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RESEARCH ARTICLE

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Efficacy of remote dielectric sensing (ReDS) in the prevention of heart failure rehospitalizations: a meta-analysis

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ABSTRACT

The clinical efficacy of remote dielectric sensing (ReDS) monitoring is not well known. Digital databases were searched to identify relevant articles. Pooled unadjusted odds ratio (OR) for dichotomous outcomes were calculated using a random-effects model. Findings were reported as a point estimate with its 95% confidence interval (CI). A total of 985 patients across seven studies were included in the meta-analysis. Patients with heart failure monitored with ReDS had significantly lower odds of hospital readmission compared with non-ReDS patients (OR = 0.40; 95% CI 0.29–0.56; $z = 5.43$ $p = 0.000$, I2 = 0%). Subgroup analysis based on the duration of follow-up showed a lower odd of readmission within 30 days (OR = 0.36; 95% CI 0.18–0.71; $z = 2.93$; $p = 0.003$; I2 5.7%), as well as between 1 and 3 months (OR = 0.42; 95% CI 0.29–0.61; $z = 4.54$; $p = 0.000$; I2 = 0.0%). ReDS effect of lower readmissions of HF was observed irrespective of the duration of follow-up (<1-month vs 1–3 months). ReDS monitoring significantly lowers the odds of HF readmission within 3 months compared to participants not using ReDS.

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KEYWORDS
Remote dielectric sensing; remote monitoring of heart failure; heart failure readmissions

1. Introduction

With over 1 million hospital stays annually, heart failure (HF) exacerbations are the leading cause of readmission in the USA [1]. Preventing readmissions is particularly important, given the mortality and cost burden associated with readmissions [2]. HF exacerbations are typically due to lung congestion [3]. Furthermore, subclinical congestion may precede symptomatic congestion by up to a month [3]. This suggests that early identification of congestive changes may prevent some HF exacerbations [3]. Remote dielectric sensing (ReDS) is a non-invasive tool that transmits low-power electromagnetic signals through the thorax between two externally applied sensors to measure absolute lung fluid content (Figure 1) [4]. This technology identifies pulmonary congestion, a manifestation of volume overload, before developing symptomatic pulmonary edema and HF exacerbation [5]. Furthermore, early detection of pulmonary congestion using ReDS allows physicians to manage medical therapy more aggressively and prevent clinical deterioration [5]. Studies have found that ReDS is highly effective in detecting pulmonary congestion [6,7]. It has been shown that a positive ReDS finding, defined as greater than 35% lung fluid content, was significantly associated with pulmonary congestion confirmed by chest CT [6,7]. The sensitivity, specificity, positive predictive value, and negative predictive value of a positive ReDS reading of 37% may be as high as 89%, 83%, 74%, and 93%, respectively [6,7]. Additionally, higher ReDS values have been found to predict 30-day significantly and 90-day readmissions following hospitalization [8,9]. Despite these findings, no meta-analysis has attempted to systematically assess the utility of ReDS monitoring in reducing HF readmissions. As a result, we designed this meta-analysis.

2. Methods

A comprehensive literature search of digital databases, including PubMed, Embase, and Cochrane, was performed from inception to 15 November 2020. Medical subject headings (MeSH) and keywords were systematically searched using the Boolean operators. The MESH terms for ReDS such as 'Remote dielectric sensing,' 'ReDS,' 'Radar electrical sensing,' 'cardiovascular monitoring device' were combined with a list of MeSH words for heart failure. Four authors screened the results from all possible combinations for relevance (AS, JK, ASr, YS). Based on our PICO (Patient Intervention

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Figure 1. Instructions on ReDS use and illustration of the ReDS technology.

Table 1. Showing baseline demographics and characteristics of included studies.

