

Lumbar punctures in the paediatric emergency medicine department at Red Cross War Memorial Children's Hospital: an evaluation

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Abbreviations

CI = Confidence Interval

CSF = Cerebrospinal Fluid

EMLA = Eutectic Mixture of Local Anaesthetics

ESBL = Extended Spectrum Beta Lactamase

IQR = Interquartile Range

LP = Lumbar Puncture

MEU = Medical Emergency Unit

OR = Odds Ratio

RBCs = Red Blood Cells

RCWMCH = Red Cross War

Memorial Children's Hospital

PR = Prevalence Ratio

SSW = Short Stay Ward

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Abstract

Background

Lumbar punctures (LPs) are frequently performed in the paediatric medical emergency unit (MEU) department to diagnose or exclude meningitis. Unsuccessful lumbar punctures (LPs) cause diagnostic uncertainty which may prolong hospital stay and result in unnecessary antibiotic treatment and increased costs to the hospital and patients. It is important to determine factors that may be effective in reducing unsuccessful LPs. There is a paucity of studies on this topic from sub-Saharan Africa. Previous studies have shown inconsistent results and the use of sedation has not previously been studied.

Aims

To determine the prevalence of unsuccessful lumbar punctures (LPs) and the factors influencing this in the medical emergency unit (MEU) and short stay ward (SSW) at Red Cross War Memorial Children's Hospital, Cape Town.

Methods

From February to April 2013 the LPs performed in the MEU and SSW at Red Cross War Memorial Children's Hospital (RCWMCH) were analysed. Details of the procedure, sedation and analgesia used, techniques and CSF results obtained were collected using a post procedure questionnaire completed by the doctor performing the procedure. All children requiring a LP in the MEU and SSW were eligible for inclusion. Children who had their LPs done in other wards or hospitals were excluded.

Results

Data were collected from 350 children: 142 (41%) were female and 208 (59%) were male. Sixty three percent were <12 months age, the median age was 4.8 (IRQ 1.5-21.7) months. Their median weight-for-age z-score was -0.97 (IQR -2.2 to 0.1). LPs were done to exclude meningitis in 99% (347) of cases. 86% of the practitioners reported they had done >50 LPs. The LP was unsuccessful (traumatic or dry) in 113/350 (32%) cases.

Sedation was used in 107 (31%) children and appeared to reduce the likelihood of an unsuccessful LP, $p=0.002$; RR 0.50 (95%CI 0.34-0.78) except in those under 3 months of age where sedation did not significantly reduce the likelihood, $p=0.557$; RR 1.20 (95%CI 0.66-2.18). In those where no sedation was used (242), local anaesthetic with Eutectic Mixture of Local Anaesthetics (EMLA) cream alone did not significantly reduce the prevalence of an unsuccessful LP, $p=0.154$; RR 0.73 (95%CI 0.46-1.16).

A 22 gauge spinal needle with Quincke bevel was used in 292 (83%) LPs. Of these the stylet was removed early (after passage through subcutaneous tissue rather than later in the subarachnoid space) in 15%. Early stylet removal was associated with an increase in the rate of unsuccessful LP, $p=0.02$ RR 0.65 (95%CI 0.45-0.94). No significant difference was found in the rate of unsuccessful LPs with increased experience of the physician or holder, family member presence or LPs done during the day compared to the night. The median duration of treatment in hospital was 4 (IQR 2-5) days, range 1-21 days in 79 children.

Conclusion

There is a high prevalence of unsuccessful LPs at this institution. The results suggest that sedation may reduce the risk of an unsuccessful LP but is not routinely used. Unsuccessful LPs were increased when the early stylet removal technique was used. Whether a procedural sedation protocol in the MEU and SSW reduces the rate of unsuccessful LPs and length of hospital stay requires further study.

Background

Bacterial meningitis is a serious disease affecting adults and children which results in the deaths of an estimated 180,000 children aged 1 month to 5 years per year worldwide¹. The rapid diagnosis and treatment of meningitis is crucial to reducing morbidity and mortality². Lumbar punctures(LPs) are frequently performed in the paediatric emergency medicine department to diagnose or exclude meningitis. The diagnosis or exclusion of meningitis is confounded by the presence of blood in the cerebrospinal fluid (CSF) which occurs when a LP is traumatic. A traumatic LP occurs when red blood cells are introduced into the CSF as a result of the needle puncturing one of the venous plexuses located close to the dura of the spinal canal. Studies have reported the incidence of traumatic LPs in children to be between 10 and 30%³. Studies of the factors influencing the incidence of traumatic LPs have shown varying results. Red Cross War Memorial Children's Hospital (RCWMCH) does approximately 3,000-3,500 LPs per year and in 2009 the proportion of traumatic LPs was found to be 21.4% of samples sent to the laboratory (Muloiwa, personal communication). The number of unsuccessful LPs is unknown as we do not know the incidence of dry taps or those where samples were not sent to the laboratory.

Unsuccessful LPs include dry taps and traumatic (or bloody) taps. These unsuccessful LPs are traumatic for the child and parents, especially when repeat procedures are needed. They also cause diagnostic uncertainty which prolongs hospital stay and may result in unnecessary antibiotic treatment. If meningitis cannot be excluded after the first LP, children who might otherwise have been discharged from the hospital are often admitted and treated with third generation cephalosporins to cover for the possible diagnosis of bacterial meningitis. These children may then either have a repeat LP or be given a full course of antibiotics. Exposure to third generation cephalosporins has been shown to increase the risk of acquisition of extended spectrum beta lactamase-producing (ESBL) organisms⁴. Admitting the child to the hospital puts them at risk of nosocomial infections which may then prolong their stay as well as place them at risk for mortality. These unnecessary or prolonged admissions result in increased costs to the hospital and patients.

A LP is a painful procedure for a child and can be very frightening. This must be taken into consideration whenever the procedure is performed. A child is held in a tightly flexed position for a LP but if they are either in pain e.g., from meningitis, or anxious they tend not to remain still which may affect the success of the procedure. The risks and benefits of analgesics or sedatives and the effect they will have on the procedure must be considered and a decision made regarding the method most appropriate to the setting.

There has been increasing recognition that neonates, including those born prematurely, have fully developed nerve pathways, perceive pain in the same way as older children and adults and that subjecting them to pain in early life may be detrimental both in the short term with effects on physiologic instability and in the long term with regards to development and pain management in later life⁵. However, it is still common practice to perform LPs on children, and especially on neonates, without any form of analgesia. A study by Quinn et al., in 1993 showed that 95%(174 of 183) of children who had LPs performed in an emergency department in the USA received no analgesia⁶. In 2010 Fein et al., showed an increase in pain management, but still only 23.4%(83 of 353) of children received any form of pain control; 17%(60) received local anaesthetic, 12.2%(43) received sedation and 5.4%(19) received both. Younger patients were shown to receive pain management less frequently ($p < 0.001$)⁷. No studies are available from Africa to compare pain management practices.

Internationally various groups and task forces have made statements regarding pain in children including the American Academy of Pediatrics in 2001 who stated that local anaesthetics and strategies to soothe and minimize distress should be considered for even simple procedures such as LPs⁸. South African guidelines for sedation and analgesia in children were published in 2010 but it is not known to what extent these have been implemented⁹. This may be due to a lack of awareness of their existence or the fact that institutions have not formalised them. These guidelines recommend that local anaesthetic and simple analgesics be used for neonates having LPs; and that local anaesthetic (EMLA cream or lignocaine) and anxiolytic medication be used for older children⁹. There are currently no formal guidelines for procedural sedation in use in the emergency department of RCWMCH regarding LPs so the method used is up to the discretion of individual doctors.

The high incidence of unsuccessful LPs observed in our emergency medicine department with the consequences of increased hospital stay as outlined above led us to undertake an audit of current practice. The conflicting results from previous studies led us to believe that it is important to identify what factors may be important in reducing unsuccessful LPs in our setting. We wished to determine if the use of sedation is important as there is currently no evidence for or against this. We aimed to identify risk factors that could be modified in order to reduce the number of unsuccessful LPs. We then planned to introduce a protocol for LPs with the aim of improving the cost-effectiveness of our procedures. We hoped that a protocol would increase diagnostic yield which may then reduce unnecessary treatment and stay in hospital as well as provide adequate analgesia and sedation for children undergoing the procedure. Future studies would be needed to assess the impact of any protocol we produced following this study. There is a paucity of studies from sub-Saharan Africa addressing the issue of unsuccessful LPs as well as the use of procedural sedation in children undergoing LP. We believe that this study will attempt to address these issues in an African setting.

