## 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

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| **Study** | **Design/Aim** | **Subjects/circumstances/ Setting** | **Intervention/Pain measure** | **Results** | **Quality score** |
| Amin et al, 2014 [[1](#_ENREF_1)] | Double-blind randomized (placebo-controlled) studyTo evaluate the role of gabapentin premedication in the management of post-operative pain following adenotonsillectomy in children. | 120 children aged 4 – 6 yearsExc: chronic illness, epilepsyPostoperative (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 GroupG 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 andGroup 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) trialTo 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 yearsExc: developmental delayPostoperative (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 anaesthesiaPain 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 trialTo 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 yearsExc: neurological diseasePostoperative (penile surgeries)Recovery and ward | 2 groups – participants randomised to:Group P: penile block, 0.25% bupivacaine, 0.5 mg/kgGroup C: caudal block, 0.25% bupivacaine, 0.5 mg/kgPain 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 trialTo 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 impairmentProcedural (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 placeboAdministered via nebuliser 10minutes prior to NGT insertionPain 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 trialTo 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 monthsExc: neurologic, neuromuscular, psychiatric, seizurePostoperative (lower abdominal and urogenital procedures)PACU | 5 groups – participants randomised to:Group B – control group, bupivacaine onlyTreatment groups bupivacaine and Group BN.25 – 0.25 mug/kg neostigmineGroup BN.50 – 0.5 mug/kg neostigmineGroup BN.75 – 0.75mug/kg neostigmineGroup BN1.0 - 1 mug/kg neostigmineAdministered intrathecallyPain 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 studyTo 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 yearsExc: developmental delay or mental retardationPostoperativeDay surgery unit | 4 groups – participants randomised to:Group 1: 0.2% ropivacaine 0.75 ml/kgGroups 2,3 & 4 receieved 0.2% plain ropivacaine 0.75 ml/kg and: Group 2: 0.5 µg/kg dexmedetomidineGroup 3: 1.0 dexmedetomidine Group 4: 1.5 µg/kg dexmedetomidine Administered as a caudal blockPain 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 yearsExc: 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 scoresNo difference in parental perception of child’s discomfort. | 3 |
| Brown et al, 2014 [[8](#_ENREF_8)] | Parallel-group, superiority,randomized controlled trialTo investigate the association betweenDittoTM use and speed of burn wound re-epithelialization. | 73 children aged 4 – 13 yearsExc: Cognitive, visual & auditory impairment, autisticProcedural (dressing change)Burn centre | 2 groups – participants randomised to:Standard group - standard preparation and standard distraction Intervention group - DittoTM procedur-al preparation and DittoTM distractionPain 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 scoresWounds 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 trialTo 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 yearsExc: previous nasendoscopy Procedural (nasendoscopy)Otolaryngology ambulatory clinic | 3 groups – participants randomised to:Group A (control) – 0.9% sodium chlorideGroup B - xylometazoline hydrochloride, 0.05%Group C - lidocaine hydrochloride, 1%, with xylometazoline hydrochloride, 0.05%0.5ml solution sprayed in nostrils 10 min before procedurePain 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 trialTo 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 yearsExc: developmental delay, neurological injury, psychiatric diagnosisPostoperative (strabismus repair)PACU | 2 groups – participants randomised to:TIVA group - intravenous induction and maintenance of anaesthesia with propofol and remifentanilSEVO group - inhalational induction and maintenance of anaesthesia with sevofluranePain scoring: FLACC | Incidence of ED was higher withSEVO (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) trialTo 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 monthsExc: neurological diseases, seizuresPostoperative (hypospadius repair)Not stated | 4 groups – participants randomised to:R1.25 group - 1.25 mg/ml ropivacaineR1.25F 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 fentanylPain 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 trialTo 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 mthsExc: acute or chronic diseaseProcedural (immunisation)Ambulatory paediatric clinics of two hospitals | 3 groups – participants randomised to:Placebo group – sterile waterSucrose group 1 – 50% sucroseSucrose group 2 – 75% sucrose 2ml given orally prior to immunisationPain 