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An acoustic method of automatically evaluating patient inhaler technique

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***Abstract* — Chronic respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD) affect millions of people worldwide. Inhalers are devices utilized to deliver medication in small doses directly to the airways in the treatment of asthma and COPD. Despite the proven effectiveness of inhaler medication in controlling symptoms, many patients suffer from technique errors leading to decreased levels of medication efficacy. This study employs a recording device attached to a commonly used dry powder inhaler (DPI) to obtain the acoustic signals of patients taking their inhaler medication. The audio files provide information on how a patient uses their inhaler over a period of one month. Manually listening to such a large quantity of audio files would be a time consuming and monotonous process and therefore an algorithm that could automatically carry out this task would be of great benefit. An algorithm was thus designed and developed to detect inhalation, exhalation and blister events in the audio signals, analyze the quantity of each event, the order in which the events took place and finally provide a score on the overall performance. The algorithm was tested on a dataset of 185 audio files obtained from five community dwelling asthmatic patients in real world environments. Evaluation of the algorithm on this dataset revealed that it had an accuracy of 92.8% in deciding the correct technique score compared to manual detection methods.**

I. Introduction

Respiratory tract diseases are those which affect the airways. Two of the most well-known chronic respiratory diseases are asthma and chronic obstructive pulmonary disease (COPD). Asthma causes the airways to become narrow, constricted and inflamed. This in turn leads to recurring periods of wheezing, chest tightness, shortness of breath and coughing. Over 235 million people currently suffer from asthma worldwide, while it is the most common chronic disease amongst children [1]. COPD is a life threatening disease that blocks the airways, making breathing difficult. There are two main types of COPD; emphysema, which causes a weakening of the lung structure and chronic bronchitis, which causes inflammation and narrowing of the airways. Symptoms of COPD include shortness of breath, coughing and sputum production. It is estimated that 600 million people suffer some form of COPD, while nearly 3 million people die annually from this disease [2]. Although chronic respiratory diseases such as asthma and COPD are incurable, if treated correctly with medication they can be controlled.

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Inhalers are small, portable, hand held devices which are used to deliver medication directly to the lungs via the oral cavity. There are two main types of inhaler devices; the metered dose inhaler (MDI) and the dry powder inhaler (DPI). MDIs deliver medication in the form of an aerosol spray, while DPIs are breath actuated devices which deliver the medication in dry powder form. When used correctly inhalers have been shown to greatly improve patients clinical outcomes [3], however many patients fail to use their inhaler as directed [4].

Non-adherence to inhaler medication is a major problem. Rates of non-adherence among patients suffering from asthma alone range from 30% to 70% [5]. It is estimated that up to $300 billion is spent annually in the US treating the non-adherence of chronic diseases, with asthma and COPD amongst the diseases with the lowest adherence rates [6]. Non-adherence to inhaler medication can refer to patients missing doses, overdosing or carrying out technique errors that lead to a decrease in the overall efficacy of the medication. One source of non-adherence to medication is poor technique. Many patients fail to use their inhaler as directed by their clinician or as set out in the inhaler manufacturer's instructions for use. Poor technique needs to be identified and addressed. To resolve this issue a device was developed that can monitor patients' inhaler technique. The INCA (Inhaler Compliance Assessment) device can be attached to the side of a DPI, from where it unobtrusively records patients using their inhaler in real world environments. The INCA device contains a microphone that records audio each time the inhaler is used. The acoustic profile of the different stages required to achieve successful drug delivery can be identified from these audio recordings. Analysis of these audio files provides information regarding a patient's inhaler technique. However, manually listening to these audio files is a tedious and time consuming process and therefore an algorithm that could automatically analyze the recordings would be of great benefit.

Given the type of technique errors observed in inhaler use, the main steps in inhaler use to be identified are inhalations and exhalations. Several studies have previously described algorithms that were developed to detect and remove breaths in speech and song signals [7], in passages of speech spoken by cognitively impaired subjects [8] and in sleep recordings [9]. An algorithm has also previously been developed by the authors of this study that can automatically identify inhalations during inhaler use [10]. The primary objective of this study was to design a method of analyzing patient inhaler technique and provide feedback on performance. To do this an algorithm was designed and developed to automatically detect inhalations, exhalations and drug blistering. The presence of these events and the order in which they take place can provide vital information regarding a patient's technique.