Our hypothesis was that children that do not have any procedural sedation are more likely to have unsuccessful LPs.

Aims and Objectives

Aims

The aim of the study was to determine the prevalence of unsuccessful lumbar puncture (LP) and to examine the factors influencing this in the medical emergency unit (MEU) and short stay ward (SSW) at RCWMCH.

Objectives

Primary objective: to assess the prevalence of unsuccessful LPs by measuring the number of successful and unsuccessful/traumatic LPs by CSF results analysis.

Secondary objective: to assess factors that may influence the success of LPs:

- Use of local anaesthetic (EMLA cream or lignocaine)
- Use of sedation
- The type of needle used and timing of removal of the stylet
- Experience of the person holding the child during LP
- Movement of the patient during the procedure
- Seniority and experience of the practitioner performing the LP
- Parental presence during the procedure

Literature Review

A literature search was performed using MEDLINE (<http://www.ncbi.nlm.nih.gov/pubmed>) limiting the articles to 'English language', 'Humans' and 'Child: birth to 18 years'. The search criteria were:

Participants: Children up to 18 years old

Interventions: Lumbar puncture OR Spinal puncture (MeSH)

Comparisons: Any

Outcomes: Any

Study Design: Any

Searching for the intervention criteria retrieved 2,311 papers. These were screened and the most relevant articles found using two further search strings, 'Lumbar puncture' OR 'Spinal puncture' (MeSH) AND 'success' followed by 'Lumbar puncture' OR 'Spinal puncture' (MeSH) AND 'sedation'. Key articles identified from these searches were retrieved and reviewed in full text. For those where full text was available, the reference list was reviewed for other relevant studies. Letters and comments were excluded. Papers that examined factors such as patient position, ultrasound use or stimulation training were excluded as these factors were not relevant to the current study. Studies focusing on spinal anaesthesia were excluded as were those comparing different drugs used for sedation. The seventeen papers found were then analysed with regards to their findings that were relevant to the current study.

The prevalence of traumatic LP

Only one study was found in which the main aim was to establish the incidence of traumatic LP. Between 2003 and 2004 Glatstein et al., studied 127 lumbar punctures in Tel Aviv, Israel, and found their rate of traumatic taps to be 26.2% (27 of 103) in children under 2 years and 12.5% (3 of 24) for children over 2 years¹⁰. They also found that the rate was significantly ($p=0.0074$) lower if only one attempt was required for LP.

Other studies examining the risk factors for traumatic LP also include the incidence as an outcome and the rates vary. In 2002 a study done in the USA by Howard et al., reported a rate of only 10% traumatic LPs (using a definition of >500 RBCs/mm³). They noted that in

infants that rate increased to 23%. Although this was a large study of 5 609 LPs, they were all done on a selected group of children with acute lymphoblastic leukaemia, most of whom were sedated¹¹. The number who received sedation was not reported. In 2006 another study from the USA by Baxter et al., reported on 594 LPs done on children under 12 months of age. The success rate for LPs was 74% (i.e., 26% (277 of 377) of the LPs were unsuccessful using a threshold of $>1,000$ RBCs/mm³). They also found an increased risk in children under 3 months compared to over 3 months (Odds Ratio, OR = 3.1 95% confidence interval (CI) 1.2-8.5) but did not include any children older than 1 year¹². Between 2003 and 2005 Nigrovic et al., from Boston, studied 1,459 LPs on children aged 0-22 years and found that 40% (513 of 1,474) were unsuccessful on the first attempt (using a threshold of >500 RBCs/mm³). This study varied from others as it focused on the first attempt rather than allowing more attempts in one procedure and measuring the final outcome of the procedure. It also focused on LPs with $>10,000$ RBCs/mm³, but on further analysis of the data the actual failure rate for each LP was 23% using a cutoff of >500 RBCs/mm³. This study also showed an increase in traumatic LPs in infants under 3 months of age (OR 2.2; 95%CI 1.6-3.1)³. The incidence of unsuccessful LP therefore appears to vary according to various factors including age, clinical setting, and thresholds used but appears to be between 10 and 30%.

Several studies were found that examined the risk factors for unsuccessful or traumatic lumbar puncture. The results were not consistent; most agreed that younger age of the patient, not using local anaesthetic and late removal of the stylet worsened outcomes^{3,11,12}. The influence of physician experience and other factors had varying results and no clear consensus was found.

Use of local anaesthetic

The use of local anaesthetic for LPs in children has been examined in several studies. Subcutaneously injected lidocaine or EMLA (eutectic mixture of local anaesthetics) have been used. EMLA should be applied as a topical cream 1 hour before the procedure in order for it to be effective. In 1989 pain from medical procedures was gaining increasing recognition as a concern for patients, families and medical staff. Halperin et al., did a study of EMLA use for various medical procedures including LPs. They showed that the use of EMLA was significantly associated with less pain than placebo when children were asked to rate their pain score using a visual analogue scale. None of the children included in the study received sedation. This was a small study of 14 children and did not include

neonates but it was the first study to look at EMLA use for LP. It did not examine the effect of local anaesthetic on the success of the LP¹³.

Initial studies examined the use of local analgesia and its effect on physiological effects whilst performing the LP. In a study in 1991 Porter et al., failed to show that the use of subcutaneous lidocaine had any effect on the physiologic response to LP. This was a small study of 81 neonates before dosage guidelines for lidocaine were available for neonates and it did not assess behavioural responses. It was noted that the physiological effects seen were mainly in response to the preparation and positioning for LP. It also noted that no adverse effects were associated with the use of lidocaine and that the number of punctures needed was not significantly increased by the use of lidocaine, suggesting that it did not reduce success rates. It suggested that because the preparation and handling for LP causes maximum physiologic responses, sedation for the procedure may be more appropriate to reduce the potentially destabilising effect¹⁴. However no further studies addressing this were found.

In 1993 Pinheiro et al., studied the use of local anaesthesia for LPs in neonates looking at whether, due to reduced struggling of the baby, it increased the chance of success. The researchers stated in this study that lidocaine reduced physiologic instability for LPs in neonates, but the evidence cited could not be found. They also stated that the lack of effect found in Porter's study¹⁴ may be explained by holding the infants with the neck flexed therefore maximising instability prior to lidocaine use. Pinheiro et al., studied 100 neonates using an adapted position without the neck flexed, and found that lidocaine use reduced struggling scores but did not affect the number of attempts needed or the incidence of traumatic LPs. Their success rate was also not affected by the level of training of the physician. In this study they stated that LPs are often performed urgently in the NICU and waiting 1 hour for topical creams would not be appropriate. This was a case-control study and they planned to allocate neonates randomly to local anaesthetic or not. However, they found in a pilot study that parents objected to their neonate being allocated to the no local anaesthetic arm so the study design was altered to giving local anaesthetic part of the week and not giving it at other times. This suggests that parents wish for their children to receive analgesia, and it may not be ethical to withhold it. No detrimental effects of lidocaine were found. The success rate for LPs in this study was only 45% on the first attempt but their overall success rate was not stated. The researchers stated that the

use of sedation did not alter the results but no details were given on the sedation used or the numbers involved¹⁵.

A study of 100 children done by Carraccio et al., in 1996, studied children under 3 years of age who required an LP. Children were randomised to receive local anaesthetic or not. No mention is made of whether any sedation was used or not. Their results showed that the use of lidocaine appeared to increase the number of attempts required for the LP when a cutoff of >1000 RBCs/mm³ but this effect disappeared when a cutoff of $>10,000$ RBCs/mm³ was used. They also found that the level of physician experience did not affect the outcome. Based on their findings they advocated the use of local anaesthetic. They did not note any difference in outcomes between different ages¹⁶.

