Development of a breath alcohol analyzer for use on patients in emergency care

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Abstract— **The quantification of breath alcohol concentration is considered important input in medical diagnosis and triage at emergency medical care. In many severe emergency cases, for example head injuries, stroke, heart attack, diabetes, or psychological illness, the medical condition of the patient can be mistaken for alcohol intoxication. In cases like these, quantification of the alcohol concentration would facilitate and speed up the diagnostic procedure. However, the use of breath analyzers in medical care is limited as state-of-the-art devices require active involvement of the patient, and expiratory volume and flow incompatible with patients respiratory function. This paper presents a prototype of a handheld breath analyzer based on infrared spectroscopy which does not require the patient's cooperation and also provides direct feedback on the quality of the breath test by measurement of the expired partial pressure of CO_2, PCO_2.**

Keywords— **Emergency medicine, Breath analysis, Breath alcohol, Infrared spectroscopy.**

I. INTRODUCTION

A large number of patients in need of emergency medical care, especially at night-time, are under the influence of alcohol [1-3]. In emergency care it is of importance for the medical personnel to distinguish if the depression of consciousness is related to the effects of alcohol or to a severe medical condition [1, 3-7]. Non-invasive and rapid measurement of alcohol concentration is important to prevent misdiagnosis, delay of diagnosis, but also to screen for potentially dangerous alcohol-drug use [1, 3, 5-6, 8-9]. For example, the behaviour of a patient suffering from head injury, stroke, cardiac infarction, hypo-glycaemia, psychiatric illness or who is in severe physical pain can easily be misinterpreted as alcohol intoxication [4, 6]. In the case of factual intoxication, it would be useful to follow the trend of the ethanol concentration for the decision of alcoholic detoxification, further diagnosis due to suspicion of intake of other toxic substances, and also during methanol detoxification using ethanol [7].

Alternatives to breath alcohol analysis are analysis of blood, saliva or urine, or the subjective opinion of the medical staff, possibly influenced by several other factors. Blood analysis, which is commonly used in emergency care [2, 10], has considerable drawbacks due to its invasiveness, and long analyze time.

There are breath analyzers designated for medical usage on the market today. However, medical personnel do experience problems with these breath analyzers due to the need for a tight seal between the patient's mouth and the mouthpiece of the instrument.

In addition, the steadily increasing ethanol concentration during expiration (Fig. 1) leads to requirements of expired volume and duration for an approved breath test, which may be difficult for patients with impaired respiratory function.

Due to the problem of achieving a qualitative breath test from a non-cooperative patient or a patient with depressed consciousness, the accuracy of breath analyzers has been questioned, and tested [5, 10-12]. State of the art breath analyzers are not equipped with independent sample quality control, and thus occurrence of low or false-negative breath tests in obviously intoxicated patients can occur due to unreliable sampling. In addition to the importance of selectivity to ethanol, diagnosis in emergency care could be further facilitated with an indication of possible presence of other substances in the expired air, for example methanol [2].

This paper presents a new breath analyzer for measurement on uncooperative patients or patients with depressed consciousness. Significant advantages of the new breath analyzer are the sample quality check indicating that the air analyzed originates from the airways, the small sampling volume, and the operator initiated sampling.

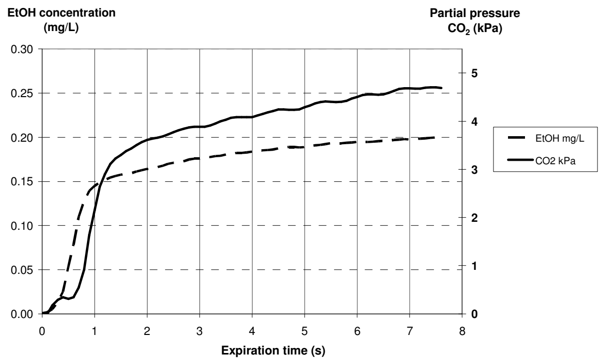

Fig. 1 Expirogram for ethanol and CO_2 recorded by a modified evidential breath analyzer (Evidenzer, Nanopuls AB, Sweden).

II. IMPLEMENTATION

The breath analyzer prototype presented in this paper shares a common technology platform with an alcolock for vehicle integration, which has been described earlier [13]. This section will describe the basic measurement principle, some clinical aspects, and the difference regarding air sampling, and initiation of measurement by the operator that distinguish this prototype from the alcolock prototype.

In the alcolock application the measurement of breath alcohol in diluted air is enabled through estimation of and correction for the mixing of the breath test with ambient air. The basic physiological assumptions and approximations for this measurement principle are that the dilution of the sampled air can be estimated through comparison between the partial pressure of CO_2 in expired air (PCO_2) and the expected end expiratory PCO_2. This factor of dilution is then used for calculation of the alcohol (ethanol) concentration in non-diluted end expiratory air, Equation (1).

$$\frac{C_{end-expEtOH}}{C_{measuredEtOH}} = \frac{C_{end-expCO2}}{C_{measuredCO2}} \qquad (1)$$

In the medical application the breath sample is collected with a receptor placed over the patient's mouth or nose. In addition to measurement of the breath alcohol concentration (BrAC), a value of the expired PCO_2 is presented. A high value of PCO_2 is considered valuable physiological input of the patient's respiratory function, whereas a low PCO_2 primarily indicates poor sample quality.

