

Perception and management of induced pain through vaccination injection in infants aged 0-11 months in Parakou immunization sites in 2019

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Abstract

Background: One of the iatrogenous induced pain in infant's remains that one of vaccination trough injection. Authors through this work are assessing the perception and management of pain experienced by infants during vaccine injection reported by their mothers in infants in Parakou's immunization's sites in 2019.

Methods: Authors used a descriptive cross-sectional and analytical method after a non random sampling exhaustive recruitment of mothers and infants couples attending the 8 vaccination sites in Parakou town during the period of July to October 2019. Assessment was done through Evendol and NFCS pain assessment scales.

Results: The average age of the 375 mothers included in our study was 27 years \pm 6.44 years. The mean age of infants was 3.26 months \pm 3.06 months with a sex ratio of 0.9. Of the infants vaccinated by injection, 41.60% reached a level of treatable pain and 96.42% a level of intense pain respectively through Evendol and NFCS scales. Pharmacological methods were the main methods used by mothers before and after vaccination to relieve pain in infants. Infant's age, type of vaccine, vaccine route of administration, were the main factors influencing the expression of pain in the infant vaccinated by injection.

Conclusion: Iatrogenic pain such as that linked to infant vaccination through injection must be prevented and well managed by age-appropriate pharmacological and non-pharmacological methods.

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Introduction

Pain is an inherent part of life. It accompanies man from birth to the end of his life [1]. In children, it is nociceptive, neuropathic, idiopathic or psychogenic [2]. It affects all organs. Several situations generate pain in everyday life, such as birth trauma, discomfort and health problems, dental problems and medical care (curative and preventive). Among

the latter, vaccination administered by injection occupies a good place [1]. For about three decades, one of the indisputable advances in protecting life and reducing the burden of disease has been immunization. It remains one of the safest, cheapest and most effective ways to protect children and adults against many serious diseases. However, little consideration is given to the pain generated during the act of administering vaccines when they

are in injectable form, apart from general recommendations.

The management of pain in the health care system and in the hospital system, especially in children, has become unavoidable nowadays. Both parents and caregivers are affected by the pain experienced by the child during different types of care or medical procedures and make it their concern in various ways. Much work has been done on the management of pain experienced by children by these different actors [1,3]. Accompanying the child in this context of pain becomes the focus of concern. Some advocate non-pharmacological methods such as distraction, sugar solutions or breastfeeding, while others opt for pharmacological solutions. In developing countries, with the introduction of primary health care, immunization has become a reality offered to populations. But little consideration is given to the management of pain caused by injections during vaccination in these countries. Through this work, we wanted to evaluate the perception and management of pain in infants aged 0-11 months vaccinated with antigens injected by their mothers at the vaccination sites in Parakou (Benin) in 2019.

Materials and Methods

Study setting

The study took place in the town of Parakou (Northern Benin), more precisely in the vaccination sites of Parakou. It has a total of 23 health facilities including eight vaccination sites.

Study methods

This was a descriptive cross-sectional study with an analytical aim that took place from July to October 2019 on the vaccination sites in the city of Parakou. The target population consisted of all mother-infant couples in these vaccination sites. We included infants and their mothers coming for vaccination at one of the vaccination sites in the city of Parakou during our survey period. Any mother-infant couple included but who refused was excluded. Recruitment of mother-infant couples was carried out by successive inclusion in the order of arrival for vaccination. The minimum sample size was calculated using the Schwartz formula.

A structured face-to-face interview with the mother was used to collect data, completed by pain assessment using the visual hetero assessment

scales adapted to our study, such as the Evendol scale [4,5] before and after injection and the NFCS scale [4,5] during injection. This assessment was performed by a trained investigator.

The variable of interest was the result of the evaluation of pain before and after the vaccination procedure and then during injection vaccination of the infant obtained by hetero-evaluation with the Evendol and NFCS scales respectively. For the Evendol scale, the modalities were the level of treatable pain achieved (LTPR) and not reached (LTPNR). For the NFCS scale, three modalities were selected: low pain level (LPL: score between 0 and 1), medium pain level (MPL: score between 2 and 3) and severe pain level (SPL: score ≥ 4). As explanatory variables we studied the socio-demographic characteristics of mothers and infants (age and sex of the infants, age, religion, cultural beliefs of the mothers), psychological characteristics (maturity, previous painful experiences), vaccination history and current vaccinations, therapeutic characteristics (type and means of pain treatment).

This assessment was not focused on vaccine injection technique. However, taking into account the fact that nurses working on each of the 8 vaccinations facilities will have to work with their own injection method a former training and on site training have been conducted. Every six month i.e., twice a year, a monitoring process is conducted toward these caregivers.

