Functionality of a Facemask Datalogger with Valved Holding Chamber: Preliminary Data of Application Force From Parents With Asthmatic Children

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Summary

Background: For good lung deposition, when using a pressurized metered dose inhaler (pMDI) with valved holding chamber (VHC) and facemask, it is essential that the facemask provides a good seal, and comfortable fit. Actual parameters for in vitro bench testing of newly developed facemasks, to predict clinical use, are not well known. For this reason, a custom instrumented OptiChamber Diamond VHC with medium LiteTouch facemask, known as the Facemask Datalogger, was developed to measure application force and air flow through the VHC and facemask. The aim was to test usability of the Facemask Datalogger and to collect in vivo data using the Facemask Datalogger. Outcomes were application force (measured as weight), and time needed to empty the VHC (T_{VHC}).

Methods: Thirty asthmatic children aged 1-5 years, already using a pMDI/VHC with facemask. Using the Facemask Datalogger, one parent applied the facemask on the child simulating normal inhalation, and force and flow were recorded. This was repeated 3 times.

Results: Mean application force: 411 g (SD ±161). Inter-subject variability of mean force: 39% (CV) and mean intra-subject variability of mean force 23% (CV). Mean (T_{VHC}): 6.9 s (SD ±5.5), and T_{VHC} was significantly negatively correlated with age (r= -0.6; p<0.001)

Conclusion: The Facemask Datalogger is a useful tool to measure in vivo application force on a facemask and air flow through a VHC. Mean force measured was lower than that referenced in previous in vitro studies. These results will assist development and testing of new facemasks in vitro.

Introduction

Pressurized metered dose inhalers (pMDIs) combined with a valved holding chamber (VHC) with attached facemask are the first choice of inhaler device for young asthmatic children (1). A tight seal of the facemask to the face has been shown to be crucial for efficient aerosol delivery to the lungs. Young children often dislike the use of a facemask, causing them to struggle. When the child struggles during administration of aerosols, it is hard to maintain a tight seal between facemask and the face of the child, which will substantially decrease lung deposition (2-4). Furthermore, depending on the design of the facemask, one needs to apply more or less force to place the facemask tightly fitting on the face (5). The more force that is needed, the less comfortable it will be for a child, and the more a child will struggle against the inhalation procedure, reducing the inhaled dose. Thus, a seal between the patient's face and the VHC facemask is critical, and the design and material used important (6).

A number of combinations of VHCs with facemasks are commercially available. There are still new facemasks being developed that are aimed to improve inhalation therapy in young children. In vitro testing is an important part of the development process of VHC facemasks before they are used in vivo. The in vitro tests allow a wide range of isolated parameters to be independently investigated in a systematic way. For example, VHC facemask design (including dead space) and the facemask-patient interface (including, age-dependent facial geometry, seal efficiency, application force, and application angle) can be readily studied in vitro (5). The parameters are, however, assumptions of the situation in vivo. It is not known how much force is used to press the facemask with a tight seal on the face. Also, mostly sinusoidal breathing patterns are used to simulate breathing during in vitro testing. In the development of facemasks there is a need for good equipment and in vivo derived data to simulate the in vivo situation as accurately as possible (7). This would improve the design of facemasks before they are introduced commercially, and would make the development better and more efficient.

A custom built Facemask Datalogger using a modified OptiChamber Diamond VHC and detachable LiteTouch facemask (Philips Respironics, Respiratory Drug Delivery, Parsippany, NJ) has been developed to measure several parameters, in vivo, which can be translated to and used in the in vitro situation. The application force, measured as weight, applied through a facemask, with attached VHC, on the child's face can be recorded with this equipment. Furthermore, the flow and volume of inhaled air through the VHC and the time needed to empty the VHC can be measured and recorded. Studies with dataloggers attached to the VHCs have been done before, showing that the use of these devices in vivo is feasible (8, 9).

In this study we aimed to test the usefulness and acceptability of the Facemask Datalogger to collect in vivo data in young children. We used a newly designed facemask, the medium LiteTouch (Philips Respironics, Respiratory Drug Delivery, Parsippany, NJ). The primary end-point was the force applied to the face of the child by the parent. Secondary end-points were: intra- and inter-subject variability of force and time needed to empty the VHC.

Methods and materials

Study design: This pilot study was an observational study.

Subjects: Thirty children aged 1-5 years with doctor diagnosed asthma, using a pMDI/VHC with facemask were enrolled from the outpatient asthma clinic Kinderhaven in Rotterdam. The study procedure was performed during one study visit. Children with facial malformations, or acute asthma symptoms at the time of the study, were excluded.