The larger studies performed by Baxter et al., in 2002 and by Nigrovic et al., in 2007 found that local anaesthetic improved success rates for LPs in children. Baxter et al., showed that LPs performed with local anaesthetic were twice as likely to be successful (OR 2.2; 95%CI 1.04-4.6). In this study, 74% of 280 children received local anaesthetic, mostly with EMLA cream, only 4% of those using anaesthetic injected lidocaine. Therefore the number of controls without local anaesthetic was low but a significant difference was found. The children in this study were all under 1 year but the greatest improvement in success rate was seen in the children over 3 months¹². Nigrovic et al., in their study of 1,459 LPs showed that local anaesthetic was used in 46% of all LPs, 7% lidocaine alone, 20% EMLA alone and 19% both agents. Lack of local anaesthetic was identified as a risk factor for traumatic LP ($p<0.05$, OR 1.6; 95%CI 1.2-2.3) in the multivariate analysis. However, local anaesthetic was not a significant contributor to success in the children under 3 months although the numbers were small (only 14% of those under 3 months received local anaesthetic). The study recommended that local anaesthetic be used for all LPs, regardless of age, to reduce pain but suggested that further randomised studies are needed to confirm the association with success³.

In 2003 Kaur et al., conducted a study in India on the use of EMLA cream for LPs in neonates. Unlike the injection of lidocaine, it was easy to use a placebo for EMLA cream and to blind the studies. Previous studies simply compared the use of lidocaine to no anaesthetic because injection of a placebo was felt to be unethical. This was a double-blind randomised controlled trial of 60 neonates. They showed that compared with a placebo, EMLA reduced pain from LP with a lower heart rate response and lower total

behavioural scores⁵. Although a small study this suggests that EMLA is effective in neonates and not just in older children.

Use of sedation

No studies were found that examined sedation use as an outcome in determining the rates of unsuccessful LP. The Glatstein study was a small study focussing on identifying the incidence but it stated that there was no correlation between rate of traumatic LP and use of sedation, physician's experience or time of day the procedure was done. However, there are no details given of how this information was obtained, what sedation was used, the numbers involved or how this conclusion was reached. It suggested that the incidence of traumatic LP was therefore related to intrinsic anatomic factors but made no mention of the large numbers of other factors that could be involved such as local anaesthetic use or timing of the stylet removal¹⁰.

As above, the lowest rate of unsuccessful LPs recorded in the papers found was in the Howard et al., study. These children with cancer have repeated LPs and multiple procedures which makes them a very different population from the children seen with possible meningitis in an emergency setting. Sedation was reportedly used for most of the procedures in this study although specific numbers were not quoted. One of the factors that the study identified as improving success rates was a change in treatment era. During the earlier years of the study the LPs were done in the ward or clinic without sedation or with conscious sedation using meperidine and pentobarbital. When the procedures were moved to a specialised procedure area where the children were given a general anaesthetic by an anaesthetist using propofol, the rate of traumatic LPs reduced from 11% to 7.1% (OR = 1.4 95% CI 1.2-1.7). However, the study found that when this factor was included in a multivariate analysis the effect disappeared. The changes made were to decrease patient pain and anxiety; the benefit of reducing unsuccessful LPs was only realised later but the consequences were noted to be many¹¹.

Nigrovic et al., stated in their study of 1,459 children that sedation was used in 16% of LPs, 8% used oral agents and 8% used intravenous or inhalational agents. Sedation use or lack thereof was not identified as a risk factor for traumatic LPs but the numbers sedated were small, so an effect may not have been seen³.

The type of needle used and timing of removal of the stylet

The most common needles used for LPs are Quincke spinal needles which contain a stylet. Those available at our hospital are 22-gauge, 38 or 75mm long with a Quincke bevel. No studies were found comparing success with other needles used. The stylet has been shown to reduce spinal headache, obstruction of the needle and the risk of spinal epidermoid tumours¹². There are multiple case reports associating spinal epidermoid tumours with LPs done with non styletted needles due to the introduction of cells from the epidermis into the spinal canal. Therefore it is generally recommended that a styletted needle is used for all LPs, although it is thought that some physicians prefer to use normal or butterfly needles for LPs in neonates. A survey of physicians by Baxter et al., in 2004 showed 5% of responders used butterfly needles for infant LPs¹⁷. However, in the larger Baxter and Nigrovic studies, the standard 22-gauge spinal needle was used for all LPs.

The Cincinnati method of LP involves removal of the stylet after passage through the epidermal and subcutaneous tissues (i.e., early removal) so CSF can be seen to drain immediately on entering the subarachnoid space¹². This is thought to be safe because the subcutaneous tissues are endodermal, not ectodermal and carry little risk of tumour formation. The other technique used for LPs involves keeping the stylet in place as the needle is passed and removing it once a pop is felt after the dura is entered, or at regular intervals to check for CSF. In children, the pop felt on entering the dura is often much more subtle than in adults. The two big studies on risk factors for traumatic LPs examined the use of early versus late removal of the stylet and the effect on success of the LP^{3,12}.

The study by Baxter et al., in 2002 showed that for infants under 12 weeks of age, early stylet removal reduced the rate of traumatic LP (OR 2.4;CI 1.1-5.2). The effect was not significant when all children under 12 months were included¹². The larger Nigrovic et al., study in 2007 showed that early removal of the stylet reduced the risk of traumatic LP for all patients (OR 1.3;95% CI 1.04-1.7). The technique was used 29% of the time although in a pilot survey the authors had assumed an equal distribution of each technique to determine the power level of the study. However, the study showed a significant reduction in traumatic LPs for all patients including children up to age 80 months with early stylet removal. As with the Baxter study, the greatest benefit was in children under 3 months (OR 1.4; 95%CI 1.02-2.0)³.

Experience of the person holding the child during LP

No studies were found that examined the effect of the level of experience of the person holding the child for LP. Several studies stated that success was thought to be related to the person holding but they were not able to study this as the experience was not recorded¹² or the same experienced people were used for all LPs¹⁰.

Movement of the patient during the procedure

Only one study was found that examined patient movement and relation to success. The large Nigrovic et al., study found that reduced patient movement was associated with increased success (OR 2.1; 95%CI 1.6-2.6). The physician performing the LP was asked to rate the patient's movement on a scale of 1 to 5 and the results were then dichotomised. For all patients, including the subgroup of infants under 3 months, patient movement was found to increase traumatic LPs significantly. Which children were more likely to move and factors leading to reduced patient movement were not discussed³.

Seniority and experience of the practitioner performing the LP

Most of the studies which have attempted to determine risk factors for traumatic LPs have included the seniority or experience of the practitioner. Some look at year of training and others at the self-reported number of LPs performed. The results vary, with some showing an effect and others not. In 1993 Pinheiro et al., found that success rate was not dependent on level of training. The study recorded the year of training, included attending physicians, but found that the success rate was similar for first year residents and more senior physicians. However, this was a small study and did not look at how much experience the doctors had of actually performing LPs¹⁵. The study by Carraccio et al., from 1996 found that the level of experience of the physician did not affect the outcome when assessing year of study or specialty¹⁶. The study by Glatstein et al., also states that physician experience was not related to increased success but no details are given¹⁰. The study by Baxter et al., showed that year of training was not a significant predictor of success in performing the LP. The authors state that a previous study showed that residents had performed >50 LPs by their third year of postgraduate training but did not ask the responders how many LPs they had performed. Attending physicians were not included in the analysis¹².

The larger studies by Howard et al., and Nigrovic et al., showed an association between increased experience of the practitioner and improved chances of successful LP. In the

study by Howard et al., on children with leukaemia it was found that the more experienced practitioners had greater success in obtaining non-traumatic LPs (OR 1.4; 95% CI 1.1-1.8). In this study practitioners were categorised according to the number of LPs they had performed, but only on a cohort of patients with acute lymphoblastic leukaemia (ALL). Those that had done more than 50 were associated with increased success. The number of other LPs they had performed and the influence of using that specific cohort are not clear. The study found that educational level was also related to increased success in the univariate analysis but that effect disappeared in multivariate analysis whilst experience remained significant. The study suggested that practice was therefore crucial to achieve optimum skill and that this was a modifiable factor, but practitioners with less experience need to build up their skills so it is not practical for only experienced practitioners to perform LPs¹¹.

Nigrovic et al., showed an increased risk of traumatic LP with less physician experience (OR 1.08; 95% CI 1.1-2.2). In their study, attending physicians were included but consultant neurologists and neurosurgeons were excluded. This study also used the number of LPs performed rather than year of experience. This was said to be due to the varied nature of specialties represented so the year of experience may not correlate with LPs performed. On multivariate analysis the study showed that both number of LPs and year of experience correlated with increased success when a cutoff of $>10,000$ RBCs/mm³ was used but the effect was not seen when a cutoff of >500 RBCs/mm³ was used. The reason for this is unclear. The study suggested that further research was needed to evaluate the effects of simulation training and the presence of senior physicians during the procedure³. This may suggest that the smaller studies did not have enough power to show the difference or that the more important factor is the number of LPs rather than educational level.