The principle of measuring the concentration of ethanol and CO_2 is based on infrared (IR) transmission spectroscopy. High sensitivity and selectivity for ethanol and CO_2 are achieved through use of IR detectors with suitable wavelength, and with use of at least two sub-bands of detection for the ethanol measurement, the breath analyzer will be able to indicate presence of additional substances besides ethanol in the breath test.

The sensitivity of the breath alcohol sensor is highly dependent on the optical path of the measurement cell. Due to the low concentrations of ethanol in expired air, decimetres of optical path is required, which comes in conflict with the desirable size of a handheld instrument. The solution to this is the usage of an optical module developed by Martin [14] on the basis of White's work [15] regarding multiple reflections for increased optical path.

Fig. 2 shows an outline of the breath analyzer with an attached receptor. Due to the passive expiration from the patients a pump may be used for air sampling which is initiated by the operator.

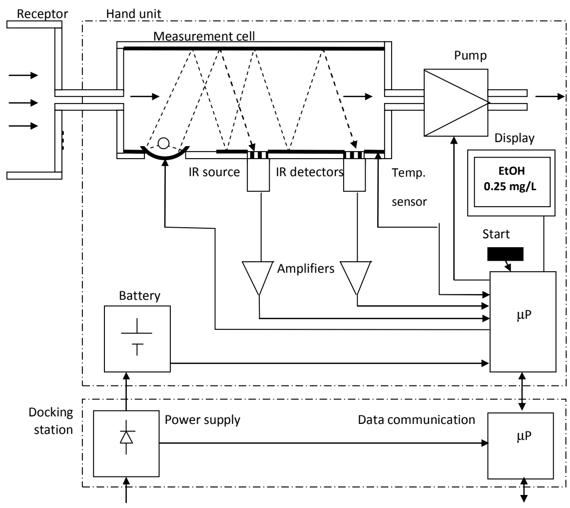

Fig. 2 Schematics of the outline of the breath analyzer.

Parallel with the technical development of the alcolock, clinical studies are being performed in order to evaluate this new method of breath alcohol measurement. One of these studies has verified that the inter-individual variation of PCO_2 in expired air is of acceptable range for a breath alcohol screening device [16]. Analysis of 116 prolonged tidal breath, (0.6-1.5 L) performed by both healthy subjects and patients with obstructive pulmonary diseases gave a mean end expiratory PCO_2 of 3.9±0.6 kPa (range 2.3-5.7 kPa).

III. Results

The results presented in this section are from measurements performed with a passively sampling prototype. Fig. 3 shows the output signals from the two IR detectors measuring the intensity of the infrared light in the chosen wavelength bands. Air was sampled with the breath analyzer held in front of four persons simulating sleep. PCO_2 was measured with the prototype and a capnograph (Microcap, Oridion, Israel), Fig. 4. The capnography PCO_2 value ranged between 1.4-4.5 kPa, with generally lower PCO_2 measured with our prototype. The difference in PCO_2 is related to the difference in air sampling: passive sampling with the prototype whereas the capnograph was equipped with a pump (50 ml/min). The sampling tube of the capnograph was placed in front of the inlet of the prototype, towards which the subjects exhaled. In Fig. 5 the ethanol concentration measured with our prototype is plotted against the BrAC measured with a reference instrument (Alco-Sensor FST, Intoximeter INC, U.S.). The prototype measured a much lower ethanol concentration due to the small expired volume and the dilution of the sample, in comparison to the undiluted vital capacity expiration performed in the reference instrument. In Fig. 6 the dilution has been compensated for. The BrAC value presented by the prototype is calculated from the ethanol to CO_2 ratio ($EtOH/CO_2$) multiplied with the mean end tidal value of 3.9 kPa. The residual standard deviation between the BrAC measured with the prototype and the reference instrument was 0.15 mg/L.

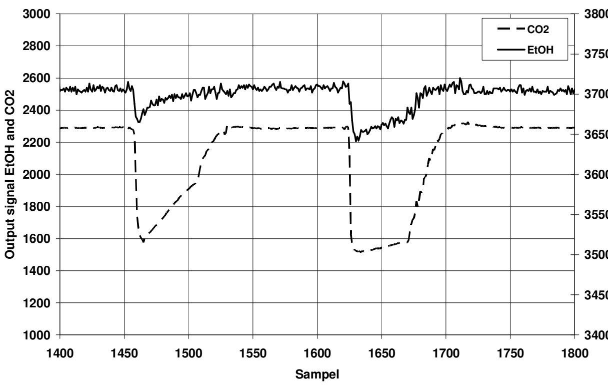

Fig 3. Decrease of the two output signals due to the concentration of ethanol and CO_2 in expired air. The figure also illustrates the two channels correlation in signal level. The ethanol signal has a linear response to increased concentration, whereas the CO_2 signal has a logarithmic response. Vertical scale is A/D bits (0.105 µV/bit)