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 groupNo 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 – 6mthsExc: critically unwell, local anaesthetic at venepuncture siteProcedural (venepuncture)Emergency department | 4 groups – participants randomised to:Group 1: sucroseGroup 2: sucrose + dummy Group 3: waterGroup 4: water + dummy  2ml given prior to venepuncture with or without dummyPain 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 trialTo compare the efficacy of intranasal(IN) dexmedetomidine with IN fentanyl for children undergoing BMT | 100 children aged 1 – 7.7 yearsExc: nil relevantPostoperative (myringotomy and tympanostomy tube placement)PACU | 4 groups – participants randomised to:Group 1 MD: midazolam premedication 0.5 mg/kg & IN dexmedetomidine 1 µg/kgGroup 3 D: IN dexmedetomidine 1 µg/kgGroup 2 MF: Midazolam premedication 0.5 mg/kg & IN fentanyl 2 µg/kgGroup 4 F: IN fentanyl 2 µg/kgPain 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 DNo 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 trialTo assess the need for routine drainage after choledochal cyst excision and Roux-en-Y hepatojejunostomy | 100 children aged < 13 yearsExc: nil relevantPostoperative (choledochal cyst excision)Not stated | 2 groups – participants randomised to:Drainage groupNon-drainage groupPain 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) trialTo 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 yearsExc: chronic painPostoperative (tonsillectomy)PACU | 4 groups – participants randomised to:F1 group: fentanyl 1 mcg/kgF2 group: fentanyl 2 mcg/kg K group: ketamine 0.5 mg/kg)FK group: fentanyl 1 mcg/kg & ketamine 0.5 mg/kgPain 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 trialTo 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 yearsExc: history of unpleasant experiences in medical settings, experience with local anesthesia injection, and any mental, visual, or auditory impairmentProcedural (dental)Dentistry clinic | 2 groups – participants randomised to:Group 1: distraction with AV glassesGroup 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 groupNo comparison made between pre and during procedure FLACC scoresIntra-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 medicationPostoperative (infra-umbilical urological & genital procedures)PACU | 4 groups – participants randomised to:Group B – 1.0ml/kg bupivocaine 0.166% with epinephrine 1:600,000Group BM - 1.0ml/kg bupivocaine 0.166% with epinephrine 1:600,000 + morphine 20mcg/kgGroup BC - 1.0ml/kg bupivocaine 0.166% with epinephrine 1:600,000 + clonidine 1.0mcg/kgGroup BMC - 1.0ml/kg bupivocaine 0.166% with epinephrine 1:600,000 + morphine 20mcg/kg + clonidine 1.0mcg/kgPain 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 trialTo 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 yearExc: chronic diseasePostoperative (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 trialTo 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 yearsExc: nil relevantPostoperative (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 normalsaline IVGroup 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 studyTo compare the relative gentleness of a silicone tape to a paper tape in healthy infants and children. | 24 infants aged 9 – 47 monthsExc: developmental delayProcedural (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 backRight group: Paper tape on the left and silicone tape on the right side of the backPain 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 trialTo compare outcomes after open or laparoscopic pyloromyotomy for thetreatment of pyloric stenosis. | 180 infants aged 11 – 108 daysExc: nil relevantPostoperative (pyloromyotomy)Not stated  | 2 groups – participants randomised to:Controlled: Open pyloromyotomyTreatment 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 design1. To evaluate the effectiveness of 2 pain protocols used interchangeably to manage early postoperative T&A pain2. To investigate whether nurses' systematic pain assessments (SPA)improve pain management | 83 children aged 3 - 12 yearsExc: nil relevantPostoperative (tonsil & adenoid surgeryPACU and ward | 4 groups – participants randomised to:Group 1: 30-50mg/kg paracetamol suppository & 0.9% saline IMGroup 2: 30-50mg/kg paracetamol suppository, 0.9% saline IM & SPAGroup 3: 30 – 50mg paracetamol suppository & 1microgram/kg fentanyl intramuscularlyGroup 4: 30 – 50mg paracetamol suppository & 1microgram/kg fentanyl intramuscularly & SPAPain 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 yearsExc: nil relevantPostoperative (myringotomy & placement of ventilating tubes)PACU | 3 groups – participants randomised to:Group 1—intranasal fentanyl 2g/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 placeboPain 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 oldExc: pre-existing neurological disease Postoperative - hernioplastyNot explicitly stated | 2 groups – participants randomised to:RM