II. Methods

A. *Background & Instrumentation*

Data was recorded from five community dwelling asthma patients (3 female & 2 male). The age range of patients recruited was 29-69 (mean 50 ± standard deviation 13). All patients used the Diskus™ DPI in this study. It was communicated to patients before they began the study that an adherence monitoring device that could monitor their temporal and technique adherence would be attached to their Diskus™ inhaler.

Each patient was given a Diskus™ inhaler from their clinician, in addition to an INCA device (Fig. 1), for a period of one month. Patients were instructed to use their inhaler as normal and they were not given any extra training or encouragement. The INCA device was bonded securely to the side of their inhaler, where it did not impact on the mechanics of use. After using their INCA enabled inhaler for one month the patients returned to their clinic from where the INCA device was removed from the inhaler and audio files were uploaded to a database.

B. *Correct Inhaler Technique*

The Diskus™ inhaler was designed to facilitate easy use and patient acceptability [11]. When patients are given a Diskus™ inhaler they are instructed on how to use the device correctly. The Diskus™ is opened by sliding a thumbgrip to expose the mouthpiece. The lever is then pulled back which opens a blister containing medication inside the mouthpiece. A click noise indicates that the foil was blistered and that there is medication available in the mouthpiece for inhalation. The patient is then instructed to exhale gently away from the mouthpiece. They then seal their lips around the mouthpiece, inhale steadily and deeply and hold their breath for 10 seconds. Once this is complete the patient should use the thumbgrip again to slide the Diskus™ back to its original position.

C. *Acoustic Recording Device*

An INCA device, manufactured by Vitalograph [12], was employed in this study. The INCA device enables the acoustics of inhaler use to be recorded for analysis. The device contains a microphone, microcontroller and battery. The microphone is a Knowles Acoustics SPM0204HE5 mini surface mount silicon microphone. The audio files are stored on the device from where they can be subsequently uploaded to a computer via a USB connection.

The INCA device can be used in conjunction with the common Diskus™ inhaler. The INCA device starts recording the acoustics once the Diskus™ inhaler is opened and switches off when the Diskus™ is closed. The acoustics of inhaler use are recorded as mono WAV files, at a sampling rate of 8000Hz and bit depth of 8 bits/sample. The device has sufficient battery life to record patient inhaler use for up to a period of one month.

Figure 1: (Left) Internal components of INCA device, (Top Right) External view of INCA device and (Bottom Right) INCA device attached to Diskus™ inhaler.

D. *Data Analysis*

The algorithm automatically examines each audio file, identifying the piercing of the blister containing the drug (1) and breath sounds (2), before differentiating the breath sounds as either inhalations or exhalations (3). The final stage (4) involves calculating a score of user technique for the audio file based on the presence of events 1-3 and the order in which they take place. The algorithm was trained using a dataset of 87 audio files obtained from the five patients and then tested on 185 separate audio files obtained from the same five patients.

The first stage of the algorithm is to detect the piercing of the blister foil containing the medication. The audio signal is segmented into overlapping windows of length 100ms, which start every 10ms. The mean power spectral density (PSD) of the signal is calculated for frequencies between 2000Hz-3000Hz. For this frequency band it was found from empirical observations in the training dataset that blister sounds had a mean power greater than -65dB. A fixed threshold was thus set with any segments greater than this threshold considered as potential blister sounds. The algorithm then examines the proposed blister sounds to remove any false positives. Potential blister sounds with maximum normalized amplitude less than 0.7 are removed, in addition to blister sounds greater than one second in duration. The mean PSD in the 20Hz-200Hz frequency band is also calculated. Any potential blisters with a power less than -62dB are considered as false positives and removed, thus leaving only the true positive blister events.

The second stage of the algorithm involves detecting breath sounds and third stage involves differentiating between inhalations and exhalations. The audio signal was filtered to remove high frequency components above 1400Hz using a low-pass type I 6^{th} order Chebyshev filter. An algorithm that utilizes MFCCs (Mel Frequency Cepstral Coefficients) was employed in this study to detect breaths in the audio signals. This method has been described in detail in a previous paper by the authors of this study, which explains the automatic identification of inhalations in asthma inhaler recordings [10]. The main components of this method involve using MFCCs, singular value decomposition (SVD) and zero crossing rate (ZCR) to accurately detect breaths.