Vaccine injection techniques

Three vaccine injection techniques are usually performed during vaccination in our settings: intradermic for BCG antigens at birth, sub cutaneous or intra muscular injection technique for pentavalent combined antigens (diphtheric, tetanus toxoid, pertussis, hepatitis B and haemophilus influenzae type b conjugate vaccine) at 6, 10 and 14th weeks of age after birth plus 13 valent pneumococcal conjugate vaccine also at 6th, 10th and 14th weeks of age. The same is done for injectable polio vaccine (IPV) at 14 weeks after birth according to Enlarged Programme of Immunization (EPI), vaccination scheme. Measle vaccine is mainly given through subcutaneous injection route at nine months of age together with anti amaril vaccine according to the same scheme.

During intradermic injection, the dose of BCG vaccine, only 0.05 ml is administered. To measure and inject such a small dose accurately, a special BCG syringe (0.1 ml), and a special BCG needle (10 mm, 26 gauge) are used. The syringe is loaded with BCG vaccine without shaking the vaccine ampoule. The Caregiver (Nurse) holds the child's arm with his left hand so that his left hand is under the arm; his thumb and fingers reach around the arm and stretch the skin tight. With his right hand he holds the syringe, with the bevel of the needle facing up towards him. He laid the syringe and needle almost flat along the child's arm. He inserts the tip of the needle just under the skin and only the bevel and a little bit more. He keeps the needle flat along the arm, so that it goes into the top layer of skin only. He should keep the bevel facing up. He does not push too far and does not point down or the needle will go under the skin. To hold the needle in position, he puts his left thumb on the lower end of the syringe near the needle, but does not touch the needle. The plunger end of the syringe is to be held between the index and middle fingers of his right hand. The plunger should then be pressed in with his right thumb. And after injecting the vaccine he should remove the needle without massaging the injection site [3].

For intramuscular vaccination, the syringe and needle must be held perpendicular to the surface of the injection site and be pushed deeply into the muscle.

In case of subcutaneous vaccine injection, the caregiver or nurse needs a sterile 0.5 ml syringe and a sterile 25 mm, 23 gauge single-use needle. He holds the child's arm from underneath. His fingers reach around and pinch up the skin, pushes the needle into the pinched-up skin. The needle should go in at a sloping angle about 45°, not straight down. He does not push the needle too far in. To control the needle, he is supposed to support the end of the syringe with his thumb and finger while he pushes the needle in. He does not touch the needle itself. He presses the plunger with his thumb to inject the vaccine and finally withdraw the needle and press the site with cotton wool [3].

The child should sit on the parent's lap. The parent's right arm should be around the child, supporting her or his head and holding the right arm. The child's left arm should be tucked around the parent's body.

The parent's left hand should hold the child's legs firmly.

Data processing and analysis

Data analysis was done using the EPI INFO 7.1.5 software. Quantitative variables were presented as means with their standard deviation and qualitative variables as percentages with 95% confidence intervals. For an association of two qualitative variables, the Pearson Chi-square test or Fisher's exact test, as the case may be, with its confidence interval and p-value was used. For the crossing of quantitative variables, the Student's T test was used. The significance threshold chosen for all the statistical analyses was the $p < 5\%$ value with a 95% confidence interval.

Ethical and deontological considerations

The survey was conducted after agreement with the Borgou Departmental Health Authorities (DDS-Borgou) and the Coordinating Doctor of the Parakou-N'dali Health Zone. Participation in the study was conditional on free and informed verbal consent from the parents of the infants concerned. There was no monetary compensation for participation in the study.

Study limitations and constraints

The main limitation in this study was the difficulty of assessing the vaccine injection technique due to the multiplicity of actors and vaccination sites. However we used the possibility to assess the vaccine injection route and its influence on pain intensity or level in infants. Most of the mothers' responses were obtained by word of mouth and no possibility was offered to verify their say. This could lead to information bias although the interviewers used conversed in their local languages directly.

On the other hand, authors did not assess nurses' practice on vaccine injection which represents one of the main limitations of this study.

Results

Socio-demographic characteristics of the surveyed infants and their mothers

A total of 375 mother-infant pairs were recorded. Among infants, there was a predominance of females (53.6%) with a sex ratio of 0.9. The mean age among infants was 3.26 months \pm 3.06 months

(3.37 months±2.99 months for boys and 3.15 months ±3.09 months for girls). The most common age range was 0 to 2 months (47.7%).

The mean age of mothers of infants of surveyed children was 27 years ± 6.44 years with extremes of 16 and 50 years. The mode of this series was 20 years. Of the 375 mothers included, 362 were in a couple or married, 3 were divorced and 10 were separated from their spouses. The mothers of the

infants in our sample had an average of 2.56 ±1.52 children with extremes of one and 10 children at most.

The mothers' highest level of education was secondary school and university level with the respective proportions of 38.93% and 7.2% and uneducated mothers accounted for 25.60% of cases (Table 1).

