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Ultra-low CONtraSt PCI vs conVENTional PCI in patients of ACS with increased risk of CI-AKI (CONSaVE-AKI)^{☆, ☆ ☆}

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ABSTRACT

Objectives: This prospective, randomized study assessed short-term outcomes and safety of ultra-low contrast percutaneous coronary intervention (ULC-PCI) vs conventional PCI in high risk for contrast induced acute kidney injury (CI-AKI) patients presenting with acute coronary syndrome (ACS).

Background: Patients at an increased risk of developing CI-AKI can be identified prior to PCI based on their pre-procedural risk scores. ULC-PCI is a novel contrast conservation strategy in such high risk patients for prevention of CI-AKI.

Methods: 82 patients undergoing PCI for ACS were enrolled having estimated glomerular filtration rate (eGFR) < 60 ml/min/1.73 m² and moderate to very high pre-procedural risk of developing CI-AKI as calculated by Maioli risk calculator. They were randomized into two groups of 41 patients each of ULC-PCI (contrast volume ≤ patient's eGFR) and conventional PCI (contrast volume ≤ 3 × patient's eGFR). Primary end point was development of CI-AKI.

Results: Baseline clinical and angiographic characteristics were similar between groups. Primary outcome of CI-AKI occurred more in patients of the conventional PCI group [7 (17.1%)] than in the ULC PCI group [(0 patients), *p* = 0.012]. Contrast volume (41.02 (±9.8) ml vs 112.54 (±25.18) ml; *P* < 0.0001) was markedly lower in the ULC-PCI group. No significant difference in secondary safety outcomes between two study arms at 30 days. IVUS was used in 17% patients in ULC PCI.

Conclusion: ULC-PCI in patients with increased risk of developing CI-AKI is feasible, appears safe, and has the potential to decrease the incidence of CI-AKI specially in resource limited setting such as ours where coronary imaging by IVUS is not possible in every patient.

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Abbreviations: IVUS, Intra Vascular ultrasound; ULC-PCI, Ultra low contrast PCI; CI-AKI, Contrast induced acute kidney injury; CIN, Contrast induced nephropathy; eGFR, estimated glomerular filtration rate.

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1. Introduction

Contrast induced acute kidney injury (CI-AKI) is an unsavory complication after coronary procedures and portends worse cardiovascular outcomes in the short as well as long term.^{1,2} A strong linear association between the amount of contrast used during the procedure and the incidence of CI-AKI has been consistently demonstrated.^{3–5} Apart from peri-procedural hydration, contrast conservation has become the cornerstone of CI-AKI prevention strategy.⁶ It is imperative that the patients at a higher risk of developing CI-AKI be identified prior to the procedure to implement these strategies which are often the only practically “modifiable” component in the hands of an interventionalist.

The risk for development of CI-AKI is a result of complex interplay of several patient related factors. A reduced glomerular filtration rate (GFR) alone may not accurately predict the risk, hence various risk scoring systems have been developed to predict the cumulative effect of these factors on the outcome of CI-AKI.^{3,7} Patients suffering from an acute coronary syndrome (ACS) represent a particularly vulnerable subgroup and are at a threefold higher risk for developing CI-AKI⁸ due to unstable hemodynamics, which may cause renal hypoxia resulting in increased susceptibility for renal dysfunction.

It is a constant source of dilemma for the interventionalist when a patient with ACS with a baseline renal dysfunction and a higher risk of CI-AKI presents. The hesitancy to intervene in such patients over the years has been termed “renalism⁹” and results in drastic underutilization of revascularization by PCI in patients with renal dysfunction and ACS.^{10–12} In view of this ever increasing sub-group of patients, contrast-sparing protocols have been devised to provide them with benefits of revascularization, while guaranteeing preservation of renal function. ‘Ultra-low contrast PCI’ (ULC-PCI) incorporates meticulous contrast sparing techniques along-with the use of imaging in form of intravascular ultrasound (IVUS) to reduce contrast administration, feasibility of which has been studied in small subset of high risk for CI-AKI patients,^{13–15} but no randomized controlled study has been conducted. The aim of this study was to compare and assess ULC-PCI and conventional PCI in terms of safety and short-term outcomes among patients with ACS and an increased pre-procedural risk of developing CI-AKI.