Parental presence during the procedure

According to a study by Beckman et al., in 2002, surveys have shown that most parents prefer to stay with their children during procedures. It was not stated where all these studies were done but some were done in the United States of America (USA) as was the Beckman study and one was done in Australia. This is a topic that will have large cultural influences. No studies from Africa were found to determine if this would be true for a South African population. The Beckman study was a survey of physicians and nurses in the USA to determine attitudes regarding parental presence for procedures and their opinions on

who should make the decision. The results indicated that 65.7% of physicians thought that parents should be present for LPs. However, the study did not examine how many parents actually were present or any effect on the success of the LP. The study stated that health care providers were less willing to allow parental presence than parents would prefer and reasons stated include parental anxiety, time required for orientation of the parents, escalating negative behaviour of children, performance anxiety and fear of litigation. The study also stated that parents and children were likely to benefit from parental presence in procedures but did not show how they would benefit or supporting evidence for this¹⁸.

The only study found that examined the success of LPs with and without parental presence, was a follow up paper by Nigrovic et al., on their study of 1459 LPs between 2003 and 2005 in Boston, USA. This study found that a family member was present for 81% of the procedures. It found no difference in success rates for either traumatic LP or number of attempts whether a family member was present or not. The study quoted evidence that the presence of a family member appeared to decrease anxiety for both the child and the parent. However, there was no association between parental presence and the amount of movement of the child. The study found an increased likelihood of parental presence if the child was over 1 year ($p=0.006$) but in this subgroup there was still no influence on success rates. There was an association with local anaesthetic use when a family member was present ($p<0.001$) which is consistent with previous studies stating that parents prefer physicians to use local anaesthetic. This study provided evidence that the presence of a family member during LP does not worsen outcomes which is often cited as a reason for non-presence and there may be benefits to the patient and family which are difficult to measure¹⁹.

Methods

Study Design

This was a cross-sectional observational study of current practice.

Setting

Red Cross War Memorial Children's Hospital (RCWMCH), Cape Town

Study population and Patient Selection

Inclusion criteria

- Children aged up to 13 years attending RCWMCH.
- All children who had a LP performed in the Medical Emergency unit (MEU) or in the short stay ward (SSW) at RCWMCH between 1st February and 30th April 2013 were eligible for inclusion.

The study participants were identified by examining the ward registers of the MEU and SSW. Children with diagnoses suggestive that they would have had a LP such as neonatal sepsis, meningitis or fever of unknown origin were identified and the folders obtained to see if they had had an attempted LP. The doctor who performed the procedure was then asked to complete a questionnaire detailing the procedure and the results were obtained from the laboratory. The questionnaires were also available in the department for doctors to complete once the procedure was completed. The study describes the method of LP, sedation and analgesia used and the incidence of traumatic or unsuccessful LP.

Exclusion criteria

- Children who had LPs in other hospitals prior to transfer to RCWMCH
- Children having their LP in other wards of the hospital
- Children with congenital abnormalities of the spine, history of a bleeding disorder and evidence of vasculitis or cellulitis over the lumbar spine.
- Children subsequently diagnosed with subarachnoid bleeding from traumatic brain injury or herpes simplex infection ¹².

Definitions

1. Traumatic LP is defined as >400 RBC/mm³ which is the visual threshold³.
2. Unsuccessful LP means the tap was dry, i.e. no CSF was obtained or it was a traumatic LP.
3. Number of attempts means the number of times the needle penetrated the skin whereas redirecting the needle without exiting the skin is a single attempt³.
4. Early stylet removal means removal of the stylet from the needle after passage through the epidermal and subcutaneous tissue rather than later in the subarachnoid space.

Procedures

The questionnaires (see appendix A) were present in the MEU and SSW. The staff working in these areas were educated with regards to the study and the need for the questionnaires to be completed. The doctors performing the LPs were asked to complete a questionnaire after each LP performed on a child under 13 years who met the inclusion criteria. The MEU and SSW admissions registers were checked daily for any children who may have had an attempted LP. The doctor who performed the procedure was then asked to complete a questionnaire if they had not already done so. The following data were collected: Age, Sex, Weight, Date and Time, Experience of practitioner (staff grade and number of LPs performed), Indication for LP, Needle used, Parental presence, Who held the child, Sedation and Analgesia used, If vital sign monitoring was in situ, If the child was moving, When the stylet was removed, Number of attempts required and LP result (including unsuccessful). The patient case files were then obtained and an attempt made to find any missing data as well as document the CSF result, to look for any complications including the incidence of post procedural headache and to record the outcome of the child's management including duration of antibiotics and length of stay.

Limitations of the Study

This study was limited to an audit of current practice. It was assumed that when EMLA was used, that it was applied and used according to the manufacturer's guidelines. The study examined what practices are currently being undertaken and aimed to identify areas

for improvement with regards to reducing the incidence of unsuccessful LPs. It did not examine the patient perspective or assess the adequacy of analgesia or sedation used. The detail and unbiased observation that is required to delineate the actual efficacy of the current practice could not be examined. No independent observers were used to assess the methods used including what drugs were given and the timing of the stylet removal. Problems during the LP may not have been reported by the doctor but the staff recruited were asked to be honest and if a procedure was difficult it would usually result in repeated attempts. It is recognised that post procedural headache may not be reported by the patient due to their age and if it is reported it may not be recorded in the folder but analysis of the patient experience is outside the scope of the study.

Consent and Ethical Approval

All data were kept anonymous and confidential; the questionnaires were stored in a locked office. At this institution informal consent for a LP is usually taken but written consent is not obtained. The aim of the study was to audit current practice and not to influence the procedure so consent was not specifically taken from the patients included in the study. Each name/folder number was linked to a study number. Study numbers were entered on an electronic database for anonymous analysis and reporting. The study protocol was submitted to the Research Ethics Committee of the University of Cape Town, and the Administration of Red Cross War Memorial Children's Hospital for approval which was granted. UCT Ethics reference: HREC/Ref: 173/2013. The study was done in accordance with the World Medical Association Declaration of Helsinki, 2013.

Statistical Analysis

This was a cross-sectional study, the outcome and exposure data were collected at the same time and therefore the prevalence and prevalence ratios were calculated to analyse the data. The primary objective of this study was to determine the prevalence of unsuccessful LPs. The study was therefore powered to describe the prevalence of unsuccessful LPs which was estimated to be 30% with a 5% margin of error. The sample size required was 300. It was estimated that a time period of 3 months would be needed to obtain the appropriate sample size. The main secondary objective was to estimate the risk reduction associated with sedation in the outcome variable (unsuccessful LPs). A prevalence ratio (PR) was used as a proxy for relative risk reduction. Pilot data suggested that the prevalence of unsuccessful LPs overall was about 30% and in the control group (not sedated) about 50%. With 300 subjects the study had 80% power to show a halving in

the risk of unsuccessful LPs with the use of sedation assuming that 50% of unsedated subjects had unsuccessful LPs. The significance level was set at $p < 0.05$.

The data were entered anonymously into an Excel database by one of the researchers and analysed using STATA, release 13, College Station, Texas, USA. Conventional descriptive methods (mean and standard deviation (SD) or median [interquartile range]) or proportions were used to describe and characterise the study population: e.g. gender, age in months, weight for age, number of traumatic LPs. The prevalence of unsuccessful LPs in our study was determined. The association between unsuccessful and successful LPs and categorical predictor variables was estimated using generalised linear regression modelling. These are reported as prevalence ratios (PRs) and their respective 95% confidence intervals. The analysis was supported by the department of emergency paediatrics and a statistician from the University of Cape Town.

Risks to the participants

There were no risks to the participants in this study. Data were collected and analysed anonymously.

Benefits to the participants

There are no direct benefits to the study patients, although the results of the study have the potential to benefit other children undergoing LPs, and potentially to guide processes in the rest of the province/country.

Results

During the three month time period three hundred and fifty six (356) LPs were identified as having been performed. For 6 of these procedures forms were not completed so data was collected on 350 procedures. The study included 142 (41%) females and 208 (59%) males. The rate of unsuccessful LP in females was 34.5% (49/142) whilst in males it was 31% (64/208). This difference was not statistically significant, $p=0.462$ PR 0.89 (95%CI 0.66-1.21) and therefore in the analysis males and females were not separated further.

