THE ADOPTION OF AUTOMATED FiO_2 CONTROL INTO POLISH NICUS: 2012–2019

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Abstract

The introduction and adoption of new technology in medicine is a continuous ever present process but it is often not studied. Insights gained from documenting such experiences can not only guide local practices but also provide valuable quality benchmarks. Automated control of FiO_2 based on continuous SpO_2 (A-FiO_2) not only reduces the challenging task of manual oxygen titration, but also has the potential to greatly improve the morbidity and mortality of extremely preterm infants. First approved for use in Europe in 2012, it is now available on most infant ventilators outside the USA. Poland was the first region in Europe to implement its clinical use. We report experience from 619 infants from 12 centers recorded in a web-based registry established in 2013 to document its use. We found the A-FiO_2 was primarily used in the first week of life in intubated infants. However it is also successfully applied in both noninvasively supported infants and in those who were difficult to wean from oxygen and who exhibited frequent desaturations. We also found the SpO_2 target range and alarm setting are not different from normal manual titration, although wider settings are also used and promise some benefit. Finally we report our plan to gather data from a national data base and detailed surveys. The surveys will document subjective aspects of this experience from a core group of centers. Details of the surveys are included and cover: experience with training and acceptance, changes in practice associated with the years of experience and barriers to broader use.

Keywords

automated oxygen control, assimilation of technology, neonatal ICU, research plan

Background

In a broad sense assimilation of technology includes many aspects. Adoption characterization includes purchase rate, increasing use rate, as well as initial and subsequent refinements of use. The uptake rate of new technologies can vary dramatically from less than a year to decades. Adoption of new medical technologies is generally slower than consumer products, often a decade or longer, but occasionally very quick. The actual adoption of new medical technologies into neonatal care has not often been studied.

A Vermont-Oxford collaborative report showed the general changes of use of various modalities in very low birth weight infants across a decade [1]. It reported, for instance, a steady increase in the use of high frequency ventilation in the 90's from one of every fourteen infants to one in four. Two neonatal technologies have been carefully studied. The clinical adoption of the use of exogenous surfactant was much anticipated and quickly put into widespread clinical use and its clinical impact documented [2]. Once the effectiveness of antenatal steroids was proven there was significant pressure to monitor its implementation in high risk obstetrics, still the transition took much longer [1]. In addition, we previously reported on the rapid adoption of a new approach to respiratory support in Poland. This included both the clinical impact [3] as well as use patterns [4] associated with the assimilation of modern non-invasive continuous positive airway pressure (CPAP) devices in Poland. Further factors beyond evi-

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dence-based proof of effectiveness that preferentially favor the use of different respiratory support modalities, have also been described by one of our research team [5].

Automated closed loop control of inspired oxygen based on SpO_2 monitoring (A-FiO_2) is a relatively new technology and is currently offered by nearly all infant ventilator manufacturers. The first units were approved for distribution in Europe in 2012, but are not yet available in the United States. Because of the timing of a widespread program to replace older mechanical ventilators in Poland's NICUs, our adoption was on the forefront of introducing A-FiO_2 globally. These activities involved both research and clinical use. Two centers participated in an international trial to evaluate A-FiO_2 effectiveness [6]. In addition 4 other papers from Polish centers have been published [7–10]. One described the initial use of A-FiO_2 at 5 centers, and others were clinical testing. In addition to providing funding for many of these A-FiO_2 systems, the Great Orchestra of Christmas Charity also funded a web-based registry, similar to that used during the introduction of nCPAP, to monitor the details of the actual clinical use of A-FiO_2 in a selected group of centers [7].

Methods

In 2013 twenty-one centers agreed to provide detailed data on their use of A-FiO_2. This web database is described elsewhere [7]. It includes a data set for each infant treated. In summary, the data set includes infant demographics, baseline clinical status, respiratory support prior to use of A-FiO_2, indication for A-FiO_2 use, settings and duration of A-FiO_2, and subjective impression of A-FiO_2 functions as well as neonatal outcome.

The aim of this project was to analyze this database to provide a representative sample of the use of A-FiO_2 in Poland and how its use might have evolved with adoption and extended experience across units.