Table 1: Distribution of infants and mothers according to their socio-demographic characteristics vaccination sites of Parakou in 2019 (n=375).

| Variables | Number (N=375) | Percentage (%) |
|--------------------------------|----------------|----------------|
| Infants sex | | |
| Male | 174 | 46.4 |
| Female | 201 | 53.6 |
| Infants age (in months) | | |
| [0 – 2] | 179 | 47.7 |
| [3 – 6] | 119 | 31.7 |
| [6 – 8] | 22 | 5.8 |
| [8 – 12] | 55 | 14.8 |
| Mothers' age (in years) | | |
| [16 – 25] | 182 | 48.5 |
| [25 – 35] | 155 | 41.3 |
| [35 – 45] | 35 | 9.4 |
| 45 and more | 3 | 0.8 |
| Matrimonial status | | |
| Married/Living in couple | 362 | 96.53 |
| Divorced | 3 | 0.8 |
| Separated | 10 | 2.67 |
| Sibling size | | |
| 1 – 3 | 285 | 76 |
| 4 – 6 | 84 | 22.4 |
| 7 – 9 | 5 | 1.33 |
| 10 and more | 1 | 0.27 |

| Instruction level | | |
|--------------------------|-----|-------|
| Any | 96 | 25.6 |
| Alphabetised | 15 | 4 |
| Primary | 91 | 24.27 |
| Secondary school | 146 | 3.93 |
| University | 27 | 7.2 |
| Religion | | |
| Christianism | 174 | 46.4 |
| Islamism | 195 | 52 |
| Endogenous | 6 | 1.6 |

Distribution of infants vaccinated according to the type of antigens received

Of the 375 infants brought in by their mothers, 363 had actually been vaccinated during the vaccination sessions. The majority of children vaccinated during this study had received the antigen for BCG (23.73%); Pentavalent antigen 1 and pneumococcal antigen 1 abbreviated as Penta-1+PCV13-1 (DTP Hepatitis B, Haemophilus type b and 13-valent conjugated anti-pneumococcal antigen first dose) was given in 17.87% of the cases, and pentavalent antigen 2 abbreviated as Penta-2+PCV13-2 (DTP Hepatitis B, Haemophilus type b and anti-pneumococcal 13-valence conjugate second dose), the pentavalent 3+PCV13-3 antigen (DTP Hepatitis B, Haemophilus type b and anti-pneumococcal 13-valence conjugate third dose) were achieved in 19.73% and 17.87% of infants, respectively. Vaccination against measles and yellow fever was carried out in 12.27% of infants. The remaining 12 of the 375 infants had received no antigen but rather a dose of vitamin A.

Pain assessment by mothers and maternal pain management

Awareness/perception of pain by surveyed mothers: Of the 375 mothers surveyed, 367 (97.87%) were aware of infant pain during vaccination and 14.40% (54) of these mothers were reluctant to bring their children for vaccination because of the pain associated with it. Sixty-four point eighty-five percent (64.85%) of mothers

thought that the pain was moderate, only one tenth (10.62%) thought that the pain was mild.

Signs associated with pain felt/expressed by infants reported by mothers: Signs of pain expression in infants reported by mothers were mostly crying / screaming / moaning, difficulty comforting the infant and insomnia with the respective proportions of 89.33, 30.13% and 26.65% (Table 2).

Table 2: Distribution of mothers according to whether or not their infants are experiencing pain during vaccination at vaccination sites in Parakou in 2019 (n=375).

| Variables | Number (N=375) | Percentage (%) |
|---|-----------------------|-----------------------|
| Pain awareness reported by mothers | 367 | 97.87 |
| Perception of pain intensity level according to infants' mothers | | |
| Low | 38 | 10.44 |
| Middle | 237 | 65.11 |
| Severe | 89 | 24.45 |
| Painful manifestations of infants reported by mothers | | |
| Crying/screaming/ moaning | 335 | 89.33 |
| Agitation | 68 | 18.13 |
| Difficulty consoling | 113 | 30.13 |

| | | |
|---|-----|-------|
| Insomnia | 100 | 26.67 |
| Anorexia | 32 | 8.53 |
| Fever | 64 | 17.07 |
| Unusual Attitudes | 70 | 18.67 |
| Methods used to alleviate pain before, during or after vaccination (n=363) | | |
| Breastfeeding | 28 | 16.37 |
| Sugared solution | 13 | 7.6 |
| Cream application | 12 | 7.02 |
| Distraction | 3 | 1.75 |
| Honey | 0 | 0 |
| Syrup | 53 | 30.99 |
| Pharmacological methods | 63 | 36.84 |
| Other methods | 5 | 2.92 |

Methods used by mothers to alleviate the pain experienced by infants before immunisation

Fewer than half of the mothers surveyed (45.60%) reported having a method of their own to alleviate the pain their infants feel before/during immunization. Among these methods, the administration of pharmacological methods comes first, followed by the administration of various

syrups in second position in the proportions of 35.59% and 29.94% respectively (Table 2).