Sixty three percent (63%) of the procedures performed were on infants <12 months age and 45% were on infants <3 months of age. The age range was 3 days to 12.6 years with median age 4.8 months (Interquartile range (IRQ) 1.5-21.7). Their median weight-for-age z-score was -0.97 (IQR -2.2 to 0.1). **Table 1** shows the rates of unsuccessful LPs for the different age groups.

Age	No. of procedures	Percentage of total	Unsuccessful LP*	PR* (95% CI*)
1-28 days (neonate)	53	15%	23 (43%)	1 (ref)
1-3 months	105	30%	44 (42%)	0.97 (0.67-1.40)
3-12 months	62	18%	28 (45%)	1.05 (0.70-1.56)
1-5 years	85	24%	13 (15%)	0.37 (0.22-0.64)
5-13 years	45	13%	5 (11%)	0.26 (0.10-0.68)
Total	350	100%	113 (32%)	

*LP - lumbar puncture; PR - prevalence ratio; 95% CI - 95% confidence interval

Table 1: Number of procedures for each age range and rates of unsuccessful lumbar puncture

The primary objective of the study was to measure the prevalence of unsuccessful LPs at Red Cross Children's Hospital. Of the 350 LPs, 113 were unsuccessful giving a prevalence of 32% (95% CI 0.3-0.4). Of these only 4 were dry taps, the rest were traumatic i.e. frank

blood or blood stained CSF (>400 RBC/mm³). In 23 cases the doctors were not aware that the CSF was bloody when it was sent. In 4 cases the doctor sending the CSF reported it to be bloody but the number of red cells did not meet the criteria for a blood stained specimen.

The secondary objectives of the study were to assess factors that may influence the success of obtaining a blood-free CSF sample. A summary of the variables is shown in

Table 2.

Variable		Number	Unsuccessful lumbar puncture	p value	Prevalence Ratio (95% Confidence Interval)
Age	<1yr	220	95 (43%)	p<0.001	1.0 (ref)
	>1yr	130	18 (14%)		0.34 (0.22-0.53)
EMLA	No	277	92 (33%)	p=0.47	1.0 (ref)
	Yes	73	21 (28%)		0.86 (0.58-1.29)
Sedation	No	242	92 (38%)	p=0.002	1.0 (ref)
	Yes	107	20 (19%)		0.50 (0.34-0.78)
Early stylet removal	No	247	75 (30%)	p=0.02	1.0 (ref)
	Yes	45	21 (47%)		1.54 (1.07-2.22)
Experience holder	Student	32	10 (31%)	p=0.90	1.0 (ref)
	Staff	318	103 (32%)		1.04 (0.60-1.78)
Movement	None	102	17 (17%)	p<0.001	1.0 (ref)
	Some	198	62 (31%)		1.88 (1.16-3.04)
	A lot	50	34 (68%)		4.08 (2.54-6.56)
Seniority practitioner	<50	49	18 (37%)	p=0.46	1.0 (ref)
	>50	301	95 (32%)		0.86 (0.58-1.29)
Parent	No	322	103 (32%)	p=0.68	1.0 (ref)
	Yes	28	10 (35%)		1.12 (0.66-1.88)

Table 2: Changes in rate of unsuccessful lumbar puncture seen with risk factors

Age

Table 1 shows the varying rates of unsuccessful LP with regards to age. The rate of unsuccessful LP increased significantly under 12 months of age with 43% being unsuccessful in infants under 1 year, 15% in children 1-5 years and 11% in children over 5 years. There was no significant further increase in unsuccessful LPs in those infants under 3 months or under 1 month compared to those under 12 months. This is a significant trend ($p < 0.001$) between increased age and reduced risk of unsuccessful LP.

The LPs in the younger children were not done more often by the more experienced ($p = 0.78$) practitioners as shown in **Table 3**.

Age	Number	No. Done by More Experienced Practitioners (>50 lumbar punctures)
1-28 days	53	45 (85%)
1-3 months	105	93 (89%)
3-12 months	62	51 (82%)
1-5 years	85	72 (85%)
5-13 years	45	40 (89%)
Total	350	303 (87%)

Table 3: Rate of Lumbar punctures done by more senior physicians

Use of local anaesthetic

Lignocaine was not used as a local anaesthetic in any of the procedures, the only local anaesthetic used was EMLA cream. No sedation or analgesia was used in 192/350 (54%) cases. For those procedures where no sedation or analgesia was used the rate of unsuccessful LP was 77/192 (40%) whereas with either EMLA or sedation the rate was 36/158 (23%). The use of any form of analgesia or sedative drug was associated with a reduction in the rate of unsuccessful LPs, $p = 0.001$, PR 0.57(95%CI 0.41-0.79).

Overall, EMLA was used as a local anaesthetic in 73/350 (21%) of cases. The rate of unsuccessful LP for those patients for whom no EMLA was used was 92/277 (33%)

compared to 21/73 (28%) when EMLA was used. This reduction was not statistically significant, $p=0.47$, PR 0.86 (95%CI 0.58-1.29).

The use of EMLA increased with age ($p<0.05$) as shown in **Table 4**. In no age group was it associated with a significant reduction in unsuccessful LPs.

Age group	EMLA*?	Number	Unsuccessful Lumbar Puncture	p value	Prevalence Ratio (95% Confidence Interval)
1-28 days	Yes	3 (6%)	1 (33%)	$p=0.74$	0.76 (0.15-3.93)
	No	50	22 (44%)		1.0 (ref)
1-3 months	Yes	12 (11%)	7 (58%)	$p=0.17$	1.47 (0.85-2.52)
	No	93	37 (40%)		1.0 (ref)
3-12 months	Yes	14 (23%)	8 (57%)	$p=0.28$	1.37 (0.78-2.42)
	No	48	20 (41%)		1.0 (ref)
1-5 years	Yes	18 (21%)	2 (11%)	$p=0.58$	0.77 (0.16-2.76)
	No	66	11 (17%)		1.0 (ref)
5-13 years	Yes	26 (42%)	3 (12%)	$p=0.92$	1.10 (0.20-6.05)
	No	19	2 (11%)		1.0 (ref)
Total	Yes	73 (21%)	21 (28%)	$p=0.47$	0.86 (0.58-1.29)
	No	277	92 (33%)		1.0 (ref)

* EMLA = Eutectic Mixture of Local Anaesthetics

Table 4: EMLA* use in different age groups

When no sedation was used, local anaesthetic (EMLA cream) was used in 51/242 (26%) and when sedation was used, EMLA was used in 22/107 (20%) cases. In those where no sedation was used (242), those without EMLA cream had a rate of unsuccessful or traumatic LP of 77/191 (40%) whereas with EMLA cream the rate was 15/51 (29%). Although this suggests that the rate of unsuccessful LP was reduced by using EMLA cream the numbers using EMLA were small and the reduction was not statistically significant, $p=0.15$; PR 0.73 (95%CI 0.46-1.16).

In those who were sedated, the use of EMLA did not significantly alter the rate of unsuccessful LP, 15/85(18%) were unsuccessful without EMLA and 6/22(27%) were unsuccessful with EMLA, $p=0.30$, PR 1.55 (95%CI 0.68-3.53). Again, the numbers using EMLA were small.

Use of sedation

Sedation was used in 107 out of 349 cases (31%), in one case it was not clear if sedation was used or not. Of 242 unsedated patients, 92(38%) were unsuccessful taps, whilst of 107 sedated patients only 21(19%) were unsuccessful showing a 50% reduction in unsuccessful procedures when sedation is used. Sedation was associated with a reduced rate of unsuccessful LP, $p=0.002$; PR 0.5 (95%CI 0.34-0.78).

The use of sedation was strongly correlated with age. Very few infants were given sedation, only 12/158 (8%) of those under 3 months received sedation whilst 95/191 (50%) of those over 3 months received sedation $p<0.001$, PR 2.2 (1.89-2.65).

Table 5 shows the effect of sedation in children above and below 3 months. Stratified analysis of the subgroup of patients under 3 months of age showed the rate of unsuccessful LP without sedation was 61/146(42%) whilst with sedation the rate was 6/12(50%). Thus sedation did not significantly alter the likelihood of unsuccessful LP in the infants under 3 months, $p=0.56$, PR 1.2 (0.66-2.12) but the numbers with sedation in this age group were very small.