group: 0.2% ropivacaine 1ml/kg and epinephrine 1 : 200,000 with 50 mg/kgmidazolam.R group: 0.2% ropivacaine 1ml/kg and epinephrine 1 : 200,000Given via caudal injectionPain 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) studyTo 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 yearsExc: pre-existing neurological disease-Postoperative - orchiopexyPACU | 2 groups – participants randomised to:Treatment group: dexamethasone 0.5 mg/kg (max 10 mg)Control group: same volume of salineAdministered intravenouslyPain scores: FLACC, CHEOPS, VASobs (not blinded)\* Fentanyl determined by FLACC/CHEOPSAcetaminophen 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, andsecondarily on enteral intake. | 50 children aged 5 – 10 monthsExc: nil relevantPostoperative - cleft palate repairWard | 2 groups – participants randomised to:O group: oral postoperative feedingNG group: NGT postoperative feedingPain 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 monthsExc: systemic disease that compromises neurological functionPostoperative - cleft lip repairNot stated | 2 groups – participants randomised to:Group A: 1 ml solution of clonidine 1microgram/kg & 0.25% bupivacaineGroup B: 1ml 0.25% bupivacaineAdministered as an infraorbital blockPain 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 illnessPostoperative - cleft lip repairNot 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 pethidinePain 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 trialTo 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 monthsExc: major illness, associated congenital anomaliesPostoperative - cleft lip repairPostoperative recovery room | 3 groups – participants randomised to:Group NB - no block for control,Group S - 0.5 ml of normal salineGroup B - 0.5 ml of 0.25% bupivacainePain 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) studyTo evaluate the effects of oral chloral hydrate on perioperative psychological and behavioural phenomena in children. | 100 children aged 1 – 5 yearsExc: Behavioural disorders and use of psychiatric medicationsPostoperative: orchiopexyDay surgery unit | 2 groups – participants randomised to:CH group: 40mg/kg chloral hydratePlacebo group: placebo in appropriate volumePain 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) studyTo 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 yearsExc: mental retardation, develop-mental delay, neurological or psychiatric illnessesPostoperative - ambulatory surgeryPACU | 2 groups – participants randomised to:D group: dexmedetomidine 1 μg/kg, followed by 0.1 μg/kg/h until the end of surgeryS group: volume matched salinePain 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 triageTo 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 yearsExc:use of prescription strength analgesic in previous 24 hoursProcedural - venipunctureOperating 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 studyTo 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 yearsExc: regional blocksPostoperative - dental workPACU | 2 groups – participants randomised to:Treatment group: Reiki therapyControl group: ‘sham’ Reiki therapyPain 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 trialTo 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 yearsExc: neurological diseasePostoperative intra-abdominal surgeryTheatre and recovery room | 2 groups – participants randomised to:Group A: 1.2 mL/Kg 0.25% bupivacaineGroup B: 1.5 mL/Kg 0.2% bupivacaine with morphine 50 µg/KgAdministered as a caudal blockPain 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) trialTo 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 yearsExc: history chronic painPostoperative - pyeloplastyTertiary referral centre | 2 groups – participants randomised to:TAP Group: ultrasound guided TAP blockFRI Group: wound infiltration with 0.4 ml/kg bupivacaine 0.25% with 1:200,000 epinephrine before incisionPain 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) trialTo determine if a combined MMDprotocol (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 withStandard Distraction (SD) (current typical treatment). | 40 children aged 3 – 10 yearsExc: cognitive impairment, sedation and anxiolyticsProcedural - burn care procedureBurns Outpatient Centre | 2 groups – participants randomised to:Group SD: standard distractionGroup MMD: Multimodal distractionPain 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 trialTo 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 anxiolyticsProcedural (burn care procedure)Burns Outpatient Centre | 4 groups – participants randomised to:SD group: standard distractionVG group: video game distractionMMD-PP group: MMD procedural preparationMMD group: MMD distractionPain 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 studyTo 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 yearsExc: nil relevantProcedural (dental) | 4 groups – participants randomised to:D1 group: dexmedetomidine 1µg/kgD2 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 differentNo significant difference in HR, RR, BP and SpO2 between groups.  | 3 |