Of the 375 mothers surveyed, 36.8% (i.e., 138 mothers) had been advised on analgesic methods by health workers and the most recommended methods were the administration of paracetamol and ibuprofen and 33% confirmed the effectiveness of these methods (i.e., 124). The remaining mothers were unaware of these methods (Table 2).

Methods used by mothers after returning home to accompany the infant in pain

Of the 363 mothers surveyed who had their infants vaccinated, 350 (96.42%) answered the question on pain management after returning home for infants vaccinated by injection. Among these 350, 63 (18%) did nothing to accompany the infant in pain after vaccination; 228 (54.28%) administered pharmacological methods; 23 (6.57%) applied shea butter to the pricked area; 19 (5.43%) said they did nothing but followed the prescriptions proposed after the injection (vaccination).

Assessment of pain in infants vaccinated with the Evendol scale and the NFCS scale

Of the 363 who were vaccinated by injection, the treatment threshold according to the Evendol scale was reached (total score ≥ 4) before vaccination in a single infant (i.e., 0.28%). After vaccination this number increased from 1 to 151 infants (i.e., 41.60%) $p=0.00001$ (Table 3).

Table 3: Distribution of infants according to the level of treatable pain reached (LTPA) before (Score 1) and after vaccination (Score 2) by the Evendol Scale.

| Variables | Number of assessed infants N=363 | | OR | p-value |
|-----------|----------------------------------|-------------|---------------------|---------|
| | Score 1 (%) | Score 2 (%) | | |
| LTPR | 001 (0.7) | 151 (99.3) | 257.8 [35.8-1855.8] | 0 |
| LTPNR | 362 (63.1) | 212 (36.9) | 1 | |

Corrected Chi² = 187.22

LTPR: Level of Treatable Pain Reached

LTPNR: Treatable Pain Level Not Reached

According to the level of pain experienced by infants during vaccination as assessed by the NFCS Scale, 350 (96.42%) infants had reached a severe

level of pain during vaccination, (score ≥ 4), 11 (3.03%) infants had reached a moderate level of pain (score from 2 to 3) and 2 (0.55%) had reached

a low level of pain (score from 0 to 1). Among the vaccinated children, 3.58% had low and moderate pain during the injection of the vaccine.

Factors influencing the expression of pain by infants after vaccination as assessed by the Evendol scale

Using the evendol scale, socio-demographic variables such as vaccination site (CS), age of the infant were statistically associated with p-values (p=0.001 and p=0.0036, respectively) with the level of pain in the infant. On the other hand, other variables such as ethnicity (p=0.7400), religion (p=0.5900), sex (p=0.2800) were not associated with pain in infants vaccinated by injection.

The study shows that, the number of times the child has already been brought for vaccination (p=0.014), the type of vaccine administered (p=0.0000), the route of vaccine administration (p=0.0000), the number of injections per vaccination session (p=0.0000), child maturity (p=0.0000), and child status before vaccination (pre-vaccination score) (p=0.0000) were statistically associated with the level of pain in infants vaccinated with injectable antigen. This information is shown in Table 4 below.

Table 4: Factors associated with the pain expression in infants surveyed at vaccination sites in Parakou in 2019 according to the Evendol scale.

| Variables | N=363 | LTPR | | OR | IC 95% OR | p-value |
|--|-------|-------|-------|------|--------------|---------|
| | | n=151 | % | | | |
| Health Centre (Vaccination sites) | | | | | | |
| Banikanni | 52 | 24 | 46.5 | 0.71 | [0.28-1.80] | 0.001 |
| Chud | 36 | 11 | 30.56 | 1.38 | [0.49-3.89] | |
| Cs com | 41 | 7 | 17.07 | 2.96 | [0.98-8.97] | |
| Gannou | 48 | 23 | 47.92 | 0.66 | [0.25-1.70] | |
| Kpebie | 64 | 30 | 46.88 | 0.69 | [0.28-1.69] | |
| Madina | 57 | 34 | 59.65 | 0.41 | [0.16-1.03] | |
| Tourou | 29 | 11 | 37.93 | 1 | - | |
| Zongo | 36 | 11 | 30.56 | 1.38 | [0.48-3.97] | |
| Infant age (in months) | | | | | | |
| [0-2] | 179 | 58 | 32.4 | 1.25 | [0.43-3.61] | 0.0036 |
|]2-6] | 115 | 60 | 52.17 | 0.55 | [0.18-1.61] | |
|]6-8] | 16 | 6 | 37.5 | 1 | - | |
|]8-12[| 50 | 27 | 50.94 | 0.51 | [0.16-1.62] | |
| Religion | | | | | | |
| Christianism | 169 | 73 | 43.2 | 5.26 | [0.57-48.06] | 0.59 |
| Islamism | 189 | 74 | 39.15 | 6.21 | [0.68-56.70] | |