2. Material and methods

2.1. Study design and patient population

The CONSaVE-AKI (Ultra-low CONtraSt PCI vs conVENTional PCI in patients of ACS with increased risk of CI-AKI) study was designed as a prospective, randomized, open-label, single center study. Consecutive patients were enrolled who needed coronary angioplasty for an ACS but were out of window period of primary PCI and had a creatinine clearance of <60 ml/min/1.73 m² as calculated by the Modification of Diet in Renal Disease [MDRM] equation and were having a moderate to high pre-procedural risk of developing CI-AKI after PCI via a risk scoring system [Maioli et al⁷] (Supplementary Fig. 1).

Patients were recruited at least 24 h prior to the procedure. The main exclusion criteria were 1) ACS undergoing primary PCI 2) Chronic Kidney Disease (CKD) on maintenance hemodialysis 3) Less than 18 years of age 4) Patient or relatives not giving consent 5) Chronic Total Occlusion (CTO) lesions (Supplementary Fig. 1).

2.2. Sample size estimation

On the basis of incidence of CI-AKI in a similar study population in previous study¹⁶

Using a sampling ratio of 1, our sample size came out to be 82 patients with 41 in each group at a power of 80% and a confidence interval of 95%. Patients were enrolled consecutively and randomized using simple random allocation by using draw of lots. The randomization was made in the cath lab just before the procedure using a premade total of 82 cards of 41 each for the two groups.

Conventional PCI- defined as a ratio of the contrast volume used to patients eGFR (CV/eGFR) of $\leq 3:1$ ULC-PCI- defined as CV/eGFR ratio of $\leq 1:1$. The study conforms to widely accepted ethical principles guiding human research (such as the Declaration of Helsinki) protocol was approved by the institutional ethics committee and all recruited patients provided informed written consent.

2.3. All patients received pre-hydration with intravenous isotonic saline at a rate of 1 ml per kilogram of body weight per hour (or 0.5 ml per hour in **patients** with severely reduced left ventricular function) starting 12 h prior to the procedure and for 24 h following the procedure

All potential nephrotoxic drugs were withheld.

2.4. Definitions

CI-AKI was defined as increase in serum creatinine ≥ 0.5 mg/dL or $\geq 25\%$ from baseline within 72 h of the procedure or a reduction of urine output to less than 0.5 ml/kg/h within 72 h of contrast administration.^{17,18} Chronic kidney disease (CKD), Acute kidney injury (AKI) and acute kidney disease (AKD) were defined as per the KDIGO guidelines.^{19,20} Lesion severity was defined as per the ACC/AHA guidelines.²¹

2.5. Coronary procedures

The procedure related decisions like access site, catheter selection, stent type, requirement of imaging and pharmacotherapy was left to the discretion of the interventional cardiologist. The contrast used in all cases was iodixanol [Visipaque 270 (GE healthcare) (Ireland, Cork, Ireland)] which is an isosmolar, non-ionic, water-soluble, radiographic contrast. While the conventional PCI was done with standard contrast conservation strategies and preferably to as low as possible, the ULC PCI utilized aggressive contrast sparing strategies¹³ as described in Table 1, Supplementary Figs. 2 and 3.

2.6. Study endpoints

The **primary endpoint** of the study was the incidence of CI-AKI within 72 h following the coronary procedures. Patients were followed for 30 days for **secondary study outcomes** namely, need for dialysis, re-hospitalization for any cause, death from any cause, repeat myocardial infarction or unplanned coronary re-interventions. Blood samples (5 ml) were obtained just prior to the procedure (day 0), after 24 h (day 1) and following 72 h (day 3) and after 1 month of the procedure. Patients were followed up till total of 30 days.

