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International consensus is needed on premedication for non-emergency neonatal intubation after survey found wide-ranging policies and practices in 70 countries

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Running Title: Survey on premedication for neonatal intubation.

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ABSTRACT

Aim

This study evaluated whether practitioners from 70 countries used premedication for non-emergency neonatal intubation and identified attitudes and experience regarding the safety, side effects and efficiency of neonatal intubation.

Methods

Invitations to take part in the survey were issued between 18 December 2018 and 4 February 2019 to users of neonatal-based websites and Facebook groups, members of professional societies and the authors of relevant publications in the last five years.

Results

We analysed 718 completed questionnaires from 40 European and 30 non-European countries. Most of the responses were from neonatologists (69.6%) and paediatric or neonatal trainees (10.3%). In units without a protocol (31.6%), more than half of the practitioners (60.4%) chose premedication according to personal preference and 37.0% - 11.9% of the overall respondents - did not use any drugs for non-emergency intubation. The most frequently reported drug combination was fentanyl, atropine and succinylcholine (6.8%). Most of the practitioners (78.5%) use the same drugs for term and preterm infants. Only 24.8% of the physicians were fully satisfied with their premedication practices.

Conclusion

Nearly 12% of the respondents did not use premedication for non-emergency neonatal intubation. The wide-ranging policies and practices found among the respondents highlight the need for international consensus guidelines.

KEY NOTES

- This 2018-2019 study explored the views of 718 practitioners from 70 countries on premedication for non-emergency neonatal intubation and most of the responses were from neonatologists (69.6%) and paediatric or neonatal trainees (10.3%).
- Nearly 12% of the respondents did not use premedication for non-emergency neonatal intubation.
- The wide-ranging policies and practices found among the respondents from 40 European and 30 non-European countries highlight the need for international consensus guidelines.

INTRODUCTION

Up until the mid 1980s, neonates and infants underwent surgical and other invasive procedures like lumbar punctures or endotracheal intubation without any medication for pain and anxiety (1). This was based on the false assumption that infants and young children do not experience painful stimuli (2).

Today, infants and neonates routinely receive premedication and analgesia during surgery. However, protocols for premedication of other painful procedures, including neonatal intubation, still vary substantially between units (3).

Endotracheal intubation is a life-saving procedure, but it risks significant potential adverse effects. The goal of premedication is to eliminate pain and discomfort and decrease the risk of bradycardia, hypotension and hypertension, increased intracranial pressure and decreased saturation, all of which have been associated with neonatal intubation (4).

Data regarding pain and anxiety management practice for neonatal intubation have been limited to single country analyses. Studies published by Simon et al and Carbajal et al in 2004 and 2018 reported that only a minority of infants received premedication before endotracheal intubation and other painful procedures (5,6). A prospective study of 13 tertiary care units in Paris, France published in 2013 showed that using premedication before intubation was either inconsistent or it did not follow current recommendations (7). Similar results were reported in a Saudi Arabian study published in 2012 (8).

In contrast, a telephone-based survey performed in 2009 and repeated in 2015 reflected increased awareness among neonatal providers. The majority (90%) of the units in the United Kingdom routinely administered premedication and this meant that 93% of infants received it before elective intubation(3,9). A 2012 study from Australia and New Zealand also reported that 93% of patients received premedication for intubation in neonatal intensive care units (NICUs) (10).

Email and online survey-based questionnaires completed by neonatal practitioners in the United States in 2006 and 2016 showed that most respondents believed that premedication should be used, but only approximately 35% reported using it regularly (11,12). Furthermore, an international registry study published in 2019 by Foglia et al confirmed the relatively high rate

(36%) of infants who did not receive premedication during non-emergency intubations performed in the United States (13).

Using premedication prevents side effects and increases intubation success rates, meaning less time and fewer attempts are required. It is recommended by the American Academy of Paediatrics for all non-emergency neonatal endotracheal intubations (4,13-15).