| | | | | | | |
|---|--------------|--------------|----------|-----------|------------------|----------------|
| Endogenous | 5 | 4 | 80 | 1 | - | |
| Sex | | | | | | |
| Male | 171 | 68 | 39.77 | 1 | - | 0.28 |
| Female | 192 | 83 | 43.23 | 0.86 | [0.57-1.31] | |
| Number of vaccination session attended | | | | | | |
| 1-2 | 157 | 52 | 33.12 | 2.09 | [1.12-3.87] | |
| 3-4 | 149 | 70 | 46.9 | 1.16 | [0.63-2.15] | 0.014 |
| 5-6 | 57 | 29 | 50.88 | 1 | - | |
| Type of vaccin administered | | | | | | |
| BCG | 89 | 13 | 14.61 | 6.37 | [2.79-14.55] | 0 |
| | N=363 | LTPR | | OR | IC 95% OR | p-value |
| | | n=151 | % | | | |
| Penta 1 | 67 | 38 | 56.72 | 0.83 | [0.39-1.76] | |
| Penta 2 | 74 | 35 | 47.3 | 1.21 | [0.58-2.53] | |
| Penta 3+ VPI | 87 | 41 | 47.12 | 1.22 | [0.59-2.50] | |
| VAA+VAR | 46 | 24 | 52.17 | 1 | - | |
| Method of pain reduction administered before vaccination | | | | | | |
| Yes | 200 | 86 | 43 | 1.34 | [0.89-2.01] | |
| No | 163 | 65 | 39.88 | 1 | - | 0.311 |
| Vaccination administration route | | | | | | |
| Intradermic | 89 | 13 | 8.61 | 1 | - | 0 |
| Intra muscular | 274 | 138 | 91.39 | 0.16 | [0.08-0.31] | |
| Age maturity (infants vs neonate) | | | | | | |
| < 1 month | 89 | 13 | 14.6 | 1 | - | |
| ≥1 month | 274 | 138 | 50.4 | 15.9 | [3.14-11.2] | 0 |
| Number of injection in a vaccination session | | | | | | |
| 1 | 89 | 13 | 14,61 | | | 0 |
| 2 | 187 | 97 | 51,87 | 0,15 | [0,08-0,30] | |
| 3 | 87 | 41 | 47,13 | 0,19 | [0,09-0,39] | |

Factors influencing the expression of pain by the infant after vaccination as assessed by the NFCS scale

Using the NFCS scale, the vaccination site variable (CS) was the only socio-demographic variable significantly associated (p=0.0000) with the level of pain in infants while other variables such as age (p=0.0868), sex (p=0.3617) did not influence the occurrence of pain in infants vaccinated by injection.

The type of vaccine administered (p=0.0000), the route of vaccine administration (p=0.0000), the number of injections per vaccination session (0.0008) and the maturity of the child (0.0008) were significantly associated with the level of pain in infants vaccinated with injectable antigen. This information is shown in Table 5.

Duration of pain relief and method used

Maternal use of a method to reduce pain prior to vaccination was not associated with whether or not the infant's pain persisted after vaccination, whereas use of a method after vaccination was significantly associated with whether or not the infant's pain persisted after vaccination (Table 6).

Vaccine injection technique

We did not study vaccine injection technique influence on pain intensity or pain expression in infants. Different caregivers (nurses) are used for vaccination session at different vaccination locations and even on one and same location nurses may vary from time to time due to the shift between nurses though there is work distribution among caregivers.

Table 5: Factors associated with the pain expression in infants surveyed at vaccination sites in Parakou in 2019 according to NFCS scale.

| Variables | SLP* | LMLP** | OR | IC | p-value |
|------------------------|--------------|------------|------|--------------|---------|
| CS | | | | | |
| Banikanni | 52 (100%) | 0 | | | |
| Chud | 35 (97.22%) | 1 (2.78%) | 1 | - | |
| Cs Com | 41 (100%) | 0 | | | |
| Gannou | 46 (97.87%) | 1 (2.13%) | 0.76 | [0.04-12.59] | 0 |
| Kpebie | 63 (98.44%) | 1 (1.56%) | 0.55 | [0.03-9.15] | |
| Madina | 57 (100%) | 0 | | | |
| Tourou | 29 (100%) | 0 | | | |
| Zongo | 27 (77.14%) | 8 (22.86%) | 10.3 | [1.22-88.02] | |
| Age (in months) | | | | | |
| [0-2] | 170 (95.51%) | 8 (4.49%) | 1 | - | 0.0868 |
|]2-6] | 114 (100%) | 0 | | | |
|]6-8] | 16 (100%) | 0 | | | |
|]8-12[| 50 (94.34%) | 3 (5.66%) | 1.27 | [0.32-4.98] | |
| Sex | | | | | |
| Female | 186 (97.89%) | 4 (2.11%) | | | 0.3617 |