| Newbury et al, 2009 [[40](#_ENREF_40)] | Parallel randomised double-blind ~~controlled~~ (comparison) studyTo 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 yearsExc: nilProcedural (intravenous cannula insertion)Emergency department | 2 groups – participants randomised to:Group A: amethocaineGroup E: EMLACream applied to two vein sitesPain scores: FLACC & VASobserver (not blinded) | No difference between success rates for Groups A or ENo difference in FLACC or VAS (observer) scores between groups A and EInter-rater reliability for FLACC – 0.86 (p<0.0001)  | 3 |
| Nilsson et al, 2013 [[41](#_ENREF_41)] | Non-blinded randomised (controlled) clinical trialTo test if serious gaming and lollipops influence pain, distress and anxiety in conjunction with a wound care session. | 62 children aged 5 – 12 yearsExc: cognitive impairment & non-Swedish speakingProcedural (wound care)Day care unit | 3 groups – participants randomised to:Serious gaming groupLollipop groupControl groupPain 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 groupsDistress (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 trialTo 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 yearsExc: cognitive impairment, non-Swedish speakingPostoperative (minor procedure)PACU | 2 groups – participants randomised to:Intervention group – music for 45min from arrival in post anaesthetic care unitControl – no musicPain 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 ofan aromatherapy intervention on the reduction of children’s distress ina perianaesthesia setting | 94 children aged 1 – 21 yearsInc: with/without cognitive impairmentPostoperative PACU | 2 groups – participants randomised to:Group LG – Lavender and ginger oilGroup J – Jojoba oilApplied topically and inhaledPain 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 studyTo evaluate a short comparison between laparoscopic and open appendicectomy in children in regards to postoperative morbidity. | 60 children aged 4 - 12 yearsExc: nil relevantPostoperative (appendicetomy)Department of surgery | 2 groups – participants randomised to:Group A: Laparoscopic appendicectomyGroup B: Open appendicectomyPain 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 studyTo compare the use of desflurane and sevoflurane to determine the postoperative emergence delirium in children undergoing cataract surgery | 88 children aged 2 – 6 yearsExc: cognitive impairmentPostoperative (cataract surgery)PACU | 2 groups – participants randomised to:Group S: desfluraneGroup D: sevofluraneBoth administered with 50% nitrous oxide to maintain anaesthesiaPain 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 trialTo 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 yearsExc: active CNS disordersPostoperative (sub-umbilical procedures) | 3 groups – participants randomised to:Group R: 0.75ml/kg ropivacaine 0.2% in normal salineGroup: RK: 0.75ml/kg ropivacaine 0.2% & 0.5mg/kg ketamineGroup RF: 0.75ml/kg ropivacaine 0.2% & 1microgram/kg fentanylPain 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 trialTo determine whether single-shot caudal epidural with high-dose morphine (100 µg/kg) diluted in0.25% 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 impairmentPostoperative (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) trialTo 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 yearsExc: neurologic, or neuromuscular diseasePostoperative (cleft lip repair)Recovery and ward  | 2 groups – participants randomised to:Group I - 1.5 mL 0.25% bupivacaineGroup II - 1.5 mL saline and 20 mg/kg rectal paracetamolPain 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 studyTo 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 yearsExc: Postoperative (Dental rehabilitation)PACUNot stated | 2 groups – participants randomised to:Control group - 1 mg/kg ketorolac intravenously within 15 minutes of case completionExperimental 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 trialTo 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 yearsExc: altered mental statusProcedural (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 gelApplied to genital mucosa 2 - 3 min before catherisation and used to lubricate catheterPain 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 trialTo 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 monthsExc: mental impairmentPostoperative (minor non-invasive procedure under inhalational anaesthetic)PACU | 2 groups – participants randomised to:Experimental group - 0.3 ml of simethiconeControl group - 0.3ml placeboPain 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 trialTo 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 relevantProcedural (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 maskN2O 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**

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