Title: ReDS-Safe HF: ReDS Guided Strategy in Heart Failure
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Dr Jesus Alvarez Garcia

" So I'm Jesus Alvarez Garcia. I'm the director of the heart failure unit at Ramon and Cajal University Hospital in Madrid, Spain. And I'm honoured to talk with you about the REDS-SAFE heart failure trial.

Importance of this Study

So, the importance of our study is that it deals with acute heart failure, and acute heart failure is still the most frequent cause of hospitalisation in elderly people, despite advances in medical treatment and residual congestion at the time of discharge is one of the main contributors into readmission risk. And this is relevant because we usually evaluate fluid overload in our clinical practice through symptoms, physical exam, X-ray, natriuretic peptides and so on. But all these methods have low sensitivity and specificity, so we really need new tools to monitor heart failure in patients in this aspect.

The ReDS System

The remote dielectric sensing is a novel device based on electromagnetic energy that can quantify accurately the pulmonary fluid concentration in a non-invasive way. The result is represented as a number, as a percentage of fluid compared to the lung volume, with 20% to 35% range as a normal measure of water content in the lungs. Moreover, previous studies have shown an excellent correlation between the ReDS values and the water content in the lungs, intensity or pulmonary artery wedge pressure in heart failure patients.

Study Design, Eligibility Criteria and Outcome Measures

So, the primary goal of our trial was to test if a ReDS guided strategy is superior to routine care in admitted heart failure patients during a one-month follow-up. The primary

outcome was combined of unplanned visits for worsening heart failure, hospitalizations for worsening heart failure, or death from any cause at 30 days after discharge. So we designed a multicenter, single-blind, randomized clinical trial with two arms, the routine care group with discharge plan based on current clinical practice, and the ReDS guided strategy with a discharge plan based on a specific value given by the device. It's important to note that all patients were tested with ReDS and blinded to the treatment groups. But only treating physicians in the routine care group were blinded to the ReDS values. Every patient was evaluated at seven days after discharge also and at 30 days by phone call. And basically we enrolled patients with a primary diagnosis of heart failure. And we excluded patients with an extreme BMI, patients on inotropes or with an LVAD or transplant patients. We excluded also patients on dialysis or those with a life expectancy less than one year due to non-cardiac reasons.

Key Findings

So we saw that the ReDS-Guided strategy significantly reduced the primary outcome with a hazard ratio of 0.94 and with a number needed to treat of six to avoid an event. We also showed that the quality of life and NYHA class was better in the ReDS-guided group. And we also showed that the median length of stay was two days longer in the ReDS-guided versus the routine care group.

How These Findings Should Impact Practice

So the usual trajectory of heart failure is marked by recurrent admissions and this implies a poor quality of life and worse prognosis for patients and a burden for the healthcare system. So reducing readmission is critical for all stakeholders. So both American and European guidelines recommend to exclude persistence of signs of clinical congestion at this chart and early after discharge. So I think our study provides some data on this aspect.

Limitations

Several limitations have to be acknowledged in our study. First, the modest sample size and second, that the trial was entirely, almost entirely conducted during the COVID-19 pandemic which may have affected the clinical outcome. So I think our trial has to be interpreted with caution because of the wide confidence interval of the hazard ratio. But however, we think that the reduction in the heart failure readmission is of really clinical relevance.

Forseeable Challenges

I think the most challenge is to convince people to use this technology in everyday practice. The technology is noninvasive, it's an easy to use tool, and it's really quick to obtain the value. So I don't see any major challenges into practice with ReDS-technology.

Next Steps

So the next steps are to do a bigger trial. I think we need further research with a bigger trial to validate our results because as I mentioned before, the limitation of our study, one of them was the modest sample size. So I think further research has to be done to validate our findings."