Age group	Sedation?	Number	Unsuccessful Lumbar Puncture	p value	Prevalence Ratio (95% Confidence Interval)
Under 3 months	No	146	61 (42%)	$p=0.56$	1.0 (ref)
	Yes	12	6 (50%)		1.20 (0.66-2.12)
Over 3 months	No	96	31 (32%)	$p=0.01$	1.0 (ref)
	Yes	95	15 (16%)		0.5 (0.28-0.85)

Table 5: Stratified analysis of effect of sedation according to age

Almost all patients who were sedated were given ketamine (93/107, 87%), either as a single agent or in combination with midazolam. **Table 6** shows the use of each agent as well as the rates of unsuccessful LP with each. There is an association between the proportion of unsuccessful LPs and the different agents used ($p < 0.05$ by Fisher's exact test). However, the small numbers of unsuccessful LPs in some groups precluded estimation of prevalence ratios.

Agent used	Number	Unsuccessful Lumbar Puncture
None	242	92 (38%)
Ketamine alone	86	13 (15%)
Midazolam alone	2	1 (50%)
Ketamine & Midazolam	7	1 (14%)
Chloral hydrate alone	12	4 (33%)
Chloral hydrate & Ketamine	6	2 (33%)

Table 6: Sedative agents used and rate of unsuccessful lumbar puncture (LP)

Basic monitoring was used in 171/350(49%) of cases. Children who were sedated were nearly all monitored, 101/107(94%). There were only six sedated children who were not monitored, of these 1 had received ketamine, the other 5 received chloral hydrate. Of those children who were not sedated only 69/242(29%) were monitored. This shows a significant association between sedation and monitoring $p < 0.001$ PR 17.72 (95%CI 7.98-39.35) .

The type of needle used and timing of removal of the stylet

A 22-gauge(G) Quincke spinal needle was used in 294/348(84%) of procedures either 38 or 75mm length (in 2 cases the needle type was unknown). The remainder (54) used standard hypodermic needles without stylets from 25G to 21G. The small numbers of unsuccessful LPs in some groups led to unstable estimates of prevalence ratios and hence were not shown in **Table 7**.

Needle used	Number	Unsuccessful Lumbar Puncture
Spinal 22G Quincke	295	97 (33%)
Hypodermic 25G	7	3 (43%)
Hypodermic 23G	37	9 (24%)
Hypodermic 22G	9	3 (33%)
Hypodermic 21G	1	0 (0%)

Table 7: Comparison of success with varying needle types

The rate of unsuccessful LP using the 22G spinal needle was 97/295(33%) whilst with other needles the rate was 15/54 (28%). The numbers not using a spinal needle were small and the difference in success rates between the two groups is not statistically significant, $p=0.47$, PR 1.18 (95%CI 0.75-1.88). When comparing each type of needle with the 22G spinal needle, the risk of unsuccessful LP was reduced when using a 23G needle (and 21G but this was only used once), the same when using a hypodermic 22G and increased when using a 25G but the prevalence ratios could not be calculated due to the small numbers.

Of those who used a needle with stylet, only 45/292(15%) removed the stylet early i.e., when through skin and subcutaneous tissue; the rest removed it once in the subarachnoid space. In 3 cases the timing of the removal of the stylet was unknown. When the stylet was removed early the rate of unsuccessful LP was 21/45(47%) whilst the rate with removal of the stylet in the subcutaneous space was 75/247(30%). The rate of unsuccessful LP appears to be higher with early removal of the stylet $p=0.02$, PR 1.54 (95%CI 1.07-2.22) but the number removing the stylet early was small. Early stylet removal was not used more by newer practitioners, the practitioners who had done <50 LPs used the technique 9% (4/45) of the time whilst the more experienced practitioners who had done >50 LPs used it 15% (38/247) of the time which is not a statistically significant difference ($p=0.25$).

Experience of the person holding the child during LP

The number of years of experience of the holder were not recorded as the person doing the procedure may not have known this information. Therefore the only categories staff

could be grouped in were whether they were students or not. The numbers of each type of person holding the child for the LP are shown in **Table 8**.

Person holding	Number	Unsuccessful Lumbar Puncture	Prevalence Ratio (95% Confidence Interval)
Junior staff (student nurse, medical student)	22	10 (45%)	1.0 (ref)
Senior staff (staff nurse, sister, doctor)	318	103 (32%)	0.7 (0.60-1.78)

Table 8: Experience of person holding the patient for LP

On analysis of the individual categories of staff, none were significantly associated with increased success. Combining the categories into junior and senior positions, the junior staff had a rate of unsuccessful LP of 10/22(45%) whilst the senior staff had a rate of 103/318(32%). This reduction in unsuccessful LPs with more senior holders was not statistically significant, $p=0.90$ PR 0.7 (95%CI 0.60-1.78). However, the numbers of junior staff were very small.

Movement of the patient during the procedure

In 102 (29%) cases, the patient was reported not to be moving at all. These patients had a rate of unsuccessful LP of 17/102(17%). Most (57%) children were said to be moving a little but it did not affect the procedure. These had a rate of unsuccessful LP of 62/198(31%). In only 50 (14%) procedures were the patients said to be moving a lot making the procedure difficult. The rate of unsuccessful LP in those was 34/50(68%). This is a statistically significant difference, with increasing amount of movement being related to an increased rate of unsuccessful LP ($p<0.001$).

Fifty six of the 242 (23%) children who were not sedated were said not to be moving at all. Of those who were sedated 46/107 (43%) were said to not be moving at all. There was a significant decrease in movement of the child with sedation, $p=0.001$ PR 0.65 (0.50-0.86). Of the children who were sedated, 12 were said to still be moving a lot making the procedure difficult. Of these 4 had received chloral hydrate and 8 had received ketamine.

Seniority and experience of the practitioner performing the LP

Most of the procedures were performed by senior staff, only 17(5%) were done by interns, the rest by medical officers, registrars or consultants. The rate of unsuccessful LP was similar across all levels of experience as shown in **Table 9**.

Staff level	Number	Unsuccessful Lumbar Puncture	Prevalence Ratio (95% Confidence Interval)
Intern	33	11 (33%)	1.0 (ref)
Medical Officer	235	78 (33%)	1.0 (0.59-1.67)
Registrar	65	18 (28%)	0.83 (0.45-1.55)
Senior registrar/ Consultant	17	6 (35%)	1.06 (0.47-2.37)

Table 9: Rates of unsuccessful lumbar puncture (LP) according to staff grade

Three hundred and one (86%) of the practitioners claimed to have done more than 50 LPs previously. Those who had done less than 50 LPs had a rate of unsuccessful LPs of 18/49(37%) whilst those with more experience had a rate of 95/301(32%). This difference was not statistically significant, $p=0.46$ PR 0.86 (95%CI 0.58-1.29).

Parental presence during the procedure

A family member was rarely present during the lumbar punctures in this study - in only 28 (8%) cases was a family member in the room. It was not clear from the study if this was because doctors/nurses had asked the family to leave or because the family did not wish to be present. The presence of a family member did not reduce the risk of unsuccessful LP. When no family member was present the rate of traumatic LP was 103/322(32%) whilst when a family member was present the rate was 10/28(35%) $p=0.68$ PR 1.12 (95%CI 0.66-1.88). This remained true when only the subgroup of children over 1 year old was analysed, $p=0.36$ PR 1.66(95%CI 0.56-4.93).

Other results

The number of attempts required for the procedure was recorded in 272 cases. Of these 272 cases, 168(61%) required only 1 attempt, 64 (38%) needed 2 attempts, 26(10%) 3 attempts and 14(5%) more than 3 attempts with the maximum recorded as 8. In this study

the final outcome of the procedure was used as an endpoint rather than the number of attempts. Of those procedures where only 1 attempt was made, 32/168(19%) were unsuccessful. When more than 1 attempt was made, the rate increased to 54/104(52%) showing that repeated passes of the needle results in an increased risk of unsuccessful LP, $p < 0.001$, PR 2.73(95%CI 1.90-3.92).

Two hundred and eleven (60%) of the procedures were done during daytime hours - 07.00-19.00. The rate of unsuccessful LPs during this time was 33% whilst during the hours 19.00-07.00 the rate was 31%. There was no significant difference between LPs done during the day and those done at night, $p = 0.764$ PR 0.95 (95%CI 0.70-1.31).