2.7. Statistical analysis

Discrete categorical data was presented as n (%); continuous data was written as either in the form of its mean and standard deviation or in the form of its median and interquartile range, as per the requirement. The Normality of quantitative data was checked by measures of Kolmogorov–Smirnov tests of Normality. Skewed data was compared using Kruskal–Wallis test followed by Mann–Whitney test. Means of normally distributed data for 2 groups was compared using One-Way ANOVA followed by Post Hoc Multiple Comparisons test. For categorical data comparisons was made by Pearson Chi-square test or Fisher’s exact test as appropriate(%). To see relationship of different variables Spearman/Pearson correlation coefficients was calculated. Repetitive measures was done to measure the significance of outcomes with time. All the statistical tests were two-sided and were performed at a significance level of $\alpha = 0.05$. Analysis was conducted using IBM SPSS STATISTICS (version 22.0).

3. Results

3.1. Baseline clinical, angiographic and procedural characteristics

Between 01st December 2019 and 31st August 2021, 82 patients were recruited into the study who were randomized into two groups of 41 patients each for conventional PCI and ULC-PCI. Table 2 highlights the clinical, angiographic and procedural data characteristics of the study groups. In general, there were no differences in clinical characteristics between the groups. In particular, mean age of the total cohort was 60.12 (\pm 8.98) years and mean pre-procedural eGFR of the cohort was 42.02(\pm 09.6) ml/min/1.73 m².

3.2. Outcome data

Table 3 shows study outcome data. The primary outcome of CI-AKI occurred more in patients of the conventional PCI group [7 (17.1%)] than in the ULC-PCI group [(0 patients), $p = 0.012$]. Out of the 7 patients having CI-AKI, 6 patients had stage 1 AKI with recovery and 1 patient had stage 3 AKI requiring dialysis.

The overall eGFR of the total cohort improved post revascularization. While the increase in eGFR in the ULC-PCI group was uniform throughout the follow-up, in the conventional PCI group, there was a significant reduction of eGFR on day 3 of the study when compared to day 1 ($p = 0.002$). The uptrend in eGFR however continued thereafter (Fig. 4).

Follow-up data at 30 days was available for all 82 patients. Secondary outcome occurred in 3 (7.3%) patients in the conventional PCI group and none in the ULC-PCI group with no significant difference between the groups. The three patients had re-hospitalization for worsening heart failure out of whom 2 patients subsequently recovered while 1 (2%) patient required subsequent dialysis and expired.

4. Discussion

Main findings of this study- 1) Patients undergoing conventional PCI had significantly more incidence of CI-AKI than ULC-PCI, 2) ULC-PCI protocol was applicable without lesion restriction (despite high lesion complexity), 3) ULC-PCI protocol was reasonably safe and effective with no difference in secondary safety outcomes between the two study arms, 4) in ACS patients with baseline renal dysfunction, PCI is associated with improved GFR.

CI-AKI has repeatedly been associated with a higher morbidity, mortality^{1,22–26} and health care costs.²⁷ The probability of developing CI-AKI increases with the number of predisposing factors.³ The volume of contrast media used during the procedure in such 'at risk' patients has been shown to be linearly associated with the development of CI-AKI.^{4,28} When the CV/eGFR ratio is less than 1, the risk of CI-AKI is significantly reduced.^{29,30} Every contrast drop should be used in a manner which adds to the decision making process for an optimal procedural outcome. Imaging by IVUS has been shown to be safe and significantly reduces the amount of contrast needed for the procedure³¹ and should be used liberally when required.

The first significant study regarding the feasibility of such an approach was done by Ali et al³² in 31 patients with advanced CKD. Rozenbaum et al performed ULC-angiography in 30 patients¹⁴ and further ULC-PCI (without IVUS) was done in 16 patients. No patient developed CI-AKI and these were the first studies to establish cardiovascular safety and feasibility of performing ULC-PCI. Azzalini

et al¹⁵ performed a non-randomized, retrospective study including 8 patients of ULC-PCI with 88% technical success where no patient developed CI-AKI as compared to 15.5% patients developing CI-AKI in the conventional PCI group. Prathap kumar et al^{33,34} performed zero contrast PCI in 15 patients with complex lesion characteristics like left main lesions and chronic total occlusion lesions with 100% technical success under IVUS guidance and reported favorable outcomes. These studies suggest that ULC-PCI either guided by angiography alone or with additional IVUS usage is feasible and can safely be used in patients with renal dysfunction to reduce the incidence of CI-AKI. Compared with Ali et al study,³² the angiographic and procedural complexity of our ULC-PCI cohort was more pronounced and at par with that in the study by Azzalini et al.¹⁵ The prevalence of B2/C lesions was 70% in our study, compared with 42% in Ali et al³² and 100% in Azzalini et al¹⁵ study respectively.

