Chest electrical impedance tomography examination, data analysis, terminology, clinical use and recommendations: consensus statement of the TRanslational EIT developmeNt stuDy group

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ONLINE SUPPLEMENT 9

Recommendations for future direction in EIT development, evaluation and use

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Introduction

The role of EIT in clinical practice, especially the critical care environment, has yet to be systematically established. In the process of clarifying EIT´s role, consensus statements are clearly needed. This section will summarize the goals and priorities of future research and device development required to create practical and clinically useful EIT systems. Through this the role of EIT in different clinical settings can be determined and then evaluated to ascertain whether benefits to outcome are possible. This initially requires consideration of the most important unmet clinical needs and gaps in scientific and clinical knowledge. Through such an approach EIT is likely to become widely adopted.

Introducing new technologies into clinical practice brings new challenges for the clinician, even when evidence of benefit exists. The success of EIT as a clinical tool will require educational resources to support clinicians. In the experience of the author group, the use of functional imaging is conceptually novel for clinicians. As evident by this review, there is now a broad clinical and engineering expertise in EIT, especially in critical care settings. A series of internet-accessible training tools, such as videos, demonstrating the correct application of EIT, problem-solving common problems (such as electrode contact issues), common clinical scenarios and how to interpret the meaning of different EIT images would greatly enhance initial clinical uptake.

Prior to clinical trial evaluation, patient-specific electrode interfaces and image reconstruction algorithms are urgently needed (1, 2). These systems should be developed through collaboration between clinicians and medical equipment manufacturers so acceptable age-specific solutions are found. The importance of chest shape in accurate image reconstruction has been detailed earlier (1-3). Collaborations aiming to share data sets of chest shapes by gender, age and developmental status will aid in this. Ideally appropriate chest algorithms should be automatically chosen for the patient´s examination. The growing market in pediatric and neonatal critical care, and the increasing obesity in adults, justifies the commercial potential in these populations, particularly as non-invasive respiratory support becomes more popular. Electrode interfaces and display of information will also need to be individualized to diverse populations and needs.

Potential unmet clinical needs

Recent shifts in the direction of modern respiratory care offer unique opportunities for new validated and practical tools. There is increasing clinician-driven demand for advanced point-of-care monitoring of physiological status. Unfortunately, many of the accepted existing bedside lung function tools, such as lung mechanics derived from airway flow recordings, require the use of an endotracheal tube. The increased shift towards non-invasive respiratory support in critical care, such as CPAP and high-flow nasal cannulae, has come at the expense of fewer reliable options for direct monitoring of lung function (4). In this environment of dichotomous clinical needs EIT is an attractive new technology. Similarly concerns regarding radiation exposure mainly in childhood limit the use of many intermittent imaging tools that have found practical value in the adult population, such as computed tomography (CT).

Clinical EIT: Towards a monitoring, diagnostic or therapeutic tool?

Improved computing and engineering capacity offers the potential for EIT to be more than a simple monitor of clinical status, either as a diagnostic tool or as part of a therapeutic intervention via feedback control of clinical care, such as delivery of mechanical respiratory support. In the first instance, EIT is likely to be more easily adopted as a monitoring tool, particularly for early identification of simple adverse events and/or in environments where existing monitoring tools are impractical, such as non-invasive respiratory support. This approach will allow evaluation of the ability of EIT to alter existing high-risk practices and/or need for static investigations (e.g. chest radiography) without compromising safety and outcomes. The ability of EIT to correctly identify endotracheal tube position (5-7), and then ultimately eliminate the routine use of chest radiography in this indication, or the use of EIT to guide need for and response to endotracheal tube suction (8-10) are two areas in which EIT could be easily assessed.

More pressing, and clinically meaningful, is the use of EIT as a means of identification and localization of air leaks. Air leaks are a relatively frequent complication of intensive care, especially in preterm infants and post surgery, and associated with important short and long-term morbidity, despite being simple to rectify if diagnosed. Currently, chest radiography or ultrasound is usually used to diagnose air leaks but clinical suspicion rarely occurs before clinical deterioration. Animal models have identified the potential for EIT to diagnose, and localize, air leaks before clinical deterioration (11-13). Clinical use has been documented in case reports (14). Simple prospective observational studies of EIT to identify air leak, in conjunction with current gold standard clinical care, would be highly informative, as well as determining the diagnostic potential of EIT. Such studies would require large sample sizes and would only be possible through multicentred collaboration. Studies assessing the role of EIT as a monitoring tool are relatively easy to design, can be powered to short term outcomes and can be performed across different age groups. Focusing on the simpler role of EIT as a monitor would also allow clinicians to become broadly familiar with the new technology. From these experiences it is likely that the development of EIT systems that can be used to guide clinical practices, especially in the more meaningful but harder therapeutic setting, can occur.

Research investigating the role of EIT as a diagnostic tool needs to consider the context of existing tools: Will EIT be used to identify conditions or clinical states in which diagnostic tools are lacking or not wide-spread, for example bedside assessment of ventilation-perfusion mismatch, or as an alternative to existing tools, for example chest radiography for air leaks? It should be remembered that EIT simply measures changes in relative volume states within the chest, and thus clinical interpretation will be essential. For example a sudden decrease in tidal ventilation in one lung region may indicate localized collapse, secretion plugging, overinflation or evolving air leak, all diagnoses with different clinical meaning. New EIT algorithms, such as regional time constant and atelectasis parameters (15, 16), may allow more direct diagnostic potential. At this stage the use of EIT as a diagnostic tool is unconfirmed, future research must first determine the conditions in which EIT may offer diagnostic potential and then systematically evaluate the validity, reliability, reproducibility, sensitivity and specificity relative to the risk, limitations and cost of current 'gold' standard tools. We would recommend that this be initially addressed through clinical studies limited to consortia of expert EIT users, allowing evidence and experience-based consensus guidelines.