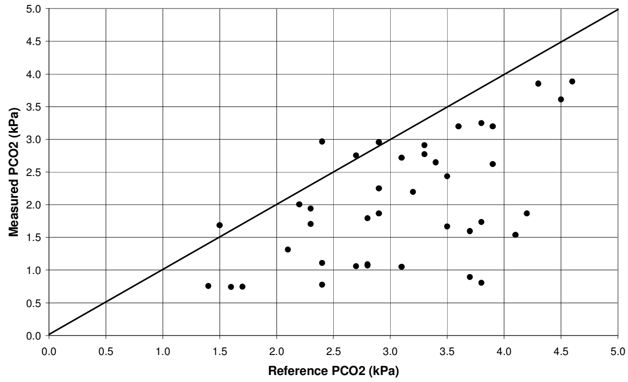

Fig 4. The PCO_2 measured in subjects who simulated sleeping, plotted against the PCO_2 measured simultaneous by a capnograph (Microcap, Oridion, Israel).

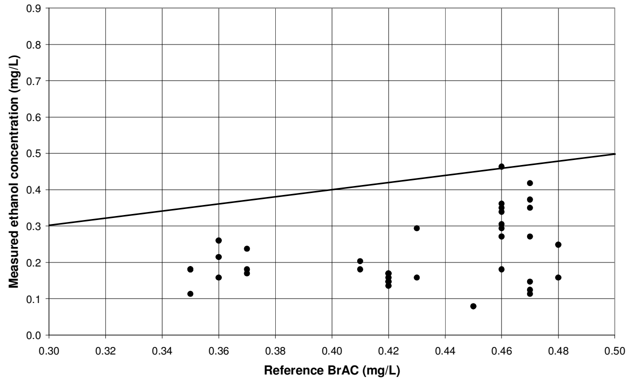

Fig 5. The ethanol concentration measured with the breath analyzer prototype in subjects who simulated sleeping, in relation to the breath alcohol concentration measured during vital capacity expiration with a reference instrument (Alco-Sensor FST, Intoximeter INC, U.S.).

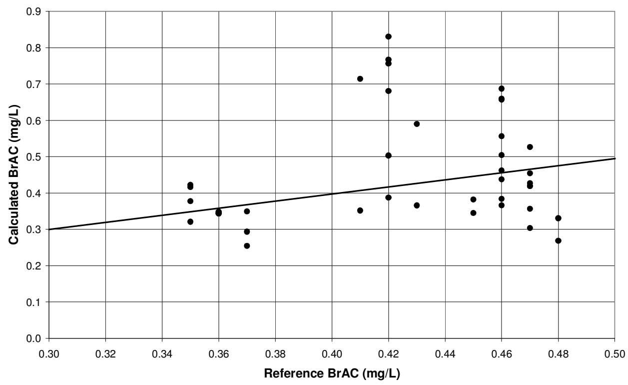

Fig 6. The breath alcohol concentration (BrAC) compensated for the sample dilution (the $EtOH/CO_2$ ratio times 3.9 kPa) plotted against the BrAC measured with the reference instrument (Alco-Sensor FST, Intoximeter INC, U.S.). The residual standard deviation was 0.15 mg/L.

IV. DISCUSSION

In emergency care, ease of use, fast response time, and reliability are important characteristics of a breath analyzer, whereas the accuracy of the measurement is not as prioritized as for evidential devices [1, 4-5]. A value of BrAC provides important input for diagnosis and therapeutic decision, but the clinical relevance of the patients' level of intoxication is left to the medical personnel, since it is affected by e.g. alcohol habits, body weight, and current food intake.

Despite the prototype's passive sampling and the small expired volumes, use of the $EtOH/CO_2$ ratio makes possible of the breath alcohol determination with a residual standard deviation of 0.15mg/L. The experimental result reported in this paper indicates that sample dilution and small expired volume can be compensated for with this measurement method. These results look promising for the continuation of the development of the breath analyzer, which may be equipped with a pump for active air sampling and a receptor designed for collecting the breath sample. In addition, the signal-to-noise ratio of the ethanol channel needs to be improved. We believe that with these changes adequate accuracy for use in medical care, even for passive breath tests, will be achieved.

Breath alcohol analysis for the purpose of exclusion of alcohol as the reason for the medical status is highly relevant with the increased demand of triage in emergency medical care. In addition to quality improvement, a breath test instead of a blood test is also expected to reduce the costs for the medical departments [7, 12].

V. CONCLUSIONS

The preliminary results presented in this article support the applicability of a new sensor technique for use on patients with depressed consciousness or un-cooperative patients, who cannot take active part in the breath test and whose expiratory volume and flow are reduced. Together with the breath alcohol concentration, the breath analyzer provides information about the partial pressure of CO_2 of the breath sample as a quality check.

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