Study shows polypill to be safe and accepted by physicians and patients in developing countries

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For a patient at high risk of cardiovascular disease (CVD), keeping up with what pills to take at different times of the day can be tedious. Window sills lined with prescription bottles – a pill for cholesterol, another for blood pressure, and an aspirin to keep blood thin and flowing – the list can get quite long and, as a result, many people, especially the elderly, often forget doses or take the wrong pill at the wrong time.

But what if there was a single pill that had all the benefits of multiple medications in one dose? Would people take it? Would doctors prescribe it? And would it be effective?

A new study done by researchers at Wake Forest Baptist Medical Center provides evidence that, in fact, such a pill may be a viable option for developing countries, where CVD is strongly emerging and the demand for cost-effective, low maintenance treatment is high.

"The idea behind the polypill is that it offers a simpler way to give medications to people so that they will have better adherence to their pills," said Elsayed Z. Soliman, M.D., M.Sc., M.S., director of the Epidemiological Cardiology Research Center (EPICARE) at Wake Forest Baptist and lead author on the study. "It's not always easy for people to consistently take multiple pills, even if they are needed to treat a serious condition, like CVD. This is especially true in developing countries, where cost of CVD medications is another major challenge.

This one pill has the potential to improve adherence while being less costly to the population in developing countries."

To adopt the polypill approach in developing countries, a large scale clinical trial is needed, Soliman added. However, before conducting such a trial, research was needed to see if it was even possible to conduct a clinical trial in a developing country.

Going into this study, there were many perceived barriers to doing research in a developing country, Soliman said. Among them, would the country have investigators capable and willing to participate in a study and the necessary follow-up? Would patients sign up to participate? And if the pill was proven to work, would doctors even feel comfortable prescribing it?

So Soliman and colleagues brought the study to Sri Lanka, where they enrolled 216 participants without diagnosed CVD, in the hope of answering some of these questions. Half of the participants received "standard' treatment for CVD risk prevention, and the other half received the polypill. Patients were recruited as planned. Two hundred three patients (94.0%) completed the treatment program and returned for their follow-up visits. No safety concerns were reported.

These findings suggest a high rate of patient acceptability, a finding that is bolstered by the fact that the majority of patients who completed the trial – 90 percent – indicated that they would take the polypill "for life" if proven to be effective in reducing CVD risk. Approximately 86 percent of the physicians surveyed agreed with and supported use of the polypill for primary prevention and 93 percent for secondary prevention of CVD. In terms of reduction in CVD risk, both the polypill and "standard treatment" resulted in marked reductions in systolic blood pressure, total cholesterol and 10-year estimated risk of CVD.

"Our trial has fulfilled its purposes," Soliman said. "We wanted to check the feasibility of doing a large-scale clinical trial with a polypill in a developing country and to examine the acceptability of the polypill by patients and physicians, and we now know that it's feasible and acceptable."

He added that the "standard" treatment in this trial was administered by highly specialized physicians in tertiary-care centers, making it a tough competitor, yet the simple polypill held its own.

Although feasibility has been demonstrated, Soliman explained that there are other important questions about the polypill that still need answers, such as: Which patient population should a polypill target: those who have not yet been diagnosed with CVD (primary prevention) or those who have a CVD diagnosis in their medical history (secondary prevention)? Also, what components should make up the pill and in what doses will they be most effective?

"There are many questions, but a single trial will never answer all of them," Soliman said. "At least now we know that it is possible to begin looking for the answers."

More information: The study was published in *Trials*.

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