The ultimate goal of any new physiological tool must be to demonstrate improvements in outcomes if progress beyond a research tool can be expected. Ideally EIT would find a role as a tool that drives direct clinical care. The promising observational adult and preclinical data in the use of EIT to guide positive end-expiratory pressure (PEEP) settings during adult and pediatric ARDS (17, 18), and newborn resuscitation at birth (19), provides an initial focus for clinical research. These could be addressed using a two-step clinical trial approach. In the first instance, the potential of EIT to guide assisted respiratory support could be assessed with short-term practical outcomes targeting utility, feasibility and safety. Once these aspects have been determined the role of using EIT to guide clinical care requires assessment in large randomized trials that target meaningful long-term outcomes, such as disability-free survival.

The use of EIT in adult ARDS offers considerable appeal. The disease is characterized by gravitational heterogeneities that can change rapidly, and respiratory support that aims to create uniformity of ventilation, through positioning, ventilator settings and minimizing interstitial edema. The existing data suggests that EIT may provide a solution to all of these needs and the functional and dynamic nature of its imaging overcomes some of the limitations of static measures (18). The well-established international ARDS consortia offer a network for the multicenter randomized control trial (RCT) evaluation of EIT as a tool for guiding the effectiveness of specific ARDS therapies and, also, monitoring disease progression compared to existing tools, such as oxygenation, lung compliance and chest radiography/CT. It is likely these trials could be performed quicker and with more meaningful power than in the pediatric population.

Severe pediatric ARDS, although not a common condition would be a reasonable clinical entity to initially evaluate the role of EIT in guiding advanced ventilator settings in children, specifically PEEP (18). At present there is no practical realtime feedback system for determining optimal PEEP in regular clinical use. Pediatric ARDS is a lung condition in which the PEEP setting is important, being associated with regional volume heterogeneity and often responsive to open lung recruitment. Patients are also often managed with a cuffed endotracheal tube and muscle relaxants (unlike neonatal acute lung disease), thus offering less variables during PEEP titration. To achieve important clinical practice change, ideally, EIT-guided PEEP titration during active disease and weaning should demonstrate improvements in long-term disease free survival as well as short-term outcomes such as reduced ventilator days. This would require a large and lengthy multicenter RCT. Such RCT are not uncommon in pediatric/neonatal critical care, but until EIT has been adopted more broadly as a clinical tool, initially to monitor lung states, it will not be feasible or likely to achieve intended goals.

Neonatal resuscitation in the delivery room is an area in which EIT may have therapeutic utility. Increasingly, neonatologists are aware that lung protective ventilation needs to be applied from as soon as possible after birth, but respiratory support is often applied with non-invasive methods (for example bag and mask ventilation) and feasible and reliable monitoring is lacking (20). Also, complicated solutions (for example PEEP titration) are not needed to achieve meaningful clinical change, as the biggest limitation to respiratory support at birth is simply adequately and repeatedly achieving tidal ventilation. In this regard EIT is ideal and could easily be implemented without advanced end-user training. The most recent neonatal International Liaison Committee for Resuscitation consensus statement has called for clinical trials of lung function monitoring tools at birth (21). A simple belt-style EIT interface offering realtime direct visualization of low resolution breath-to-breath ventilation could guide the clinician in important aspects of care, such as mask seal and pressure settings (22). It is arguable that focusing on improving these basic aspects of neonatal resuscitation is more meaningful than targeting advanced aspects of respiratory care at birth, such as tidal volume targets and PEEP levels, all of which assume that former is optimal.

The rapid through-put and general stability of the patient population compared to critical care results in less investigation of respiratory function during anaesthesia for surgery. The need for EIT use in these patients is probably less relevant than in intensive care. For example, ETT position is rarely confirmed during a routine anesthesia. Nonetheless, simple to apply EIT systems that do not interfere with other monitoring and therapeutic systems especially diathermy would be useful in guiding respiratory care in theatre. In the first instance large observational trials evaluating the utility as a monitoring tool for ETT position and atelectasis and ventilation inhomogeneity would identify whether a potential exists, and help guide appropriate clinical questions for outcome and safety based evaluation.

To date the majority of EIT research has focused on the inpatient acute care population. This has excluded an important unmet potential of EIT as a pulmonary function monitor in ambulatory settings. The ability of EIT to measure regional ventilation and aeration without an interface at the airway opening, suggests that it could be used outside of pulmonary function laboratories without expertise training. If simple electrode belts were available EIT could even be used in home or outreach environments. In the first instance EIT could be used in conjunction with existing pulmonary function testing to determine reliability and utility as an early detection and temporal disease progression monitoring tool, especially for chronic interstitial and obstructive lung disease in adults (23-25), congenital diseases like cystic fibrosis in children and adults (26) and developmental disorders related to complications of birth, such as bronchopulmonary dysplasia.

Conclusions

EIT offers the potential to find utility within a diverse range of clinical settings. To achieve meaningful clinical use a structured multidisciplinary approach is needed. Initially improved patient interfaces and population-specific image reconstruction algorithms are needed. Then integration into the clinical settings should initially aim to use EIT as an adverse events monitor. This should be paired with well-designed online training tools highlighting both good application and also pertinent EIT image patterns and examples of different clinical states, uses and diseases. This will familiarize clinicians to the technology, enhance decision-making and empower clinicians with the skills needed to generate clinically relevant questions for interventional therapies. Ultimately large trials of EIT-guided intervention powered to long-term outcomes will be needed.

Document preparation

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