To differentiate inhalations from exhalations the mean power spectral density (PSD) of identified breaths was calculated for frequencies between 2520Hz-4000Hz. It was found from empirical observations in the training dataset that inhalations had a greater power in this frequency band compared to exhalations. Based on this fact a fixed threshold was put in place. Inhalations were classified as having a mean power greater than -80dB, while exhalations had a mean power below this value. Fig. 2 contains a spectrogram which illustrates the difference in frequency components between inhalations and exhalations. The standard deviation of the ZCR for inhalations was also found to be higher for inhalations in comparison to exhalations in the training dataset. A fixed threshold of 0.045 was put in place with inhalations having a greater value compared to that of exhalations.

The last stage of the algorithm (stage four) is to analyze all of the events which took place in the audio file and make a decision regarding the quality of a patient's technique. To do this the algorithm inspects the quantity of blisters, inhalations and exhalations that have taken place and the order in which events have taken place.

The inhaler is deemed to have been used correctly if the patient first blisters the foil and secondly inhales the medication. An exhalation does not need to take place for the inhaler to have been used correctly. Exhalations can take place before the blister or after the inhalation, still leading to a 'used correctly' score. However, if the patient exhales in the time between the blister and inhale then they are judged to have committed a technique error as they may have exhaled into the mouthpiece of the inhaler and dispersed some of the medication. Any other sequence of events is deemed to be a technique error. If the algorithm detects two or more inhalations or blisters then a technique error will also be judged to have taken place.

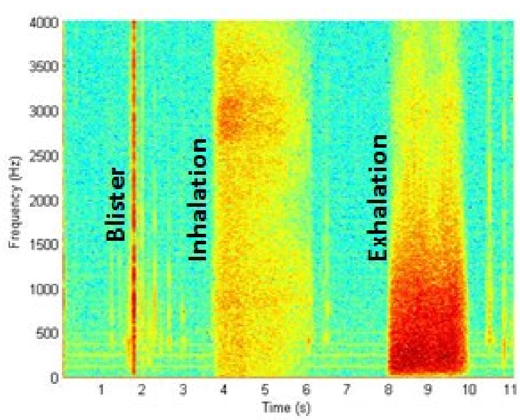

Figure 2: Spectrogram of inhaler audio signal demonstrating different spectral features of blister (1.8s), inhalation (4-6s) and exhalation (8-10s).

III. Results

The algorithm designed for this study aimed to detect blister, inhalation and exhalation events, analyze the order they took place and give a score on the overall technique of the user. Fig. 3 shows an example of the identification of the blister, inhalation and exhalation by the algorithm. In addition to the detection of events the onset and offset time of each event is calculated. To test the overall performance of the algorithm, one month's data from five community dwelling asthma patients was analyzed. The five patients produced 185 audio files in total (mean 37 ± standard deviation 13). Each file was scored as either (1) used correctly, (2) technique error or (3) not used, by two experienced independent human raters. Agreement between the two human raters was 100%. Comparison of the algorithm to the human raters in predicting the correct score was found to be 92.8%. The INCA device used in this study also provides a log of the time and date the inhaler was used. This information, in addition to the scores of how the patient uses their inhaler can be combined to provide a plot of patient inhaler use over a period of time. An example such a graph can be seen in Fig. 4.

IV. Discussion

Of the 185 audio files analyzed it was found that the algorithm had an accuracy of 92.8% in determining the correct technique score compared to that of two independent human raters. This is an encouraging initial result if this algorithm is to be used in a fully automated system that actively analyzes patient inhaler technique.

There are a number of challenges associated with analyzing patient inhaler use in real world environments. Often a great quantity of noise is generated by the patient or the background environment. The algorithms accuracy in

Table I: Algorithm accuracy compared to human raters.