Almost all of the LPs were performed to diagnose or exclude meningitis, only 3 (0.85%) were for other reasons - to measure or reduce intracranial pressure. Very few of the CSF cultures were positive, one patient had a positive gram stain with a positive culture showing *Neisseria meningitidis*. 3 patients had positive gram stains with negative cultures and 3 had negative gram stains with positive cultures.

The study also documented the outcome for the child following the LP. Only 1 child was noted in the file to have experienced a post LP headache but it is thought that this does not accurately reflect the prevalence. Many children would be given analgesia for their presenting complaint of fever and headache so it was decided using analgesia use as a marker would not reflect post procedural headache.

One hundred and ten (31%) children were discharged following their LP and 1 patient died after 7 days in hospital. Forty five (13%) patients were transferred to district and secondary level hospitals so it is not known how long they remained in hospital. One hundred and seventeen (33%) children stayed in hospital but were treated for conditions other than meningitis. Of those treated for any form of meningitis (79 children, 23%) the median duration of treatment in hospital was 4 (IQR 2-5) days, range 1-21 days. 20 of these children were deemed to have viral meningitis and discharged after 2 days lowering the median stay from the recommended minimum of 5 needed to treat bacterial meningitis.

Unsuccessful LPs were associated with a slightly longer admission, median 5 days compared to 4 days in those who had a successful LP. This was not statistically significant

($p=0.14$). However, unsuccessful LPs were associated with an increased rate of admission. In those who had unsuccessful LPs 23/113 (20%) were discharged whereas of those who had a successful LP 87/237 (37%) were discharged. This is statistically significant, $p=0.002$.

Discussion

Lumbar punctures (LPs) are frequently performed in paediatric emergency departments to diagnose or exclude meningitis. This observational study provides information on the use of sedation and the prevalence of unsuccessful LPs in children in South Africa.

In this study 350 procedures were identified during a 3 month period which suggests that Red Cross War Memorial Children's Hospital emergency medicine unit would do approximately 1400 LPs per year. This does not include the oncology unit or other wards. The majority (99%) of these LPs were done to diagnose or exclude meningitis. Accuracy of diagnosis is crucial for the patient and for the doctor to determine the correct treatment. This diagnosis may be difficult if the LP is traumatic in that the CSF is blood stained, or if the procedure is unsuccessful. Various correction methods have been proposed to help interpret traumatic LPs but none of them can be certain to identify all cases of bacterial or tuberculous meningitis. If blood alone or no CSF is obtained then the LP cannot be used for diagnosis³.

The prevalence of traumatic LP

This study showed a prevalence of unsuccessful LPs of 32%. Previous studies showed rates of between 10 and 30%. Our prevalence is on the higher side of those estimates and may be in keeping with them. There was no clear reason as to why our rates should be higher than others but determining the risk factors for unsuccessful LP may help us modify our procedures in order to reduce this rate.

The risk factors identified in this study that increased the rate of unsuccessful LP, by univariate analysis were: age less than 12 months, not using sedation, increased movement of the patient and early removal of the stylet. The finding of age as a predictor of unsuccessful LP is consistent with previous studies^{3,11,12}. In the study by Baxter et al., an increased incidence under 3 months compared with those 3-12 months was also seen¹² but this was not observed in this study. A possible confounding factor here could be that small babies are perceived as being more difficult and therefore had their LPs done by more senior personnel. However, of the babies less than 3 months 13% had their LPs done by staff who had done less than 50 LPs whilst 15% of those over 3 months had theirs done by staff who had done less than 50 LPs. This is not a statistically significant

difference ($p=0.5$). Patient age is not a modifiable factor but physicians should be aware of the difficulty of performing LPs in infants and therefore should make sure all modifiable risk factors are minimised to increase the chances of successful LP. Very young infants may pose a dilemma in that procedural sedation protocols are not well defined and there may be wariness on the part of the physician regarding what is safe to use.

Use of local anaesthetic

Previous studies have shown the benefit to the patient of using local anaesthetic in reducing the pain associated with LP^{5,13}. They have also shown that local anaesthetic increases the success of LP^{3,12,15}. The results from this study were not able to substantiate this effect as the numbers using EMLA were small and the results not statistically significant. Pain reduction was not studied here but in order to reduce the trauma and pain felt by the child, it would seem reasonable to recommend that where possible EMLA be used for all LPs, including those on infants. The evidence of both the short and long term consequences of inflicting pain on children including neonates is increasing⁵ and we should be doing everything possible to minimise this.

Use of sedation

To our knowledge this was the first study to examine the use of sedation as a risk factor for unsuccessful LPs. The lower rate of traumatic LP observed by Howard et al., in their study where almost all the patients were sedated¹¹ would suggest that sedation would be beneficial in reducing traumatic LPs but this is the first study to compare sedated with non-sedated patients. The apparent 50% reduction in the incidence of unsuccessful LPs seen in the present study suggests that sedation be used wherever possible for LPs but needs further study. Sedation has previously been shown to be safe, and the trauma and pain felt by the child will be reduced. In this study the use of sedation did not significantly reduce unsuccessful LPs in those children under 3 months of age but it should still reduce the pain and trauma felt by that child. The numbers in this study that involved sedation for infants under 3 months were very small and further study is needed to determine the effect on the rate of unsuccessful LPs if appropriate sedation is used in this group. This study was also not able to assess the efficacy of the sedation, and one explanation may be that infants were not sedated adequately. Due to the benefits of reducing pain and trauma, we would recommend protocolled sedation for this group.

Sedation was not routinely used in this study and this may be due to a lack of protocol. For sedation to be used on a regular basis there needs to be a system in place to support this: the drugs must be available; doctors must be trained in the use of sedation and managing any potential adverse effects; and monitors and equipment must be available. In our hospital this is one of the problems cited with the use of sedation, and a decision must be taken to provide the appropriate set up if increased use of sedation is recommended in policy.

The type of needle used and timing of removal of the stylet

The benefits of using a needle with a stylet have been noted in many studies¹². The risk of epidermoid tumours following LP with non-stylet needles means that neurosurgeons recommend the use of the Quincke needle for all LPs. The added benefits of reducing spinal headache and obstruction of the needle add strength to this argument. In this study the use of a 23G hypodermic needle reduced the rate of unsuccessful LP when compared with a 22G needle but the other sizes of needle were associated with the same or increased risk of unsuccessful LP. For the reasons above a Quincke needle would still be recommended.

Previous studies have shown that using the Cincinnati method for LP i.e. removal of the stylet after passage through the epidermal and subcutaneous tissue (early removal) was associated with increased success rates^{3,12}. This association was not seen in this study and in order to draw valid conclusions the procedure would need to be observed by an independent observer in order to confirm timing of the stylet removal. The risk of unsuccessful LP seemed to be increased with early stylet removal but the number using this method was small. It was not used more by the newer practitioners although it is a more recent technique. Physicians should be aware of this technique and consider its use, especially in infants, but further studies are needed to determine whether this is beneficial and large studies are needed to ensure safety in that there is no association with epidermoid tumours.

Experience of the person holding the child during LP

Legend amongst physicians would suggest that having an experienced sister holding the child for a LP is the most crucial factor in the procedure^{10,12}. No previous studies have shown this effect and the present study showed no difference in success rates with staff of

increased experience holding the child. However, the years of experience of the holder were not measured here, simply whether staff were students or not due to the questionnaire being completed by the physician retrospectively. It is also possible that experience does not correlate with better positioning, recent training in the correct position may be more effective than experience of incorrect positioning.

Movement of the patient during the procedure

Reduction in movement of the patient was shown to be strongly associated with increased success rates for LPs. This is consistent with the findings of Nigrovic et al³. This study also showed a strong association between sedation and the amount of movement i.e. if a child was sedated he or she moved less and the LP was therefore likely to be easier and more successful. Movement would also be affected by the holder of the child but no association was seen between the holder and success rates.

Movement is a very difficult variable to quantify retrospectively and the options on the questionnaire may have led to reporter bias. The questionnaires were completed retrospectively and if the reporter knew that the LP was unsuccessful, they may have been more likely to report that the child was moving more i.e. "moving a lot". Whether these children were actually moving more than those who were moving "a little but didn't affect the procedure" would be extremely difficult to quantify and we were not able to analyse this in this study.

Some of the children who were not sedated were said not to be moving at all - this may be because of the compliance of the child, the ability of the person holding the child or the severity of the illness but the reasons were not recorded in this study.