| | | | | | |
|--|--------------|-----------|------|--------------|--------|
| Male | 164 (95.91%) | 7 (4.09%) | 1.98 | [0.57-6.90] | |
| Number of vaccination session attended | | | | | |
| 1-2 | 148 (94.87%) | 8 (5.13%) | 7.94 | [0.98-64.33] | 0.0764 |
| 3-4 | 147 (99.32%) | 1 (0.68%) | 1 | - | |
| 5-6 | 55 (96.49%) | 2 (3.51%) | 6.68 | [0.59-75.44] | |
| Type of vaccin administered | | | | | |
| BCG | 80 (90.91%) | 8 (9.09%) | 8.5 | [1.03-69.49] | 0 |
| Penta 1 | 67 (100%) | 0 | | | |
| Penta 2 | 74 (100%) | 0 | | | |
| Penta 3+VPI | 85 (98.84%) | 1 (1.16%) | 1 | - | |
| VAA+ VAR | 44 (95.65%) | 2 (4.35%) | 3.86 | [0.34-43.76] | |
| Method of pain reduction administered before vaccination | | | | | |
| Yes | 156 (96.30%) | 6 (3.70%) | 1 | - | 0.5113 |
| No | 194 (97.49%) | 5 (2.51%) | 0.67 | [0.20-2.23] | |
| Vaccine administration route | | | | | |
| Intradermic | 80 (90.91%) | 8 (9.09%) | 1 | - | 0 |
| Intramuscular | 270 (98.90%) | 3 (1.10%) | 0.11 | [0.02-0.42] | |
| Number of injection in a vaccination session | | | | | |
| 1 | 80 (90.91%) | 8 (9.09%) | 1 | | 0.0008 |
| 2 | 185 (98.93%) | 2 (1.07%) | 0.1 | [0.02-0.52] | |
| 3 | 85 (98.84%) | 1 (1.16%) | 0.11 | [0.01-0.96] | |
| Age maturity (infants vs neonate) | | | | | |
| < 1 mois | 80 (90.91%) | 8 (9.09%) | 1 | | 0.0008 |
| ≥ 1 mois | 270 (98.90%) | 3 (1.10%) | 0.11 | [0.02-0.42] | |
| *SLP: Severe Level of Pain, **LMLP: Low and Middle Level of Pain | | | | | |

Discussion

The discussion of the results of the study revolves around the following three points:

- The achievement of the study objectives.
- The quality and validity of the results.

- Comparison of the results with those of other authors.

Achievement of study objectives

At the end of this survey, the objectives set were achieved. Indeed, in the course of this work, we came up with the following results:

Of the 375 mothers surveyed, 367 (97.87%) were aware of the pain in infants during vaccination and 14.40% (54) of them were reluctant to bring their children to vaccination because of the pain associated with it; 64.85% of the mothers thought that this pain was of medium intensity, and 10.62% thought that this pain was of low intensity.

The signs of pain expression in infants reported by the mothers were mostly crying / screaming / moaning and difficulty consoling the infant, with the respective proportions of 89.33%, 30.13%.

Among the 363 who were vaccinated by injection, the treatment threshold according to the evendol scale was reached (treatable pain level reached (LTPR): total score ≥ 4) before vaccination in only one infant (i.e., 0.28%). After vaccination this number increased from 1 to 151 infants (i.e., 41.60%) $p=0.0000$. Among the vaccinated children, 96.42% reached a maximum level of pain during the injection of the vaccine according to the NFCS scale.

During this work, the methods most recommended to mothers/caregivers by health personnel were the administration of pharmacological method through paracetamol and others (77.52%).

The factors influencing the expression of pain in vaccinated infants were the age of the infant ($p=0.0036$), the frequency of administration to the CS ($p=0.0140$), type of vaccine ($p=0.0000$), route of administration of the vaccine ($p=0.0000$), condition of the child ($p=0.0000$), number of injection per session ($p=0.0000$).

Quality and validity of results

Collection tool

For the collection tool, we used an interview guide. This seems more appropriate to us because the statistical units surveyed would not be able to complete the questionnaires by themselves. The interviewers trained for the interview were trained to provide the clarifications necessary for reliable data collection.

Two age-appropriate pain observation and evaluation grids were used to assess the pain felt by infants before, during and after vaccination among vaccinated infants because the latter were unable to communicate.

Bias

The main expected information bias is that related to the observation of the infant and the interpretation of the infant's attitudes for the assessment of pain in infants. To limit this bias, we trained and minimized the number of assessors for our study.