Author	Year	Study design	Sample HF	Age (years)	Age Std deviation	Male/ Female	Outcome
Roy [16]	2019	Retrospective chart review	96				ReDS vest as an outpatient for the prevention of ADHF
Barghash [18]	2019	Observational	290	62.8	14.4	184/ 106	Point-of-care ReDS is used to prevent HF readmissions during 30 days and to improve GMDT.
Abraham [4]	2019	Randomized clinical trial	268	68	12	188/80	ReDS vest as an outpatient for the prevention of ADHF
Curran [15]	2018	Observational	61				30-day HF Readmission with ReDS use
Opsha [17]	2019	Retrospective chart review	112				Primary endpoint: HF Readmission with ReDS use. Secondary endpoints included LOS, changes in diuretic therapy secondary to ReDS readings and interval change in dosing from prior admissions
Bensimhon [13]	2020	Randomized clinical trial	108	73.6		54	The study's primary outcome was the percentage of patients in each arm who had significant residual lung congestion (ReDS> 39%) at the time of proposed hospital discharge by the primary treatment team. Pre-specified secondary and exploratory outcomes included: (1) Percent readmitted in 30 and 90 days as stratified by treatment group; (2) Readmission rates in 30 and 90 days stratified by ReDS reading at the time of actual discharge; (3) Change in weight, ReDS measurement and serum creatinine from the day of proposed discharge to actual discharge
Amir [8]	2017	Prospective, longitudinally controlled study	50	73.8	10.3	31/19	HF readmission with ReDS use

Comparison Outcome) approach of research, studies from the reference lists were also rigorously screened by an independent author (backward snowballing). All randomized control trials (RCTs) and observational cohort studies (OCS), including patients age >18 years, and comparing the merits of remote dielectric sensing technology guided monitoring use in the reported history of a congestive heart including heart failure with reduced, borderline, or preserved ejection fraction. The primary study point was to see the use of ReDS on the prevention of heart failure readmissions. The secondary endpoint was to check the efficacy based on the duration of monitoring and correlation of HF readmission prevention with lung congestion.

The statistical analysis was performed using a *metan* module in *STATA V. 16*. The DerSimonian Laird test on a random-effects model was used to compute the pooled unadjusted odds ratio (OR) for dichotomous data. Data were matched on population characteristics involving people with diagnosed heart failure to assess the effect of potential confounders. Results were considered statistically significant if p-value <0.05 with 95% confidence interval, not crossing 1. A subgroup analysis was performed based on the follow-up duration of ReDS monitoring. A sensitivity analysis is based on the study weight to avoid data imputation by the more extensive, potentially influential studies. Higgins I-squared (I2) statistical model was used to explore heterogeneity if outcomes had I2 > 50%, I2 > 75% to be considered moderate and high heterogeneity. The publication bias was graphically illustrated by funnel plot symmetry and numerically checked by Harbord modified test to detect any unobserved small study effect (Regression Z/sqrt(V) on sqrt(V) where Z is efficient score and V is score variance), with a p-value >0.05 to be considered as no publication bias. The quality assessment was done using the Newcastle–Ottawa Scale (NOS) for observational studies [10]. For the prospective study, the quality was accessed for representativeness of the case and selection of control, ascertainment of exposure, a demonstration that outcome of interest was not present at the start of the

study, comparability of cohorts based on the design or analysis, assessment of the outcome and follow-up duration for cohorts, for retrospective study quality was assessed for adequacy and representativeness of case-patients, selection, the definition of control population and comparability of cohorts, ascertainment of exposure and same methods of ascertainment and adequacy of follow-up of cohorts. For Curran et al., the quality assessment was done using modified tools for a case series quality assessment [11]. The study was assessed for selection, representation, exposure, outcome adequacy, causality, and reporting. For crossover studies, the quality was accessed by the 'Cochrane systematic reviews' method [12].

3. Results

Our initial comprehensive search identified a total of 6607 articles. Sixty articles were deemed for a full review after removing 301 duplicates and 6246 irrelevant items or limited information. A prespecified inclusion criterion was applied to exclude irrelevant articles. A total of seven studies were included in our analysis. Three studies reported sub cohorts of data based on ReDS to follow-up and intervention/control arm. All the included studies were observational. A step-by-step search strategy is shown in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram (Figure 2).

A total of 985 patients were included. Baseline characteristics were mostly similar between both ReDS and non-ReDS patients. The overall mean age was 69.6 (SD = 12.23) years. The sample was 63.8% male. Diuretic regimen changes occurred in a mean of 18% and 57% of patients in the inpatient and outpatient setting, respectively. Follow-up duration ranged from 30 days to 3 months.