Patient	1	2	3	4	5
Algorithm Accuracy (%)	96.5	97.2	100	91.4	79

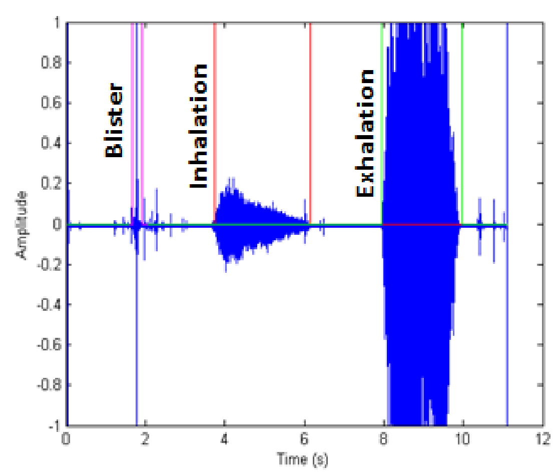

Figure 3: Detection of blister (1.8s), inhalation (4-6s) and exhalation (8-10s) by the algorithm for inhaler audio signal in time domain.

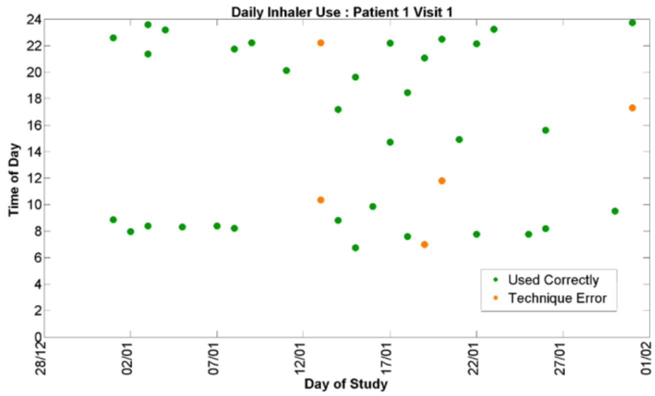

Figure 4: Chart demonstrating how data can be represented over one month period in terms of time of day inhaler was used and technique score.

predicting the performance of subject five was 79%, slightly lower than the other four patients. The primary reason for this was due to subject five consistently fumbling with their inhaler, creating a large number of blister sounding events. Short duration artifacts such as those created by fumbles make the detection of blisters particularly difficult. A number of patients knocked their inhaler against objects that created noise artifacts similar to the temporal and spectral characteristics of actual blisters. The detection of exhalations also has a number of challenges. Unlike inhalations, for which the patient has to seal their lips tightly around the mouthpiece, an exhalation can take place at any distance and direction relative to the mouthpiece. This creates a challenge as some patients exhale close to the inhaler, while other patients exhale at arm's length from their inhaler.

In many cases it has been found that patients unintentionally exhaled into the mouthpiece of the Diskus™ inhaler, dispersing some or even all of their medication. Such detrimental exhalations can only take place after a patient has first carried out the blister step and released medication into the mouthpiece of the inhaler. The algorithm designed for this study is capable of detecting this error and thus will give a used incorrectly score if such an exhale is detected. Such error detection has a number of benefits in terms of analyzing inhaler technique.

An algorithm that can automatically analyze patient inhaler technique has many advantages for both inhaler users and clinicians. Currently there is no way for clinicians to see how a patient is using their inhaler once they take the device home with them. The system described in this study provides a record of inhaler use that can be interrogated in order to assess how and when an inhaler was used over a period of days or weeks. To manually evaluate a potentially large quantity of audio files is not very feasible. Thus, an automatic algorithm may allow clinicians to efficiently monitor patients' inhaler technique over a period of time. Such information may be used to provide feedback to patients in the hope of them improving their technique. For patients, improved inhaler technique may lead to increased levels of medication efficacy. There may also be a decrease in the number of hospital admissions for exacerbations if patients improve their technique based on active feedback from their clinician.

V. Conclusions

In conclusion, an algorithm has been developed that can evaluate patient technique in a common dry powder inhaler. This algorithm creates the opportunity for clinicians to monitor inhaler users in order to understand if they are consistently using the device with the correct technique. Active feedback may encourage patients to improve their technique and take better control of their disease. Further refinements of the algorithm are needed if it is to be employed in very noisy environments. Further analysis of the power of the breath signals will also be carried out to investigate how this relates to inhaler technique. Additional data is currently being acquired to expand on the work of this study.

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