Our strategy of performing ultra-low contrast PCI was to combine the aggressive contrast conservation strategies to keep the CV/eGFR ratio ≤ 1 and if not possible to do so like in complex lesions or in multivessel involvement, to utilize IVUS as the imaging modality of choice for performing the procedure. The higher mean eGFR of our ULC-PCI arm [(as compared to previous studies (table 4)] allowed us to be less liberal with the use of IVUS guided imaging (17%). This strategy helped us reduce the contrast utilization drastically and also to effectively reduce the incidence of CI-AKI. It also becomes particularly useful in resource limited setting where coronary imaging is not always possible in every patient. Multivessel PCI was also performed in the same setting in patients who presented with multivessel involvement apart from the culprit artery causing ACS which is often the finding in CKD patients.³⁵ Overall trend in our patient cohort was of improvement in eGFR post PCI in spite of the additional insult of contrast administration and was probably related to the improved hemodynamics post revascularization. Prior to the present study, no clinical outcome based study had been performed to compare ULC-PCI and conventional PCI in a randomized manner. Our study provides insights into the feasibility of ULC-PCI and shows that it may be effective and safe in real-life practice.

Our study though is not without limitations first, this is a single-center study. Second, all procedures were exclusively performed by one experienced operator, so that the widespread applicability of the ULC-PCI protocol could not be evaluated. Third, patients of STEMI for primary PCI and patients with CTO lesions were excluded. Therefore, our results should be extrapolated to these patients with extreme caution. Finally, we had a limited follow-up of 30 days for assessing the adequacy of safety secondary outcomes.

5. Conclusion

In conclusion, The ULC-PCI protocol when compared with conventional PCI was reasonably safe and effective in reducing the incidence of CI-AKI in a high risk cohort, with no significant difference in secondary safety outcomes between the two study arms. The utilization of this protocol may increase the utilization of PCI in high-risk coronary patients with renal dysfunction and a high pre-procedural risk to develop CI-AKI.

What is known?

Contrast induced acute kidney injury (CI-AKI) is an unsavory complication after coronary procedures and portends worse cardiovascular outcomes in the short as well as long term.

What is new?

Our study provides insights into the feasibility of ULC-PCI and shows that it may be effective and safe in real-life practice over conventional PCI specially in high risk patients and in resource limited settings where coronary imaging is not always possible in every patient.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ihj.2022.08.004>.

APPENDICES

Table 1
Contrast reduction techniques utilized in ULC-PCI

Visipaque contrast 1:1 dilution. Previous angiographic images to be displayed alongside.
Use of small caliber catheters if permissible and without side-holes. Avoid puffing for guidance during the procedure
Guide to be hooked without contrast usage and confirmed by passage of a coronary guidewire into the artery by following the course of the vessel in the reference screen.
Workhorse wire to be preferred with meticulous insertion in order to avoid accidental side-branch wiring.
Confirm proper hooking of the guide with 10–20 ml of normal saline to induce temporal ECG repolarization changes (Fig. 2a)
Positioning of the stent to be done either by landmarks or strategic placement of additional guidewires into the side-branches to create a metallic silhouette. If the landing zones of the stent are highly mobile and stent placement seems difficult, 'marking wire technique' to be used with the use of an additional guidewire (Fig. 2).
Slightly longer stents to be preferred to avoid multiple contrast injections for stent positioning