Seniority and experience of the practitioner performing the LP

Two previous large studies showed that increased experience of the practitioner performing the LP in terms of the number of procedures performed rather than educational level increased the rate of successful LP^{3,11}. This study did not show that difference but the number of junior and inexperienced staff was very small so the study may not have had the power to show any difference. Red Cross War Memorial Children's Hospital is a teaching hospital and junior staff need to be trained and gain experience so it is not practical to limit the performance of LPs to experienced staff.

Parental presence during the procedure

In the USA and other developed countries it is thought that most parents would prefer to stay with their children during medical procedures. No studies were found from Africa to know if this preference is true for those from different cultures. In one study 67.5% of physicians from the USA believed that parents should be present for LPs¹⁸. Again no study was found from Africa to show what physicians with different cultural and training backgrounds believe. This study did not include a study of parent or physician preference but it did show that parents are not often present for LPs, only 8% of the time was the parent in the room. It is not clear from this study if this was the parent's, nurse's or physician's choice.

One previous study showed no difference in success rates for LPs with a family member present¹⁹. This study again showed no statistical difference in the success rate with a family member present showing that their presence neither increases nor decreases the chances of success. Therefore no recommendation can be made regarding whether family members remain with the child and it is left to the discretion of the family and physician in each case to decide whether a family member should be with the child during LP.

Limitations of this study

This study had many limitations. Firstly it was powered to assess the association of sedation use as a binary variable on unsuccessful LPs. It did not assess the efficacy of the sedating agents and therefore could only describe the association between any sedation use and the rate of unsuccessful LP. For many of the risk factors studied many of the responders used the same technique and therefore the comparison group was very small. This may have resulted in differences in success rates being missed. This study was an audit of current practice and was not able to influence the practices used. There was therefore no randomisation of patients to different procedures and no controls were used which reduces the strength of the observation.

The questionnaires were filled in by the doctors retrospectively, often after the results of the LP were known. This may have resulted in reporting bias. The study did not use observers to determine if the methods used were, depending on the result, reported differently by the person performing the procedure.

There were also some problems noted with the questionnaire. Many physicians failed to complete the question regarding the number of attempts and the layout of the questionnaire was thought to be a possible explanation for this. The form also allowed one person, one needle and one method to be reported for each procedure - sometimes if the first attempt was unsuccessful, a more experienced person may have been asked to do the procedure, the needle or other procedural factors changed. This was difficult to determine from the forms used.

This study was also limited to a study of the procedural methods. There was no measurement of the patient's pain to give an idea of the adequacy of the analgesia or sedation used and no assessment of family satisfaction with the procedure, which may have changed with different methods. Specifically for EMLA this study was not able to assess the amount used, if it was correctly administered, the method of application or the duration from application to LP which may have influenced its effectiveness. It was also difficult to determine the prevalence of post procedural headache and it was felt that this may be under reported in the patients notes.

Further studies

This initial study has provided useful information that suggests that sedation use may be associated with a reduction in unsuccessful LPs but further study is needed. It is proposed that large randomised controlled trials are needed to explore whether sedation truly does influence the outcome of LPs. These studies should include a larger study population, examine the different agents that could be used for sedation and the adequacy of that sedation with different doses. Cooperation with the anaesthetic department to look at varying levels of sedation and the risk-benefit ratios for each agent may enable a more detailed protocol for procedural sedation to be written. The study should also include independent observers to report: the methods of analgesia/sedation used, how it is administered, the timing and effectiveness of that sedation, the movement of the patient, physiological changes during the procedure and the procedural techniques used. Independent observers may also reduce reporting bias. The other variables examined in this study would need to be controlled for and each examined separately. The impact of unsuccessful LP on length of hospital stay also requires further study to determine if unsuccessful LPs are associated with increased length of stay, what costs are involved and the risk of adverse events such as nosocomial infections.

Conclusion

There is a high prevalence of traumatic LPs at this institution. This study suggests that sedation may reduce the risk of unsuccessful LPs but is not routinely used. Further efficacy studies are needed to determine the ideal medication, exact doses required and also to assess the effectiveness of sedation in reducing the pain and trauma felt by the child. This applies particularly to infants in whom sedation is often difficult. Implementation of a procedural sedation protocol would require a change in organisation of the department with the drugs, monitoring, staff and appropriate environment readily available. Whether a protocol would then change practice, whether this would increase success rates and whether this would reduce unnecessary treatment will require further audit. Larger studies are needed to determine the influence of this and other risk factors to determine if any other procedural factors can be identified to reduce the rate of unsuccessful LP.

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APPENDIX 1:

Data Collection Sheet

Lumbar Puncture Audit Feb 2013

For any queries - Dr. Claire Procter 0720717864

Date: _____

Time: _____

Weight: _____ kg

1. Are you a:

Senior Registrar

Medical Officer/COSMO/SHO

Registrar

Intern

2. How Many LPs have you done?

0-5

11-50

6-10

51+

3. Indication for LP

Exclude meningitis

Reduce Intracranial pressure

Measure opening pressure

Monitor response to treatment

Other (specify) _____

4. Needle Used

Black Spinal (22G)

Other spinal (specify) _____

Other needle (specify) _____

5. Family member present?

Yes

No

6. Person holding child

Student nurse

Staff Nurse

Sister

Medical Student

Doctor

Other _____

7. Sedation and Analgesia Used - please tick and state dose

None

EMLA

Lignocaine _____ml

Ketamine IV _____mg

Ketamine IM _____mg

Midazolam _____mg

Chloral hydrate _____mg

Morphine _____mg

Other (specify drug, dose and route) _____

8. Vital sign monitoring during the procedure? (saturation and HR)

Yes

No

9. Was the patient moving?

Not at all

A little but didn't affect the procedure

A lot - difficult procedure

10. When did you remove stylet?

When through skin/sub-cut tissue

Subarachnoid space

11. Number of attempts required (i.e.. number of times needle penetrated skin) _____

12. LP Result

Dry tap

Bloody Tap - frank blood

Blood-stained CSF

CSF obtained and sent to lab

FOR COMPLETION BY RESEARCHER

LP Result

Appearance_____

Polys _____ Lymphs_____ Erythrocytes_____

Glucose_____ Protein_____

Gram Stain_____ Culture_____

Post tap Headache

Yes

No

Treatment _____

Outcome

Discharged

Treated for meningitis - Length stay ____days

Transfer to _____

Died

Other complication_____

APPENDIX 2:

Ethics Approval Letter and Renewal



28 March 2013

HREC REF: 173/2013

Dr C Proctor
c/o Dr M Hendricks
Paediatrics
Red Cross War Memorial Children's Hospital
Rondebosch

Dear Dr Proctor

PROJECT TITLE: LUMBAR PUNCTURES IN PAEDIATRIC EMERGENCY MEDICINE DEPARTMENT AT RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL: AN EVALUATION

Thank you for addressing the issues raised by Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above mentioned study.

Approval is granted for one year till the 15 April 2014.

Please submit a progress form, using the standardised Annual Report Form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

sAriefdien



FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
<input checked="" type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	30/04/2015
<input type="checkbox"/> Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	18/2/14

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	06/08/2014					
HREC REF Number	173/2013	Current Ethics Approval was granted until	15/04/2014			
Protocol title	Lumbar punctures in Paediatric Emergency Department at Red Cross War Memorial Children's Hospital: An evaluation					
Protocol number (if applicable)						
Are there any sub-studies linked to this study?	<input type="checkbox"/> Yes x No					
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.	<table border="1" style="width: 100%;"> <tr> <td style="text-align: center;">RESEARCH ETHICS COMMITTEE</td> </tr> <tr> <td style="text-align: center;">2014 -08- 06</td> </tr> <tr> <td style="text-align: center;">HEALTH SCIENCES FACULTY UNIVERSITY OF CAPE TOWN</td> </tr> </table>			RESEARCH ETHICS COMMITTEE	2014 -08- 06	HEALTH SCIENCES FACULTY UNIVERSITY OF CAPE TOWN
RESEARCH ETHICS COMMITTEE						
2014 -08- 06						
HEALTH SCIENCES FACULTY UNIVERSITY OF CAPE TOWN						
Principal Investigator	Claire Procter					
Department / Office Internal Mail Address	Paediatrics Department, Red Cross Children's Hospital					

1.1 Does this protocol receive US Federal funding?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
1.3 Has sponsorship of this study changed? If yes, please attach a revised summary of the budget.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No