EFFECT AND SAFETY OF UNIVERSAL HIGH-DOSE HYDRATION PROTOCOL ON POST-PCI SERUM CREATININE: A 4-YEAR CUMULATIVE EXPERIENCE

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PROBLEM STATEMENT

What is the efficacy and safety of adopting a universal high-dose hydration protocol (HDHP) for all patients undergoing percutaneous coronary intervention (PCI), regardless of their Acute Kidney Injury (AKI) risk, on post-procedural creatinine?

BACKGROUND

AKI, or an increase in post-procedure serum creatinine compared to pre-procedure serum creatinine (ΔCr) by ≥ 0.3 mg/dL, is an important complication of PCI. Peri-procedural hydration with isotonic saline infusion is commonly used to reduce AKI. However, the most effective and safe dose remains undefined.

Previously, we hypothesized that in many patients undergoing PCI, there is a peri-procedural volume deficit that could potentially predispose a patient to AKI. Therefore, we proposed that a universal HDHP for all PCI cases regardless of the AKI risk could address this deficit safely.

In our previous pilot study conducted from April 2018 to January 2020 (n=134), we found that patients who received universal HDHP had a statistically significant drop in post-procedural serum Cr compared to the control group who did not receive HDHP post-PCI. Based on these findings, we continued to apply our protocol prospectively for 28 months after the submission of the pilot study. Here, we evaluate the consistency and safety of our new data set.

Updates from Previous Submission: This presentation is a continuation and extension of an abstract accepted to the ACC Quality Summit last year. Our pilot study data for the 134 patients who underwent PCI in April 2018 - January 2020 was exceedingly promising. Here we include an additional 155 patients from February 2020 - May 2022. The new data is consistent with the previous data as the universal high-dose hydration protocol was associated with a statistically significant negative ΔCr compared to the control group (treatment, n=155 // mean ΔCr = -0.092, control n= 37 // mean ΔCr = +0.130, p= 0.015). With this new submission, we were able to increase the study sample size and therefore power, increase the time period and number of years included in the study, and confirm the previously obtained results.

VALUE PROPOSITION

Our study suggests that the strategy of a universal HDHP can potentially reduce the incidence of AKI and therefore lower patients' morbidity and mortality.

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RESULTS

When compared to the control group, the new treatment cohort had a statistically significant decrease in ΔCr (treatment, n=155, mean ΔCr = -0.092 // control, n= 37, mean ΔCr = +0.130 // p= 0.015). Furthermore, when analyzing the cumulative data from the pilot study and current prospectively studied cohort compared to the control, the results remained significant (n = 289, mean ΔCr = -0.089 // p = 0.016).

Only 7 patients in the total study population (pilot = 3, current study = 4) needed to be given diuretics after PCI. None of the patients developed flash pulmonary edema or needed intubation or prolonged hospitalization.

FIGURE 1

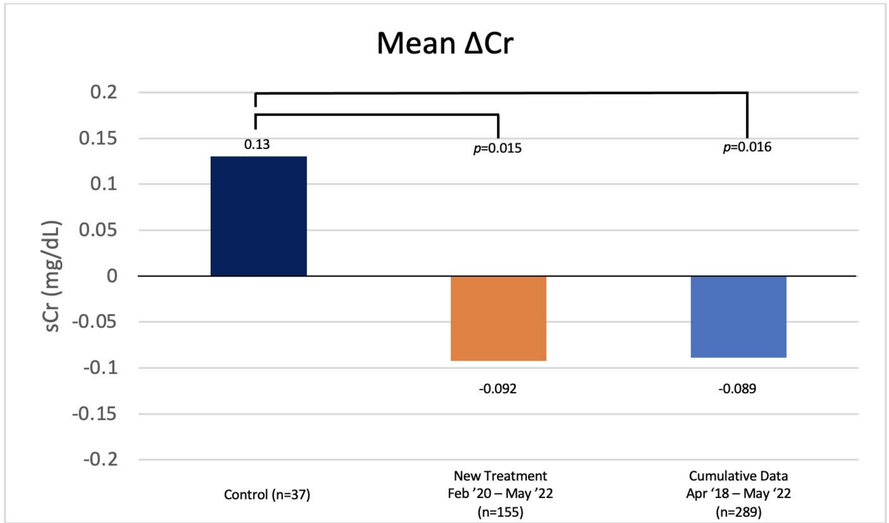

Figure 1. Change in serum creatinine after receiving the high-dose hydration protocol compared to control in new treatment group and cumulative group over the past 4 years.

CONCLUSION

The cumulative experience (pilot and current study) of 289 patients over a 4-year period further demonstrates that the policy of a universal HDHP is safe and associated with a downtrend of ΔCr, and hence could potentially reduce the risk of AKI.

We believe a randomized controlled clinical trial, preferably multi-centered, is still worth pursuing in the future to further validate these replicated findings.

Study limitations: single center experience, relatively small sample size.

METHODS

In April of 2018, we implemented a new HDHP for all PCI patients regardless of their AKI risk. This universal HDHP involves post-PCI normal saline infusion at 125 mL/hr for 12 hours, followed by 100 mL/hr (not exceeding 2 L). In patients with symptomatic left ventricular dysfunction, the rates can be reduced to 100 mL/hr and 75 mL/hr, respectively, or even discontinued at the physician's discretion.

Pre-PCI serum creatinine (Pre-sCr) is obtained the morning of the intervention or just before intervention, while post-PCI serum creatinine (Post-sCr) is obtained within 24 hours, after at least 12 hours of hydration. Peri-procedural fluid management and the use of diuretics were almost exclusively managed by the cardiology team with close coordination with other teams involved in the care of these patients. This protocol was discussed with other involved parties including hospitalists, medical floor, and intensive care unit teams. Our dedicated "chest-pain coordinator" followed all patients to assure compliance with this protocol and to report any deviation or untoward outcomes.

From February 2020 to May 2022, we prospectively applied our protocol for an additional 155 patients who underwent PCI. The control group remained the same as in the pilot study. Post-procedural ΔCr was compared between treatment and control groups.

The statistical analysis was carried out by running a t-test for equality of means between the two groups.

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DISCLOSURE INFORMATION/ACKNOWLEDGEMENTS

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