Results

The analysis included 619 case report records. A-FiO_2 systems were used primary in preterm infants (83%). It was applied primarily as part of routine care (71%). Its indication for non routine uses were weaning oxygen (17%) and managing infants with frequent desaturations (11%). A-FiO_2 was used primarily in intubated infants (83%), thought nearly half were managed noninvasively at some point prior to starting A-FiO_2.

A-FiO_2 was primarily used to manage infants with gestational ages between 25–31 weeks. However overal use reflected a wide range of 22–41 weeks. Initiation of A-FiO_2 was usually in the first 2 days of life with an inital inspired oxygen of 30–50%. These were not rescue interventions as the maximum oxygen requirement in the period before intervention was typically higher (40–100%).

The most common control range was 90–95% SpO_2, which was rarely changed during management (5%). Although ranges were at times set much wider. The high SpO_2 alarm was most commonly set between 95–98% SpO_2. The low alarm was typically set between 85–88%. Although they were at times set much wider. A-FiO_2 was typically used between 1 and 7 days, but as long as 59 days.

A-FiO_2 was rated as effective in nearly all cases (25% very effective, 72% effective). It was only reported as ineffective in 3 of the 619 cases. In most cases the alarms were rated as being frequent but not persistent (71%) and infrequent or rare 21% of the time. In 8% of the cases the alarms were rated as excessive (frequent and persistent). This was much more common (22%) when the alarms were set close to the SpO_2 control range.

We were aware that only 12 of the 21 centers that had agreed to participate in the registry had documented use. With this review we found that only 5 has registered cases throughout the intended period (2014–2019). These 5 sites had, in fact, contributed all but 3% of the cases, and nearly all of these were between 2014 and 2017. While 619 is still a robust experience, we decided that evaluation of trends in use across years or within centers were inappropriate without further assessment of compliance with prospective enrollment in each center across the years.

Discussion

We reported on the aggregate experience of the use of A-FiO_2 with 619 infants, mostly from 5 centers between 2014 and 2017. Its application is primarily for routine management of intubated infants in the first days of life, though it is used also with success in infants who are not intubated and also who have difficulty weaning oxygen or have frequent desaturations. These findings are consistant with the report of our initial experience [7].

This analysis has limitations. First it is unclear whether our report, while reflecting a large number of infants, is a sample of convenience or truly reflective of A-FiO_2 use. That is, was the experience different in centers with system but not reporting, or with subjects not reported by participating centers? For that reason and also because it reflects the experience of 5 centers, it is not clear whether it can be projected to the several hundred centers that routinely intubate and ventilate babies in Poland.

In consideration of those limitations, in the summer

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of 2019 we decided to extend and broaden this project to provide a truly representive picture of the adoption of A-FiO_2 in Poland. To accomplish this we deemed it necessary to collect and integrate disparate information describing the level of adoption of A-FiO_2 as well as how it is used and perceived.

We believe this should be of broad academic interest for two reasons. First, the impact of SpO_2 targeting on neonatal outcomes has been widely studied [11]. However, the published evaluations of A-FiO_2 have been less comprehensive. These A-FiO_2 studies have focused on the control of SpO_2 over a short period of time (i.e., 2.5–24 hours) and mostly in carefully controlled settings [12]. Though these studies have consistently reported excellent effectiveness, there have only been a few reports of its routine use [7, 9, 13]. While of great potential benefit, the assessment of the impact of A-FiO_2 on outcomes is just now started [14, 15]. Secondly, the use of A-FiO_2 technology outside of Poland is only beginning, and to our knowledge, no center or region has the years of experience with routine use that is available from Poland.

There are three sources of data that will be used for this extended project. These are national statistics, a previously implemented web based database and a series of site surveys developed for this project. The description of and intended use of each is described in the first three sub-sections below.