In order to minimise the bias created by the difficulty in interpreting the questions, interviewers were chosen taking into account the mastery of local languages, the training of the interviewers and after a pre-test of the questionnaire.

Comparison and explanation of results with those of other authors

In this work, the sample was more represented by mothers aged 16-25 years (48.53%); this finding corroborates that reported by Kennedy et al. on attitudes, concerns and sources of information about vaccines reported by parents of young children. They reported that mothers aged 25-34 years accounted for 44.9% of the sample [6,7]. This difference could be explained by the diversity of statistical units in each sample but also by cultural differences in the respective settings. Indeed, the 25-34 age groups represents the age group of mature mothers. In the population of our study, the most represented mothers were younger.

Mothers with a high school education were representative in 38.93% of the cases in our study and mothers without education followed with a rate of 25.60%. This result is different from that reported by Kennedy et al. in their work. They reported that mothers with higher education represented 36.1% of the sample [6,7]. This difference could be explained by the framework of the two studies and the educational level of the mothers in both contexts, which would be higher in the United States than in Benin.

Data on the religion of mothers of vaccinated children are rarely described in the scientific literature. Nevertheless, in one of the works reported by the African authors, a frequency of 67.84% of Muslim mothers was found, which would testify to the proportion of Muslims in the general population [7,8].

Intensity of pain felt by infants aged 0-11 months vaccinated by injection at the different vaccination sites in Parakou in 2019

In this study, more than two-fifths (41.60%) of infants aged 0-11 months vaccinated by injection reached a treatable level of pain according to the Evendol scale. According to the NFCS scale, on the other hand, the level of severe pain was found in 96.42% of cases. This could be explained by the fact that the items observed in the two scales are different and complementary, but above all because they are observed and evaluated at different times during the vaccination procedure (before and after the procedure for the first and during the vaccination procedure for the second).

Methods used and/or recommended by Parakou health workers to accompany the vaccinated child.

During our study, the methods most recommended to mothers/carers of children by the health professionals were the administration of pharmacological methods like paracetamol and ibuprofen for children aged more than 6 months of age (77.52%). The main reasons for these health professionals' prescriptions were to reduce pain and prevent the onset of fever (92.31%) in vaccinated

infants. The effect of ibuprofen has been reported by Fournière in pain related to child care [5].

Methods used by mothers to alleviate pain during and after vaccination of their infants

In our study, most mothers of infants administered paracetamol in all its forms, in 116 cases (33.14%) to reduce pain. However, it is known that the pharmacological methods used are those intended to reduce pain according to collective knowledge. Other mothers in our work stated that they use little known methods, although in a marginal proportion.

In African countries and in Benin, the use of creams (EMLA), analgesic patches and MOEPA are not common even in the medical field, contrary to what Fournière, Carbajal and Taddio and many other authors report [9,10].

Also in the literature, it is said that the use of pharmacological methods was not advised before vaccination because it has no effect on pain during injection. Our results have also shown this (Table 6). However, Pascal's work has shown the opposite [3].

Table 6: Relation between the duration of pain persistence related to vaccination and method used by mothers before and after vaccination.

| Variables | J1-J3 | J4-J8 | OR | IC | p-value |
|----------------------------------|-------------|-----------|------|-------------|---------|
| Method before vaccination | | | | | |
| Yes | 146 (90.12) | 16 (9.88) | 1 | | |
| No | 161 (92.53) | 13 (7.47) | 0.73 | [0.34-1.58] | 0.4448 |
| Method after vaccination | | | | | |
| Any | 57 (95%) | 3 (5%) | 0.6 | [0.17-2.13] | 0.03 |
| PM* | 220 (92.05) | 19 (7.95) | 1 | | |
| NPM** | 29 (80.56) | 7 (19.44) | 2.79 | [1.08-7.32] | |

*PM: Pharmacological Methods **NPM: Non Pharmacological Methods

In the absence of pharmacological methods, non-pharmacological methods such as the reassuring presence of the mother, the use of sugar solutions associated with non-nutritive sucking [10,11], cuddling and distraction etc... contribute to making the pain experienced by the infant during vaccination bearable, according to the work reported by Pascal [3]. However, the use of non-

pharmacological methods seems to increase the duration of pain persistence after vaccination compared to pharmacological methods by 2.79 times according to the results of our work. Based on our results, no conclusions can be drawn if any method is not used.

Factors influencing good pain management in vaccinated infants

In our study the age of the infant was significantly associated with the infant's pain management ($p=0.0036$). The type of vaccine administered ($p=0.0000$) was significantly associated with the level of pain in the infant vaccinated with injectable antigen in our study.

