ. The effect of caudal vs intravenous morphine on early extubation and postoperative analgesic requirements for stage 2 and 3 single‐ventricle palliation: a double blind randomized trial. Pediatric Anesthesia 2011;21(4):441-453.

[48] Takmaz SA, Uysal HY, Uysal A, Kocer U, Dikmen B, Baltaci B. Bilateral extraoral, infraorbital nerve block for postoperative pain relief after cleft lip repair in pediatric patients: a randomized, double-blind controlled study. Annals of Plastic Surgery 2009;63(1):59-62.

[49] Townsend JA, Ganzberg S, Thikkurissy S. The effect of local anesthetic on quality of recovery characteristics following dental rehabilitation under general anesthesia in children. Anesthesia Progress 2009;56(4):115-122.

[50] Vaughan M, Paton EA, Bush A, Pershad J. Does lidocaine gel alleviate the pain of bladder catheterization in young children? A randomized, controlled trial. Pediatrics 2005;116(4):917-920.

[51] Voepel-Lewis TD, Malviya S, Burke C, D'Agostino R, Hadden SM, Siewert M, Tait AR. Evaluation of simethicone for the treatment of postoperative abdominal discomfort in infants. Journal of Clinical Anesthesia 1998;10(2):91-94.

[52] Zier JL, Rivard PF, Krach LE, Wendorf HR. Effectiveness of sedation using nitrous oxide compared with enteral midazolam for botulinum toxin A injections in children. Developmental Medicine & Child Neurology 2008;50(11):854-858.