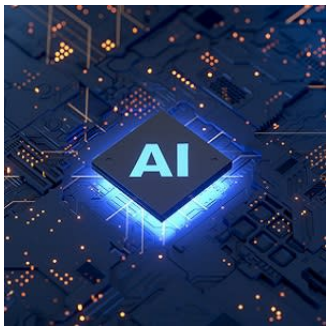
ICU
MANAGEMENT & PRACTICE

Clinical Trials of Artificial Intelligence



With the introduction of computers and advanced technology, the majority of patient data is now captured digitally. And this has allowed opportunities for machine learning. Today, machine learning is frequently used to make diagnosis or predict disease outcomes, optimise treatment decisions and determine the prognosis of patients.

While there is growing excitement about the promise of artificial intelligence (AI) in medicine, there are still a significant number of experts who have concerns about the negative impact of AI including loss of patient autonomy, decline in physician manpower and/or unintended bias. Others also claim that AI is overhyped because there is very little data to show that patient outcomes have actually improved with this technology.

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One major issue complicating the clinical benefits of AI is the lack of clinical trial data. Even though the FDA recently approved the use of the AI tool (SaMDs) for diagnosis of diabetic retinopathy with digital fundoscopy and early warning stroke on CT scans, this approval is not based on any type of randomised clinical trial. AI may have a lot of potential in healthcare and AI tools are powerful enough to alter clinician actions significantly, but some experts believe that before we give in to the hype, it is important to have randomised trials before such adoption.

In this review, researchers report findings from a clinical trial on how AI-derived clinical decision support tools may provide the need for more randomised clinical trials in healthcare.

In this study entitled the Hypotension Prediction During Surgery (HYPE) trial, 68 patients who were undergoing non-cardiac surgery were randomised to intraoperative management guided by an AI-based early warning system (intervention group) or standard care (control group). The primary objective was to determine if the intervention decreased the duration and depth of intraoperative hypotension. In the intervention group, the arterial pressure was monitored by an AI tool, which extracted data continuously and promoted an alarm if hypotension was going to occur within the next 15 minutes. The control group was monitored by anaesthesiologists.

The study revealed that AI tools allowed for successful intervention when hypotension was anticipated. In the AI group, there were fewer episodes of prolonged hypotension and the duration of hypotension was shorter compared to the control group. Hence, in the AI intervention group, anaesthesiologists acted quickly and selected different treatments.

However, we still need more clinical trials because there are certain limitations with this study. First of all, there are many causes of hypotension during anaesthesia and the algorithms generated were built on old data and all variables and causes of hypotension were not considered. More data input of all variables can make more accurate predictions. Second, in this study, warning systems had to be introduced to alert the anaesthesiologists about any impending problem during anaesthesia. The problem is that AI can be so sensitive that it generates many alarms, some of which do not require any type of intervention except observation. Third, the study was limited by the end point of hypotension and the sample size was too small to determine overall safety.

In short, there are still many unresolved issues with the use of AI in heatlhcare. The algorithms generated depend on data input. And the more the data input, the better the accuracy. However, the role of clinical acumen by physicians will always be necessary. Nobody is denying the potential of AI but as the application of AI increases in healthcare, there is a need for more randomised clinical trials to determine its short and long term benefits.

Source: JAMA
Image Credit: iStock

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