The use of ReDS devices was associated with lower odds of HF readmissions as compared to non-ReDS (OR = 0.40; 95% CI 0.29–0.56; $z = 5.43$ $p < 0.0001$, I2 = 0%) (Figure 3). Furthermore, subgroup analysis was done based on the duration of follow-up. We found that ReDS was associated with lower odds of readmission within 30 days as compared to non-ReDS (OR = 0.36; 95% CI 0.18–0.71; $z = 2.93$; $p = 0.003$; I2 5.7%). Moreover, we also found significantly lower odds of readmission of HF with ReDS monitoring between 1 and 3 months (OR = 0.42; 95% CI 0.29–0.61; $z = 4.54$; $p < 0.0001$; I2 = 0.0%) (Figure 4). ReDS effect of lower readmissions of HF was observed irrespective of follow-up duration (<1-month vs. 1–3 months). None of the included studies mentioned the favorable effect of ReDS on mortality, and mostly, the device was used for symptomatic monitoring. The overall quality of studies included moderate, and the NOS score was 6/8.

4. Publication bias

Our funnel plot was symmetrical on visual assessment, with an equal number of studies on each side of the vertical axis (Figure 5). There was no publication bias demonstrated. The limited scatter on the graph was due to sampling variation. Harbord modified test did not show any publication bias due to small study effect ($t = -1.19$; 95% CI −2.88 to 1.06; $p = 0.289$) (Figure 6).

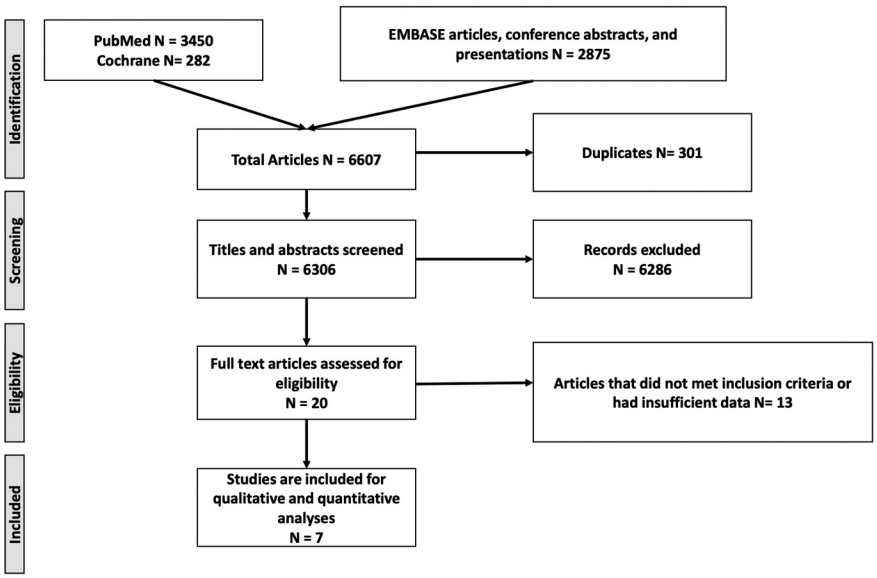

Figure 2. PRISMA flow diagram of search strategy based on inclusion criteria.

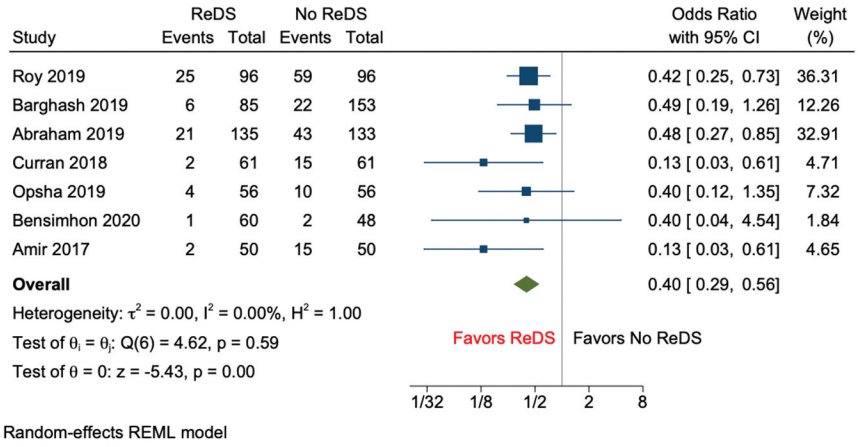

Figure 3. Forest plot showing HF readmissions among treatment (ReDS) and controls (non-ReDS) groups. Heterogeneity was 0.0% and *p*-values here represent heterogeneity was statistically nonsignificant.