However, there is still little consensus in Europe as to which medication or combination of drugs should be endorsed, despite the fact that data are available. The European Consensus Guidelines on Respiratory Distress Syndrome do not recommend a specific protocol (16).

We decided to carry out the first survey to identify variations in premedication protocols for intubation in tertiary neonatal units in different countries. It is our hope that the results of this questionnaire will be used to prepare educational programmes that aim to increase the awareness of procedural pain in NICUs and of potential complications in neonates who do not receive medication before neonatal intubation.

METHODS

This cross-sectional study was performed between 18 December 2018 and 4 February 2019. It focused on physicians - both specialists and trainees - and neonatal nurse practitioners, working in NICUs with experience of performing neonatal intubation. We had initially intended to concentrate on Europe, but the international responses we received meant that we expanded the focus of the study. During January 2019 we posted details of the survey on 99nicu.org, a website that is dedicated to neonatal staff around the world, and on Facebook groups for neonatology professionals, including one called NICU Professionals and another called All Neonatology and Paediatrics. Email invitations were also sent to all the European neonatology professionals whose e-mail addresses were accessible to the researchers. The mailing list included those who had participated in the European survey on less invasive surfactant administration (17) and members of European Society of Paediatric and Neonatal Intensive Care. The researchers also searched PubMed and contacted the corresponding authors of neonatal themed articles published in the last five years. LinkedIn users were also contacted if they said that they practised one of the following professions:
neonatologist, paediatric intensivist, paediatric trainee, advanced nurse practitioner.

The invitations included a link to an Internet-based open survey and a short description (Appendix S1). Only neonatal professionals from Europe were expressively invited to participate

in the survey, but country of origin was not an exclusion criterion. Only professionals who had performed at least five non-emergency endotracheal intubations in the last five years were able to complete the questionnaire. Entering the survey provided informed consent and no incentives were offered to take part in the study.

To ensure that the content and language of the survey were valid, the questionnaire was developed by two investigators with expertise in neonatal intubation (JM, JSS). The content was based on a MEDLINE search for relevant articles published in English between 1960-2018 and verified by the statistical team. The online survey was developed using LimeSurvey version 2.72.3 (LimeSurvey GmbH Survey Services & Consulting, Hamburg, Germany). We pilot tested the online survey for clarity, readability and functionality on four neonatal professionals with different levels of experience and from different workplaces. Their feedback was incorporated into the final version of the questionnaire.

The term non-emergency endotracheal intubation covered all elective and semi-elective endotracheal intubation procedures performed outside the delivery room.

The survey contained 205 questions on five screens and these covered: the respondent's status, premedication protocol, premedication practice, complications that had been experienced and the availability of documentation, such as national or local protocols (Appendix S2). The number of questions completed by each respondent ranged from 38 and 62, depending on the number of relevant items. These included the existence of any protocols, the number of drugs used and whether premedication was similar for term and preterm babies. The key items, such as the existence of any protocol, were mandatory and they could not progress to the next screen without answering them. No other consistency or completeness checks were performed. We aimed to collect as many responses about the fundamental questions as possible, without risking respondent drop out. Respondents were allowed to review and change any of their answers at any time before submitting the survey. The questions were presented in a fixed order and the respondents were asked to be careful that they did not submit the same survey response more than once. Cookies were not used, so that multiple respondents could complete the questionnaire using same device, such as a hospital computer. We did not limit the responses to just one per unit, because premedication practices may have varied from person to person if there was not a unit protocol.

The answers and the metadata – the date of completion and the Internet protocol address - were automatically saved in a PostgreSQL database, version 9.6 (PostgreSQL Global

Development Group, California USA). The data were stored on a secured server that was accessible through a password protected web-based platform. The survey was anonymous: no personal data were collected and no connections between particular invitations and responses were made.

A convenience sample of answers was collected, and these represented a large group of neonatal providers with different levels of experience in intubation and varied approaches to the use of premedication.