Materials: In this study, a VHC facemask (medium LiteTouch facemask, Figure 1) was used in combination with a small volume VHC (OptiChamber Diamond, Figure 1). The Facemask Datalogger instrumentation (Figure 2) comprised two sets of instruments, one to record information on the flow through the VHC, and the other to record information concerning the application used to seal the facemask to the patient’s face.The flow instrumentation set is attached to a custom inhaler boot and canister and records the flow through the actuator. The application force instrumentation set is permanently attached to two halves of the of the OCD and records the amount of force transmitted from the rear of the VHC (pMDI actuator end) to the front of the VHC (facemask end) via three load cells placed around the circumference of the OptiChamber Diamond. Signals from both instrumentation sets are communicated to a PC via wire.

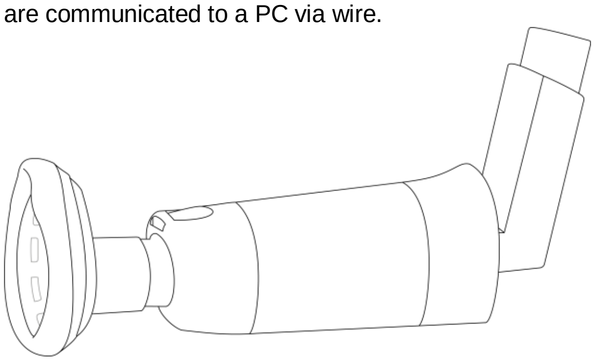

Figure 1: Medium LiteTouch facemask in combination with a Optichamber Diamond, Philips Respironics

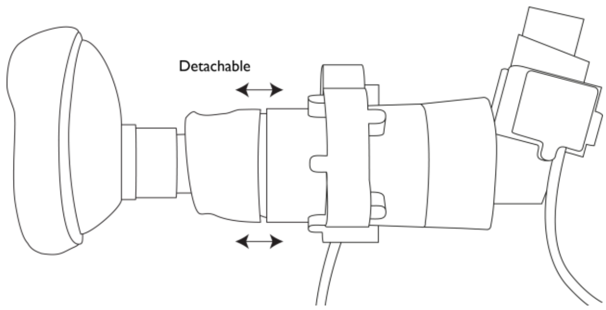

Figure 2: Facemask Datalogger assembly

Study procedure: Prior to each patient session, the Facemask Datalogger force and flow instrumentation was verified via a calibration routine. The Facemask Datalogger was designed such that the entire facemask and one one-way valve system can be removed and replaced for each patient, to minimize cross contamination. During the study procedure, the child sat on the lap of the parent. The facemask was applied to the face by the parent (Figure 3). Parents were asked to simulate a normal inhalation procedure, and to ensure a tight seal with the facemask. Each measurement was repeated 3 times with each patient. A measurement was considered completed if at least twice the volume of the VHC/facemask (2x 160 mL) was replaced. This was considered sufficient to withdraw all aerosol from a VHC (8, 10, 11).

Figure 3: The Facemask Force/Flow Datalogger in vivo

Statistical analysis: Descriptive statistical analysis was used to calculate mean force and T_{VHC} per patient, as well as overall means. T_{VHC} is defined as time needed to replace twice the volume (320 mL) of the VHC/facemask. Inter- and intra-subject variability of force was expressed as coefficient of variation (%).
Correlation of T_{VHC} with age was calculated with a Spearman correlation test. Parental application force was expressed as a weight equivalent in grams. T_{VHC} was expressed as time in seconds.

Results

30 young asthmatic children completed the study procedure. Patient characteristics were: 21 boys and 9 girls, mean age 3.2 years (SD ±1.0), mean weight 15.1 kg (SD ±3.3) and mean length 96.3 cm (SD ±9.3).

Overall, the Facemask Datalogger was well accepted by the children and the parents. Two children cried during the study procedure. Parents liked the soft material of the LiteTouch facemask. The results for force and intra- and inter-subject variability expressed as coefficient of variation (CV%) are shown in table 1. T_{VHC} was significantly negatively correlated with age (r=-0.63; p<0.001) (Figure 4). There was a weak negative correlation of age and force (r=-0.36; p=0.048) (Figure 5).