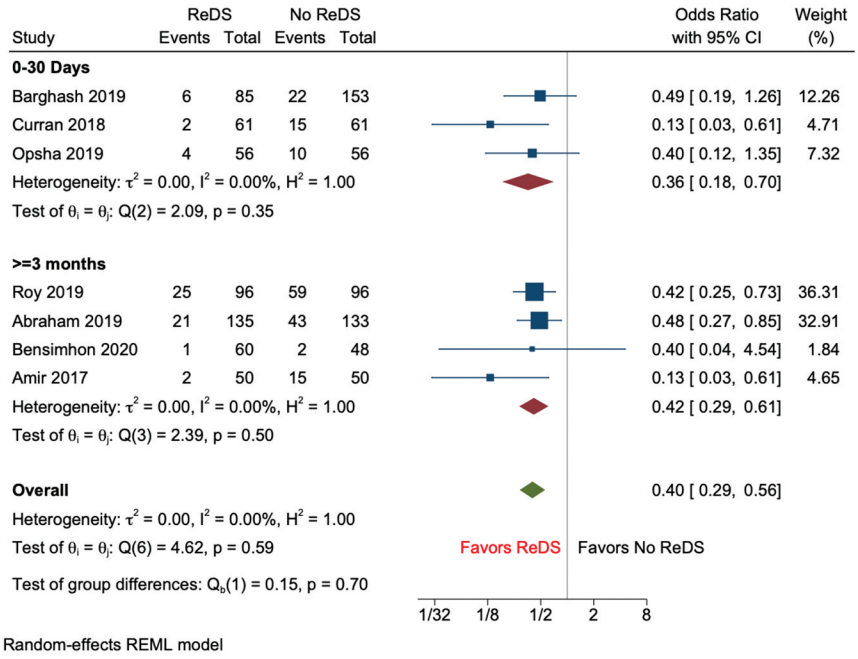

Figure 4. Forest plot showing HF readmission with ReDS monitoring and its effectiveness based on duration and intervention/control arm. Heterogeneity was 0–11.5% and *p*-values here represent heterogeneity was statistically nonsignificant.

5. Discussions

Our meta-analysis objective was to examine the efficacy of ReDS in the prevention of heart failure rehospitalizations. Our meta-analysis compiled the findings of seven studies that utilized ReDS monitoring on heart failure patients following discharge. On average, we found that ReDS use in the inpatient and outpatient setting led to diuretic regimen changes in 18% and 57% of patients, respectively. Furthermore, our meta-analysis found that patients monitored with ReDS had significantly lower odds of being readmitted for HF concerns within 30 days. Moreover, we found a significant association between ReDS monitoring and lower readmission odds between 30 days and 3 months. Our findings suggest that ReDS monitoring helps manage heart failure patients within at least the first 3 months following a prior hospitalization.

HF exacerbations are a healthcare burden across the worldwide health system. ReDS emerged as a non-invasive technique to detect worsening lung congestion as a measure to predict future exacerbation [4,5]. ReDS guided monitoring of congestion can bring a change in diuretic dosing and/or frequency to prevent exacerbations [8,13]. The prevention of HF readmissions by ReDS monitoring was first reported in 2012 in a study by Rappaport et al. This study by Rappaport reported that ReDS might help prevent HF readmissions [14]. They followed 18 patients who underwent ReDS monitoring at home for approximately 90 days after discharge. They found