Table 2
Baseline clinical, angiographic and procedural characteristics

VARIABLE	TOTAL (N = 82)	ULC-PCI (N = 41)	CONVENTIONAL PCI (N = 41)	P VALUE
Age (years) (S.D.)	60.8 (±8.47)	61.44 (±8.8)	60.17 (±8.17)	0.501
Age >73 years	13 (16%)	8 (20%)	5 (12%)	0.547
Sex	Male			
Diabetes	61 (74%)	31 (76%)	30 (73%)	1.0
Hypertension	66 (80.5%)	34 (83%)	32 (78%)	0.781
Anaemia	64 (78%)	28 (68%)	36 (88%)	0.06
Hypotension	60 (73.2%)	30 (73%)	30 (73%)	1.0
Heart failure Killip class				
Class I	6 (7.3%)	2 (4.9%)	4 (9.8%)	0.675
Class II	65 (79.3%)	32 (78%)	33 (80.5%)	0.641
Class III	9 (11%)	6 (14.6%)	3 (7.3%)	
Class IV	2 (2.4%)	1 (2.4%)	1 (2.4%)	
Class V	6 (7.3%)	2 (4.9%)	4 (9.8%)	
Estimated GFR (mL/min/1.73 m ²) (S.D.)	42.02 (±09.6)	42.20 (±9.96)	41.87 (±9.34)	0.878
Serum creatinine prior to procedure	1.653 (±0.471)	1.644 (±0.426)	1.62 (±0.504)	0.786
GFR <44 ml/min/1.73 m ²	56 (68.3%)	29 (70.7%)	27 (65.9%)	0.813
GFR <30 ml/min/1.73 m ²	14 (17.1%)	6 (14.6%)	8 (19.5%)	0.770
Acute kidney Disease	30 (36.6%)	15 (36.6%)	15 (36.6%)	1.0
Chronic kidney disease	52 (63.4%)	26 (63.4%)	26 (63.4%)	1.0
Maioli risk score	7.2 (±1.9)	7.37 (±2.01)	7.02 (±1.8)	0.424
SVD	32 (39%)	18 (22%)	14 (17%)	0.497
DVD	35 (43%)	17 (21%)	18 (22%)	1.0
TVD	15 (18%)	6 (7%)	9 (12%)	0.276
Target vessel				
LAD	50 (45%)	23 (21%)	27 (24%)	1.0
LCX-OM	23 (21%)	11 (10%)	12 (11%)	1.0
RCA	33 (29%)	15 (13%)	18 (16%)	1.0
PDA/PLV	3 (3%)	0 (0%)	3 (3%)	0.241
LM	3 (3%)	1 (1%)	2 (2%)	1.0
SVG-OM	1 (1.2%)	1 (2.4%)	0	1.0
Lesion complexity (ACC/AHA)				
Type A	5 (6%)	4 (5%)	1 (1%)	0.359
Type B1	20 (24%)	11 (13%)	9 (11%)	0.798
Type B2	22 (27%)	11 (13%)	11 (13%)	1.0
Type C	35 (43%)	15 (18%)	20 (24%)	0.372
Number of Stents placed (DES)	1.59 (±0.68)	1.46 (±0.66)	1.71 (±0.71)	0.107
Contrast volume used (ml)	76.78 (±40.68)	41.02 (±9.8)	112.54 (±25.18)	<0.0001
Use of IVUS guidance	8 (9.7%)	7 (17%)	1 (2.4%)	<0.0001
CV/eGFR (ratio)	1.8 (±0.88)	0.976 (±0.08)	2.68 (±0.35)	<0.0001
Fluoroscopy time (min)	34.77 (±8.06)	36.46 (±8.84)	33.07 (±6.90)	0.056

ULC-PCI – Ultra-low contrast PCI, CAD – coronary artery disease, ACS – acute coronary syndrome. () Parenthesis mark the percentages or the standard deviation as highlighted.