Table 1: Results of 30 patients		
Force*	411.0 g	±161
Intra-subject variability of force*	23%	±14
Inter-subject variability of force	39%	
T_{VHC}*	6.9 s	±5.5
*** Mean results with SD**		

Table 1: Results of force and variability

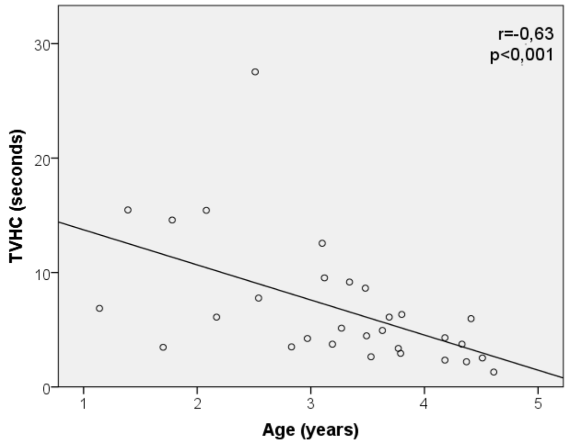

Figure 4: Scatter plot of age versus T_{VHC}

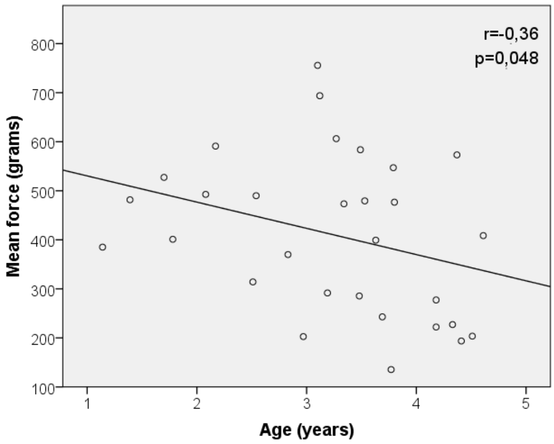

Figure 5: Scatter plot of age versus mean force

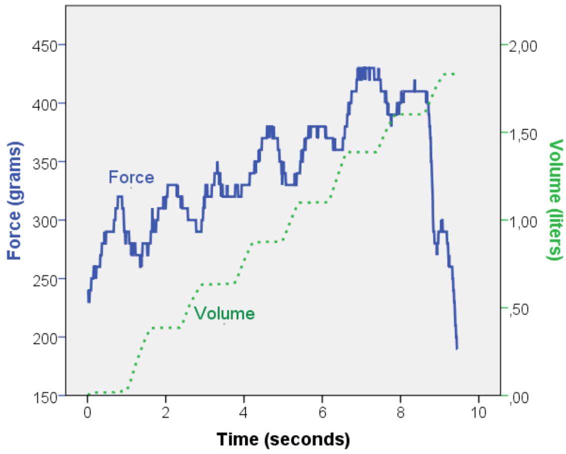

Figure 6: An example of a cooperative child

An example of a measurement from a cooperative child can be seen in figure 6. The amount of air in each breath was, approximately, similar, indicating that the facemask sealed well on the face.

Discussion

This is the first study using the Facemask Datalogger in vivo and has been shown to be a useful tool for collecting in vivo data from young children during use of a VHC with a facemask.

No other studies that have investigated the forces on VHC facemasks in vivo were found. The mean force found in this study was considerably lower than that used in former in vitro studies. Shah et al. used weight equivalent forces varying between 680 g and 3.4 kg when testing facemasks in vitro; the forces they used were based on experts' opinions (5). It is possible that the forces used in these previous studies were related to the design of the facemask systems that were evaluated, but the lower mean force used in the current study might also be due to the design of the LiteTouch facemask. This design consists of a very soft plastic cushion that surrounds the facemask, which makes it easier to achieve a good seal on the face and feels comfortable for the child.

There was a relatively high inter-subject variability in applied force found in this study. This might be explained by differences in the shapes of faces, or by differences in cooperation between children; also the weak negative correlation of age and force might also be explained by these factors. We are currently still analyzing these possible explanations. Within patients, the force applied by the parent is fairly consistent, reflected by the low intra-subject variability.

The negative correlation of age and T_{VHC} we found could possibly be explained by the tidal volumes of older children, which are larger, and therefore require fewer breaths to replace 320 mL.

Since no data on the force applied through VHC facemasks from in vivo studies exists, our results will be useful for future studies. As shown in several studies, facemask seal is a very important aspect of the design of a facemask (5, 6, 12). Furthermore, the Facemask Datalogger can be used to compare different facemasks, both in vivo and in vitro.

Conclusion

The Facemask Datalogger along with the medium LiteTouch facemask were well accepted, and are useful tools to measure, in vivo, the force applied on a facemask, the flow, and the replaced volume through a VHC. The mean force we found is lower than described in other studies based on expert's opinions. These data will be helpful in the development and testing of new facemasks.

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