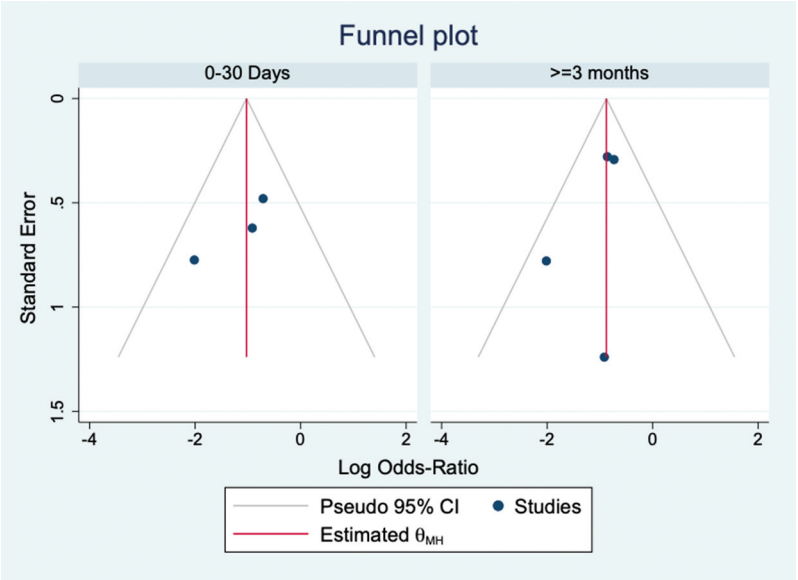

Figure 5. Funnel Plot showing graphical symmetry of plot ruling any publication bias based on duration of follow-up of ReDS monitoring.

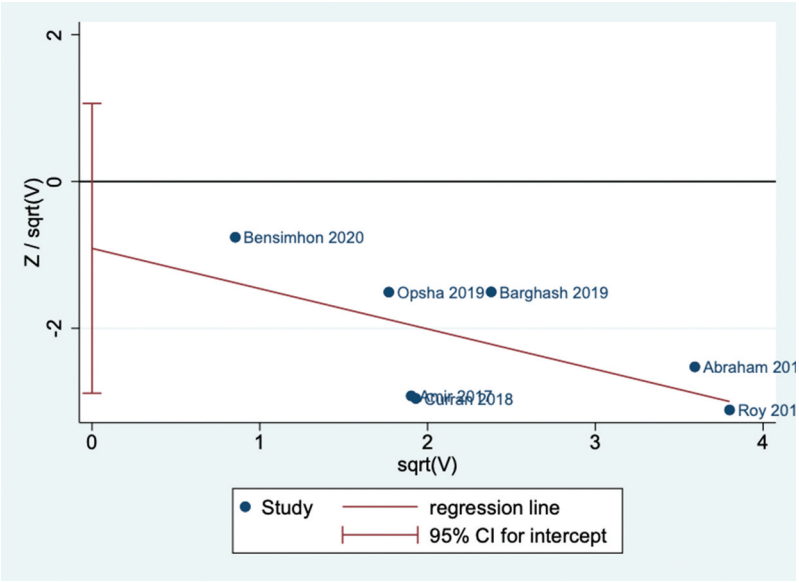

Figure 6. Showing Harbord regression analysis graph, Circles are studies. Oblique line is the regression line. The 95% CI for intercept is presented as 'I' form.

that only six patients were readmitted with HF exacerbation within 28 days. Readmitted patients had a 17% increase in pulmonary congestion than a 2.5% increase in congestion in the ReDS group. Interestingly, investigators also found that ReDS could detect worsening lung congestion status 22 days before future HF exacerbation. However, their findings were preliminary, with a very small sample size and inadequate comparison groups. As a result, we did not include this study in our analysis. Amir et al. was the first study that we included in our meta-analysis. They followed 50 adult patients with Stage C heart failure that underwent ReDS monitoring with a 3-month follow-up [8]. Amir's study found that ReDS significantly reduced readmissions. However, Amir's study was limited by the selection bias due to no randomization in study cohorts. Several small studies also assessed the effect of ReDS on HF readmissions. Curran et al. found a significant reduction in hospital readmission following the implementation of ReDS-guided diuretic protocols [15]. Additionally, Roy et al. found a significant decrease in hospital readmission within 3 months [16]. Finally, Opsha et al. retrospectively compared patients in a ReDS group with patients in a control group [17]. They found that patients in the ReDS group had a significant decrease in their odds of readmission within 30 days and their length of stay upon readmission. More recently, Abraham et al. and Bargash et al. are two more extensive studies