Response rates

The questionnaire was not restricted to a specific, limited group of people. Because it was addressed to a broad range of NICU and neonatal unit professionals, only limited web survey metrics could be assessed, with selected measures tailored to the questionnaire. The response rate was defined as the ratio of partially completed questionnaires to the total number of people who accessed the questionnaire. The completion rate was defined as the ratio of fully completed questionnaires to the number of partially completed questionnaires. For technical reasons, it was not possible to assess the response rate based onsite visitors, such as the view rate and the participation rate. For example, some respondents may have come back and completed it when they had more time.

Analysis

The questionnaire was initially designed for European professionals. However, it was posted on international websites, which were visited by professionals outside Europe. The high number of non-European responders enabled us to perform additional calculations. The analysis was carried on all the data that were provided, from both complete and incomplete surveys. It was also stratified by European and non-European countries.

The research protocol was approved by the Bioethics Committee of the Medical University of Warsaw.

RESULTS

The website was visited 1257 times and 718 questionnaires were submitted by 633 respondents from 40 European countries and 85 from 30 non-European countries. The responses came from 454 medical centres and the number of respondents from the same medical units varied from one to 11, with a mean of 1.58 and a median of one. We found that 457/718 (63.6%) questionnaires were fully completed (Table 1). The distribution of the responses from European and non-

European countries was similar. The majority of the responses (48.1%) were received from neonatologists working in level three units in Europe and more than half of the neonatal intubations were performed by neonatologists (Table 1).

The ratio of European practitioners following a written protocol is illustrated in Figure 1. Worldwide, 31.6% of the practitioners from 145 of the 454 medical centres claimed that they worked in a unit without a written protocol for neonatal intubation. Of those, 37.0% of the respondents reported that they did not use any premedication for non-emergency intubation. This equated to 11.9% of all the 718 respondents. Of the practitioners that used premedication, 60.4% chose the drugs according to personal preference. Single drug use was higher in the no protocol group (42/227, 18.5%) than protocol group (3/388, 0.8%).

Most practitioners (78.5%) reported using the same drugs for term and preterm infants (Table 2). The most frequently prescribed combination for premedication was fentanyl, atropine and succinylcholine, at 6.8% (data not presented).

The highest level of drug use uniformity was observed in Sweden and the UK. In the Swedish centres, 23/27 (85.1%) of the neonatal providers reported using the same combination of (remi) fentanyl, thiopental, atropine, succinylcholine and morphine. In the UK, 69/79 (87.3%) reported using the same combination of fentanyl, atropine and succinylcholine.

Routine sedatives were reported by 43.3% of the respondents, with 21.6% saying they only used them in special cases. A further 15.3% said they did not use any sedatives. The most frequently reported reason for not prescribing sedatives was avoiding adverse events (42.6%).

The frequency of muscle relaxants and vagolytics use was higher when respondents who followed protocols in their unit were compared with those who did not: 40.5% versus 7.0% and 38.7% versus 4.0%, respectively (Table 3).

A number of concerns were reported about the use of muscle relaxants and these included loss of spontaneous respiratory drive or masking pain or seizures (15.0%). The main reasons for not using them was that it was unnecessary (17.7%).

Respondents were asked about their satisfaction with the premedication they were using at the time of the survey. Nearly a quarter (24.8%) were completely content and didn't feel they needed

to change. However, there was a higher level of satisfaction in the protocol group than those who did not follow a protocol (32.5% versus 11.9%).

Only 19.3% of the respondents kept records of personal intubations and only 11.4% said that their unit kept a register for intubations and any adverse events.