Table 3
Study outcomes

VARIABLE		TOTAL (N = 82)	ULC-PCI (N = 41)	CONVENTIONAL PCI (N = 41)	P VALUE
Primary outcome		7 (8.5%)	0 (0%)	7 (17.1%)	0.012
Primary outcome	Moderate risk group, 32 (39%)	1/32 (3.1%)	0/17 (0%)	1/15 (6.7%)	0.469
	High risk group, 35 (42.7%)	3/35 (8.6%)	0/14 (0%)	3/21 (14.3%)	0.259
	Very high risk group 15 (18.3%)	3/15 (20%)	0/10 (0%)	3/5 (60%)	0.022
	High + Very high risk group, 49 (60%)	6/49 (12.2%)	0/23 (0%)	6/26 (23%)	0.024
CI-AKI		7 (8.55%)	0 (0%)	7 (17.1%)	0.012
CI-AKI day 1		1 (1.2%)	0 (0%)	1 (2.4%)	1.0
CI-AKI day 3		6 (7.3%)	0 (0%)	6 (14.6%)	0.026
CI-AKI day 30		0 (0%)	0 (0%)	0 (0%)	1.0
Estimated GFR (mL/min/1.73 m ²)	GFR day 0	42.02 (±09.6)	42.20 (±9.96)	41.87 (±9.34)	0.878
	GFR day 1	45.22 (±10.58)	46.01 (±10.58)	44.43 (±10.64)	0.501
	GFR day 3	44.99 (±12.34)	48.58 (±12.38)	41.4 (±11.56)	0.008
	GFR day 30	47.38 (±11.86)	49.35 (±12.18)	45.36 (±11.32)	0.131
Need for dialysis		1 (1%)	0 (0%)	1 (2%)	1
Secondary outcome		3 (3.7%)	0 (0%)	3 (7.3%)	0.241
Re-hospitalization		3 (3.7%)	0 (0%)	3 (7.3%)	0.241
Death from any cause		1 (1%)	0 (0%)	1 (2%)	1
Repeat MI		0 (0%)	0 (0%)	0 (0%)	0
Unplanned coronary interventions/Stent thrombosis		0 (0%)	0 (0%)	0 (0%)	0

ULC-PCI – Ultra-low contrast PCI, CV – contrast volume, GFR – glomerular filtration rate, SVD – single vessel disease, DVD – double vessel disease, TVD – triple vessel disease, LM – left main artery, LAD – left anterior descending, LCx-OM – Left circumflex-obtuse marginal, RCA – right coronary artery, PDA-PLV – Posterior descending artery-posterior left ventricular artery, PCI – percutaneous coronary intervention, Type B1, B2, C lesion – according to the ACC/AHA - American college of cardiology/American heart association category of type of coronary artery lesion, IVUS – intravascular ultrasound, DES – drug eluting stents.

Table 4
Comparison of studies exploring ultra-low contrast techniques

	Nayak et al ¹³ 2010	Ali et al ³² 2016 (Staged PCI)	Rozenbaum et al ¹⁴ 2018	Sacha et al ³⁶ (Staged PCI) 2019	Azzalini et al ¹⁶ 2019		Kumar et al ³³ 2021	CONSAVE-AKI		CONSAVE-AKI ULC-PCI Under IVUS
					ULC-PCI	Conventional PCI		ULC-PCI	Conventional PCI	
Patients (n)	4	31	16	20	8	103	15	42	42	7
Indication for PCI (Major)	CSA	CSA	ACS	ACS	CSA + ACS		CSA	ACS		ACS
eGFR (ml/min/1.73 m ²)	21.5	16	31.8	24.8	19	25	31	42	41.8	29
Contrast volume (ml)	9	0	26	5	8.8	90	<eGFR f/b ZC-PCI	41	112.5	29
CV per stent (ml)	9	0	20	2.5	8.8	76	NIL	28	66.2	15
Stents placed (mean)	–	1	1.31	2	1	1	2.5	1.46	1.71	2
IVUS	100%	100% + FFR	0%	IVUS	100%	16%	100	17%	2.3%	100%
CV/eGFR	0.42	–	0.82	–	0.5	3.9	<1	0.97	2.68	1
CI-AKI	Nil	Nil	Nil	10%	Nil	15.5%	NIL	Nil	17.1%	Nil
Type B2/C lesion	–	42%	38%	–	100%	–	–	70%	–	–

PCI – percutaneous coronary intervention, eGFR – estimated glomerular filtration rate, CV – contrast volume, IVUS – intravascular ultrasound, CI-AKI – contrast induced acute kidney injury, Type B1, B2, C lesion – according to the ACC/AHA - American college of cardiology/American heart association category of type of coronary artery lesion, ULC-PCI – Ultra-low contrast PCI.

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