Data from National Databases

Most readers will lack familiarity with neonatal healthcare environment in Poland, therefore a short description needs to be provided. This overview will include the number of special care nurseries, number of admissions and some details on the hierarchy of the levels of care. The latter categorization will make use of ICD-9 codes. These data are available from the National Health Fund, and the Neonatal Society. We also defined advanced respiratory support as routinely intubating infants and providing extended respiratory support. This would exclude centers from this higher category when they only intubate as part of a transport effort, or for surfactant administration.

Data from Web-based registry

Subjective information (Table 1) will be used to evaluate compliance, which is the degree of complete participation. We did observe a ramp up in use of the registry at the beginning in 2013 and also a tailing off starting in 2018. We will evaluate to what degree this reflects use of A-FiO_2, or compliance with reporting. After excluding centers that were not compliant with their obligation or for some reason A-FiO_2 access became unavailable, we expect to be left with a robust multicenter sample of about 500–600 cases. We have defined this group as the Participating Centers.

Site surveys

Written survey instruments were developed in English and approved in October. They have been translated to Polish and will be sent to appropriate centers in early 2020. When completed they will be reviewed by the project team, with clarification sought as needed. After these are culled, it is expected there will be between 200–250 confirmed in the Advanced Respiratory category and that about 10% will have A-FiO_2 experience. This data on these Advanced Respiratory support centers will include the size of the unit and annual admissions as well as the number of invasive and noninvasive respiratory devices.

In addition, for the centers with A-FiO_2 experience, a survey will include information about the number and type of A-FiO_2 systems and their year of acquisition. For those centers with A-FiO_2 experience, a summary of their current opinion about its use will be gathered, using a ranked Likert scale. As shown in Table 2ab, this includes 10 questions covering its perceived effectiveness, training and indications for use.

Additional information about their experience and opinions will be gathered from these Participating Centers. These questions are shown in Tables 3a–g. Table 3a addresses 5 areas of perceived benefits, and limitations of performance and support. Table 3b–c explore ideal indications for use and barriers to their adoption. Table 3d evaluates potential problems with use. Table 3e explores changes in use based on experience. Table 3f documents its initial implementation and Table 3g current practices.

This survey will be sent to the Participating Centers as they are identified. Care will be taken to insure that the responses represent the opinions in the unit, and not just of the chief, or a research coordinator. The survey instrument provides an opportunity for reporting divergent opinions. We expect there might be different opinions among nurses and among physicians, and also between the two groups. To further encourage this, a request will be made for each site to meet and discuss the scaling of each answer and further to record divergent opinions. The implementation of this process will be monitored, and a team member will visit each site, either to audit compliance or to participate in the gathering and reconciliation of opinions.

Statistical analysis

Summary descriptive data will be provided for each of the groups of centers. Analyses will focus on the Participating Centers (estimated 500–600 cases from 5 centers). These analyses will address potential differences among centers, differences associated with indications for use, and changes in practice over time. A value of $p<0.05$ will be considered statistically significant. The data will be compiled in an excel database. Tabulation and analyses will be performed with XLSTAT (v20, Addinsoft Paris France).

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Table 1: Assessment of Compliance.

Does enrollment reflect actual use?		
2014	Complete (>90%) ☐☐☐☐☐	No <10%)
2015	Complete (>90%) ☐☐☐☐☐	No <10%)
2016	Complete (>90%) ☐☐☐☐☐	No <10%)
2017	Complete (>90%) ☐☐☐☐☐	No <10%)
2018	Complete (>90%) ☐☐☐☐☐	No <10%)
2019	Complete (>90%) ☐☐☐☐☐	No <10%)

For each year, if NO, why not? _____
if Complete, why not more? _____

Table 2: Overview: Assessment of A-FiO_2 experience.

a) Rate current subjective impressions about A-FiO_2 use		
How often is A-FiO_2 used:	Routinely ☐☐☐☐☐	Never
Effectiveness of A-FiO_2:	Excellent ☐☐☐☐☐	Poor
Effectiveness of Alarms:	Excellent ☐☐☐☐☐	Excessive
A-FiO_2 ever erratic:	Never ☐☐☐☐☐	Regularly
Rate of acceptance by staff:	Quickly ☐☐☐☐☐	Resistant
Training by distributor:	Excellent ☐☐☐☐☐	Insufficient

b) Current Indications for use		
all infants receiving respiratory support:	Yes ☐☐☐☐☐	No
all unstable infants receiving respiratory support:	Yes ☐☐☐☐☐	No
only intubated infants:	Yes ☐☐☐☐☐	No
only preterm infants:	Yes ☐☐☐☐☐	No