DISCUSSION

This was the first survey to report the use of premedication for neonatal intubation by combining data from different countries. We conducted an Internet-based survey across 40 European and 30 non-European countries. Data were collected on practitioners, premedication for intubation protocols, attitudes and practitioners' experiences regarding safety, side effects and efficiency. Just over half the respondents from 70 countries reported following a protocol for premedication for neonatal intubation. The largest number of responses came from neonatologists followed by paediatric or neonatal trainees. More than a third of the respondents who did not follow a protocol did not provide any type of premedication for neonatal intubation and this equated to just under 12% of the total responses. The most frequently reported combination of drugs was fentanyl, atropine and succinylcholine. The main reason for not providing pain and anxiety relief for endotracheal intubation were concerns about potential drug side effects.

When we developed the survey, we followed the Checklist for Reporting Results of Internet E-Surveys statement (18). However, we do acknowledge that using convenience samples in Internet-based open surveys can lead to considerable bias due to the self-selection of participants, also known as the volunteer effect. In addition, the probability of selection bias was unknown (19). As mentioned by Eysenbach (18), the risk of common workstations shared by personnel within one unit remained a challenge in the data analyses. Furthermore, we invited individual participants to respond to the survey, which might have led to an unequal representation of units. We must also accept that, given the retrospective character of our study, all the data on the frequency of observed side effects were limited by human memory.

Considering the above, we need to be careful when interpreting our results. Survey data and actual practice are usually not the same. However, the low rate of premedication use reported in our survey was consistent with a prospective register study published by Foglia et al (13).

Repeated painful stimuli may lead to poor neurodevelopment outcomes (1). Despite this common knowledge, more than one-third of the respondents in the no protocol group still failed to provide adequate comfort for infants undergoing endotracheal intubation. Some of the reasons reported by our participants were concerns about adverse reaction, toxic drug effects, inadequate time to administer medication and the perception that the risks outweighed the benefits of premedication for intubation. However, a trial that evaluated the use of fentanyl, which was the most frequently used analgesic in our study, plus atropine and a paralytic agent showed no significant adverse effects in neonates (20). One of the primary concerns related to using fentanyl, which is chest wall rigidity, can be reduced by slow administration and reversed by naloxone (21).

Nearly 100% of the units in Australia, US and UK provide written protocols for neonatal intubation(10,15, 22). Our study showed that a significant number of respondents practicing in Eastern Europe did not follow written guidelines for intubation premedication. This was most probably a result of false assumptions and low awareness of the possible consequences of repeated painful stimuli, leading to a lack of local unit policies or practitioners being unaware of a written protocol.

Our study included questions about the use of sedatives, analgesics and muscle relaxants. Fentanyl was the most popular analgesic agent, as it was in most other reported studies (6). However, another study published in 2012 stated that morphine remained the most popular analgesic in Australia and New Zealand (10) . Fentanyl has a number of desirable characteristics when it is used as a premedication analgesic, including a more rapid onset and shorter duration of action than morphine. That is probably the reason for its popularity among physicians (20, 23).

In the UK and Australia, the most predominant muscle relaxant has been reported to be suxamethonium (3,10). In contrast, a French survey revealed that most practitioners preferred benzodiazepine, with or without opioid sedation or muscle relaxants (5). A cohort study of NICUs that participated in the National Emergency Airway Registry for Neonates, revealed that the use of neuromuscular blockades was associated with favourable intubation outcomes (13). However, potential disadvantages were cited as reasons for not including muscle relaxants in premedication protocols, such as cessation of breathing and de-recruitment of alveolar space during the procedure.

Propofol was used by 16.2% and 10.9% of the respondents in our study for term and preterm infants respectively. Practitioners also reported using propofol during intubate, surfactant, extubate or less invasive surfactant administration procedures. One of the reasons given for using propofol as a single agent was that it rarely causes apnoea at low doses, which enables physicians to avoid prolonged periods of ventilation. A randomised controlled trial showed that propofol at the currently recommended dose was effective in only 50% of neonates and that many infants did not actually recover quickly and needed prolonged periods of ventilation (24). On the contrary, a study published in 2018 showed quick recovery in the propofol group, but the risk of hypotension was higher among these infants, even though they did spontaneously recover (25).