Studies conducted in the United States of America and Canada, cited in the WHO Weekly Epidemiological Bulletin, indicate that 24% to 40% of parents are concerned about the pain associated with child immunizations; 85% believe that it is the responsibility of providers to take care to make immunizations less painful, and 95% of them want to learn how to reduce the pain their children experience during immunization [11-13]. A recent study in South Africa found that giving several vaccinations at the same visit was acceptable to parents and caregivers, but encouraged strategies to reduce pain during the immunization visit, as pain is one of the major concerns for caregivers of children who receive several injections in one session [11,12].

Even when administered with the correct technique and a needle of the appropriate length and calibre, injectable vaccines cause pain at the time of vaccination, the degree of which varies according to the composition of the vaccine. When several vaccines are co-administered, the order of injection affects the level of discomfort caused by vaccination, with the first administration of the most painful and the last of the least painful increasing the cumulative pain felt [11-13].

The administration of vaccines containing several antigens should follow the WHO recommendations from least painful to most painful, for example starting with oral vaccines (oral polio) and continuing at the same time as breastfeeding with injectable vaccines [11,12]. Health workers in this context should respect the rules of neutrality, remain cooperative and ensure the presence and cooperation of mothers (breastfeeding during vaccination, holding the child by the mother during the vaccination procedure, distracting the infant when possible etc.) [11,12]. This means distracting the child, encouraging parents to do so, or encouraging the child to distract himself alone for children over 3 years of age [3].

Thus, when the Rotavirus vaccine is available in the vaccination programme, it is recommended to start with this vaccine, which contains sucrose as an

excipient that would reduce pain, when it is followed by other injectable vaccines [11,12].

In this work, the route of vaccine administration was related ($p=0.0000$) to the level of pain in infants vaccinated with injectable antigen. This result differs from that of Pascal et al. on "Vaccination-related pain in children aged 0-6 years". In his study, the route of vaccine administration was not statistically related (0.0724) [3]. This difference may be reflected in the age ranges considered in the two studies.

The difference in pain level appeared to be significant between the intradermal (BCG) route and the intramuscular or subcutaneous route ($p=0.0000$). This is similar to the results reported by Pascal, where it is reported that it is the subcutaneous route that is less algogenic [3], whereas in his work, Taddio, found no significant difference between the route of administration and the level of pain relief or exaggeration when injecting vaccines [9,10]. However, improvement in vaccine administration and injection techniques could significantly contribute to reducing the pain caused by the administration of vaccines by major reduction in contact time with nociceptors of different types (Meissner corpuscle, Ruffini corpuscle, Pacini corpuscle and rich nervous endings) depending on the vaccination technique in the intra dermal, subcutaneous and intramuscular injection [14]. One should then make balance between the necessity of pain reduction during vaccination and efficacy of vaccine especially through some route for it is known that vaccine administered through sub cutaneous route have low tissue diffusion rate and lead to less immunogenic reaction [15]. It is also known from a pathophysiological point of view, that the route of injection is determined by the type of vaccine: live attenuated or inactivated, depending on the immune response it is intended to stimulate. Thus, for inactivated vaccines, the intramuscular (IM) route appears to be the recommended one because of the local effect of antigen management. The immune response is induced by the locoregional inflammatory response induced itself by the administration of the vaccine [3].

Maturity of the child

Child maturity ($p=0.0008$) was significantly associated with the level of pain in infants

vaccinated with injectable antigen. This result differs from that of Pascal et al. ($p=0.128$) [3].

As for young age, in this work it was found that infants over one month of age had a treatable pain threshold 15 times higher than that of newborns ($p=0.00000$) using the evendol scale whereas with the NFCS scale the trend seems to be statistically reversed ($p=0.00008$). All in all, according to the experts, the perception of pain in the smallest infants (newborns and infants) involves the notion of implicit unconscious memory linked to the memory of past painful events such as previous vaccination sessions [4,11-14,16,17] by these infants compared to newborns who are at their first dose. This appears to be confirmed by the association between the level of pain and the number of vaccination sessions or doses already received by the infant ($p=0.014$). Pascal et al. reported in their work that iatrogenic pain that is poorly relieved induces an increase in the pain experienced during subsequent gestures, as well as a fear of care [3]. It has also been reported that the intensity of pain experienced during these vaccination procedures is often lessened by health personnel compared to that experienced by parents and children themselves [16,17]. This aspect of the issue has not been studied in our work.

Conclusion

Vaccination by injection is also a source of iatrogenic pain that has long been hidden and is becoming a concern for both health workers and parents of vaccinated infants. This recognition could allow adequate management and thus improve adherence to vaccination and maintain a good level of vaccination coverage in African countries, but also trigger the implementation of a real strategy to reduce this pain in vaccinated infants. This passes through improvement of vaccine injection technique, choice of vaccine injection routes in balance with efficacy of vaccine antigens administered and combination of various distraction techniques of the infants to be protected.

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