Table 3: Detailed experience from Participating Center.

a) About the benefits of A-FiO_2?		
better maintenance of SpO_2 in normoxemia	Yes ☐☐☐☐☐	No
reducing episodes of extreme SpO_2 exposure	Yes ☐☐☐☐☐	No
reducing the risk of periodic nurse distraction	Yes ☐☐☐☐☐	No
reducing nursing work load	Yes ☐☐☐☐☐	No
reducing false/nuisance SpO_2 alarms	Yes ☐☐☐☐☐	No

b) About infants whom A-FiO_2 should ideally be used?		
all infants receiving respiratory support:	Yes ☐☐☐☐☐	No
all unstable infants receiving respiratory support:	Yes ☐☐☐☐☐	No
only intubated infants:	Yes ☐☐☐☐☐	No
only preterm infants:	Yes ☐☐☐☐☐	No

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c) About why A-FiO_2 is not used more in this unit?

not enough systems with A-FiO_2:	Yes ☐☐☐☐☐ No
A-FiO_2 limited to intubated and NIPPV:	Yes ☐☐☐☐☐ No
some clinicians do not prefer the vent with A-FiO_2:	Yes ☐☐☐☐☐ No
some clinicians do not like A-FiO_2:	Yes ☐☐☐☐☐ No
clinicians do not like the higher alarm frequency:	Yes ☐☐☐☐☐ No
A-FiO_2 is not always effective:	Yes ☐☐☐☐☐ No
lack of adequate training on use of A-FiO_2:	Yes ☐☐☐☐☐ No

d) About problems with A-FiO_2

excessive alarm frequency (alarm fatigue)	Yes ☐☐☐☐☐ No
over reliance on automatic control (ignoring alarms)	Yes ☐☐☐☐☐ No
A-FiO_2 increase of FiO_2 masked clinical deterioration	Yes ☐☐☐☐☐ No
erratic SpO_2 control	Yes ☐☐☐☐☐ No
A-FiO_2 function stopped	Yes ☐☐☐☐☐ No
A-FiO_2 SpO_2 reading different from SpO_2 monitor	Yes ☐☐☐☐☐ No
Any other problem	Yes ☐☐☐☐☐ No

For any of these not NO, discuss and describe both details and frequency

e) About changes in your use of A-FiO_2 that came with increased experience

Setting level for the control range	Yes ☐☐☐☐☐ No
Setting of the SpO_2 alarm thresholds	Yes ☐☐☐☐☐ No
Setting of the SpO_2 alarm delay	Yes ☐☐☐☐☐ No
Indications for use (infant size, diagnosis, acuity)	Yes ☐☐☐☐☐ No

For any of these not NO, discuss and describe details including whether it was unit wide or related to individual clinicians.

f) About the initial integration of A-FiO_2 into your unit

Did you receive training from the distributor or manufacture	Yes ☐ No ☐
Was the initial training adequate?	Yes ☐☐☐☐☐ No
Time between training and start of routine use	_____ weeks
How long is the orientation for physicians new to A-FiO_2	_____ hours
How long is the orientation for nurses new to A-FiO_2	_____ hours

g) About the current use of A-FiO_2 in your unit?

Prescribed target ranges are part of the medical record	Yes ☐ No ☐
Prescribed SpO_2 alarm levels are part of the medical record	Yes ☐☐☐☐☐ No
A-FiO_2 is turned on or off only by the attending physician	Yes ☐☐☐☐☐ No
Target Ranges are set or reset only by the attending physician	Yes ☐☐☐☐☐ No
Alarm delays are set or reset only by the attending physician	Yes ☐☐☐☐☐ No
SpO_2 Alarm delays are usually set at	_____ seconds
SpO_2 Alarm delays are on occasion set between	_____-_____ s

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