reporting on the effect of ReDS on HF readmissions. Abraham et al. analyzed data from the SMILE trial, a prospective multicenter randomized clinical trial that examined ReDS-guided HF management [4]. Their total sample was 268, with a nearly even split between patients in the ReDS and randomized control groups. Similar to Opsha's study, they found a significant reduction in readmissions and length of hospitalizations in the ReDS group. However, they did not find a significant difference in mortality between the groups. Bargash et al. examined 290 patients and found a significant reduction in 30-day readmission compared to the control group [18]. Finally, Bensimhon et al. is the most recent and complete study included in our meta-analysis [13]. They followed 108 patients, with 60 in the treatment arm and 48 in the control arm. The study examined the effect of ReDS on fluid overload/lung congestion, length of stay, 30-day readmission, and 90-day readmissions. They found that ReDS monitoring was associated with a significantly decreased risk of readmission for HF within 30 days and a notable trend towards significant 90 days. Furthermore, they found that patients that were decongested (ReDS <39%) before discharge with ReDS had a significant decrease in readmission at 30 days compared to those who were not adequately decongested (ReDS ≥39%). They did not find significant differences between the ReDS group and the control group. Our study found that ReDS can lower HF readmission within 3 months, with odds of 0.40. The data about ReDS association with mortality are not available in studies, but ReDS lowers HF's readmissions that can be related to the symptomatic improvement.

Besides HF readmissions, several studies examined the effect ReDS monitoring had on diuretic dose changes. Amir, Bargash, and Opsha's studies found that ReDS led to adjustments in outpatient diuretic regimens in 44%, 50%, and 68% of patients, respectively [8,17,18]. Furthermore, Bensimhon and Opsha's studies found that ReDS led to adjustments in inpatient diuretic regimens in 30% and 5% of patients, respectively [13,17]. Across all studies, we found an average change in diuretic regimens with ReDS use in 18% of patients in the inpatient setting and 57% of patients in the outpatient setting.

Cardiomems, a more invasive technology, has shown similar efficacy in reducing HF readmission [19–22]. Cardiomems is an implantable wireless hemodynamic monitoring system that provides clinician with real-time pulmonary artery pressures [22]. Similar to ReDS, increased pulmonary artery pressure suggests pulmonary congestion. In the CHAMPION trial, medication adjustments guided by pulmonary artery pressure in HF patients reduced HF hospitalization rates compared with reliance solely on clinical symptoms [20]. However, unlike ReDS, it is an invasive technology and therefore has safety concerns. Furthermore, current data on the safety of the technology are limited [21]. As a result, ReDS may be a safer alternative for reducing HF readmission.

5.1. Limitations

ReDS is a recent novelty and different technology from Cardiomems, and a few studies have examined the safety and efficacy of ReDS monitoring. Therefore, our data were limited by studies that did not fully explain the events or number or type of medication adjusted after ReDS reading. Furthermore, diuretic regimen modifications were not mentioned in all studies. We were also limited in our ability to examine the effect of ReDS on long-term follow-up of 6 months to 1 year because no studies examined ReDS monitoring for that long. Given the limitation in data available, we did not perform meta-regression based on age as studies by Curran and Opsha et al. did not report age [15,17]. Finally, we could not examine the effect of ReDS on cardiovascular mortality because no study reported such findings.

6. Conclusion

The current meta-analysis is the first to look into the efficacy of ReDS in preventing heart failure rehospitalizations. By compiling the findings of seven studies, we analyzed a total sample of 985 patients. We found that ReDS monitoring decreases the odds of HF readmission within 3 months of hospitalization. Additional studies are necessary to fully understand the beneficial impact of ReDS monitoring in managing HF patients.

Highlights

- ReDS monitoring helps decrease hospital readmissions in HF as compared to non-ReDS.
- ReDS monitoring helps decrease readmission within 3 months. The benefit of the long duration of ReDS monitoring is still debatable, and extensive studies should be performed to clarify this clinical question.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Author contribution

Yasar Sattar and Mohamed Zghouzi contributed equally to the manuscript as first co-authors

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