Our survey showed that, despite national and unit-based recommendations for non-emergency intubation, a significant percentage of practitioners still avoided premedication. Educational initiatives and on-going educational programmes may improve compliance with guidelines, as shown in published studies (26,27) .

CONCLUSION

Education about the potential harms and complications of intubation without analgesia and sedation should be enforced worldwide, as false assumptions and myths still prevail. Our survey of healthcare professionals in 70 European and non-European countries found wide-ranging policies and practices. This highlights the need for international consensus that is based on expertise and clinical trials.

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List of abbreviations

NICU, Neonatal intensive care unit

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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PubMed Central PMCID: PMC5051203 conflicts of interest to disclose.

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Table 1. Characteristics of the 718 respondents

	All countries n=718 (%)	European countries n=633 (%)	non-European countries n=85 (%)
Position			
Neonatologist	500 (69.6)	447 (70.6)	53 (62.4)
Paediatric/neonatal trainee	76 (10.6)	66 (10.4)	10 (11.8)
Paediatric intensivist	49 (6.8)	45 (7.1)	4 (4.7)
Paediatrician	44 (6.1)	33 (5.2)	11 (12.9)
Advanced neonatal nurse practitioner	18 (2.5)	17 (2.7)	1 (1.2)
Anaesthetist	16 (2.2)	16 (2.5)	0 (0.0)
Nurse	7 (0.9)	5 (0.8)	2 (2.4)
Other *	6 (0.8)	2 (0.3)	4 (4.7)
Missing data	2 (0.3)	2 (0.3)	0 (0.0)
Level of care			
NICU Level 3	551 (76.7)	488 (77.1)	63 (74.1)
NICU Level 2	98 (13.6)	83 (13.1)	15 (17.6)
PICU	39 (5.4)	83 (13.1)	1 (1.2)
Maternity/Special care	11 (1.5)	8 (1.3)	3 (3.5)
General paediatrics	9 (1.3)	6 (0.9)	3 (3.5)
Transport	6 (0.8)	6 (0.9)	0 (0.0)
Paediatric emergency unit	3 (0.4)	3 (0.5)	0 (0.0)
Missing data	1 (0.1)	1 (0.2)	1 (0.0)

*Other: Respiratory therapist, physician assistant, midwife

PICU, Paediatric intensive care unit.

Table 2. Frequency of reported drug use depending by gestational age

Drug group	Term n= 321 (%)	Preterm infants n=284 (%)
Analgesic		
Fentanyl	175 (54.5)	151 (53.2)
Ketamine	35 (10.9)	28 (9.9)
Morphine	34 (10.6)	33 (11.6)
Hypnotic/Sedative		
Midazolam	91 (28.3)	55 (19.4)
Propofol	52 (16.2)	31 (10.9)
Thiopental	27 (8.4)	19 (6.7)
Muscle relaxant		
Succinylcholine	72 (22.4)	60 (21.1)
Rocuronium	36 (11.2)	23 (8.1)
Vagolytic		
Atropine	121 (37.7)	101 (35.6)

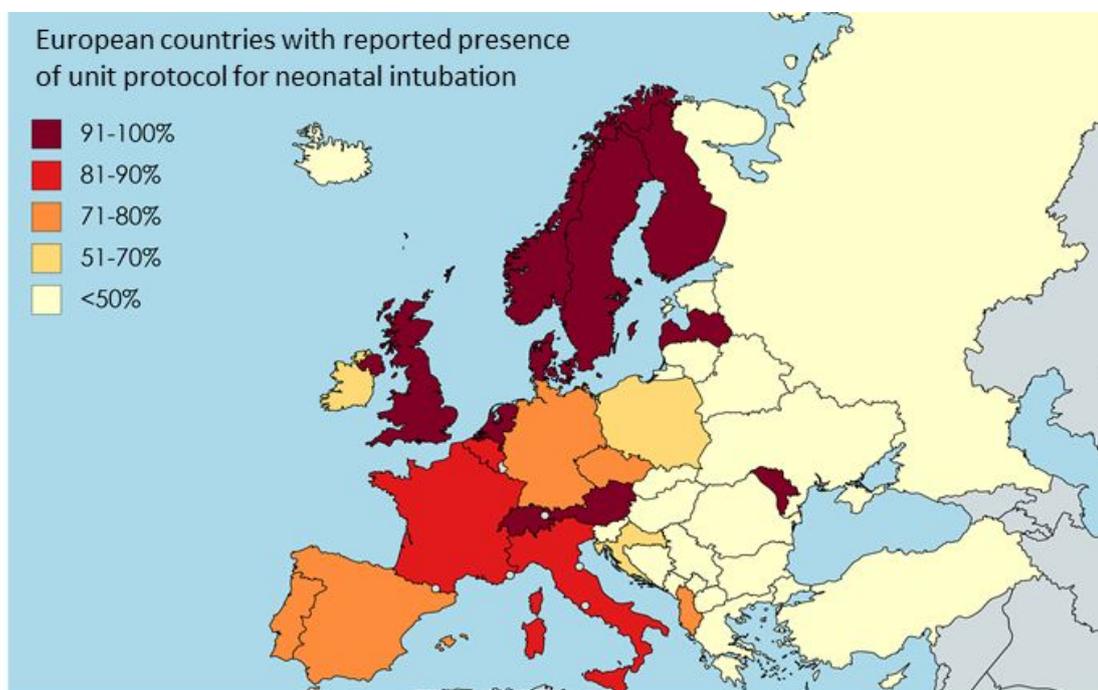
Preterm infants were born at less than 37 weeks of gestation.

Table 3. Use of muscle relaxants and vagolytics

	All respondents n=615 (%)	Unit protocol n=388 (%)	No unit protocol n=227 (%)
Use of muscle relaxants			
No	205 (33.3)	85 (21.9)	120 (52.9)
Yes, only in special cases	118 (19.2)	92 (23.7)	26 (11.5)
Yes, routinely	173 (28.1)	157 (40.5)	16 (7.0)
Missing data	119 (19.3)	54 (13.9)	65 (28.6)
Use of vagolytics			
No	244 (39.7)	112 (28.9)	132 (58.1)
Yes, only in special cases	82 (13.3)	66 (17.0)	16 (7.0)

Yes, routinely	159 (25.9)	150 (38.7)	9 (4.0)
Missing data	130 (21.1)	60 (15.5)	70 (30.8)

Figure 1. Proportion of respondents with unit protocol in Europe.



Country	Respondents	Units	%	Country	Respondents	Units	%	Country	Respondents	Units	%
Albania	6	4	75	Germany	29	25	80	Macedonia	3	2	50
Austria	17	12	100	Greece	18	5	40	Moldova	2	1	100
Belarus	5	1	0	Hungary	33	18	39	Romania	15	9	11
Belgium	11	8	88	Iceland	1	1	0	Russia	2	2	50
Bosnia and Herzegovina	6	4	50	Ireland	9	6	67	Serbia	17	7	43
Bulgaria	5	5	0	Italy	22	21	81	Slovakia	7	4	50
Croatia	8	5	60	Kosovo	3	1	0	Slovenia	1	1	0
Cyprus	1	1	0	Latvia	5	1	100	Spain	19	13	77
Czech Republic	5	5	80	Lithuania	14	5	20	Sweden	35	13	100
Denmark	8	4	100	Montenegro	1	1	0	Switzerland	6	5	100
Estonia	5	4	25	Netherlands	27	12	92	Turkey	28	20	45
Finland	7	6	100	Norway	12	6	100	UK	100	58	97
France	21	16	88	Poland	100	50	56	Ukraine	11	9	22
				Portugal	8	4	75				