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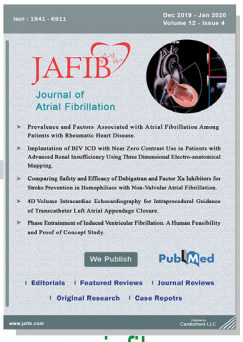

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Implantation of BIV ICD with Near Zero Contrast Use in Patients with Advanced Renal Insufficiency Using Three Dimensional Electro-anatomical Mapping.

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Abstract

Background: Biventricular (BIV) ICD implantations are traditionally performed using contrast and fluoroscopic guidance. Contrast use in patient with advanced renal disease can cause deterioration of renal function and even lead to dialysis.

Objective: To evaluate the feasibility of utilizing 3 D mapping technique in reducing or eliminating contrast use in patient with advanced renal disease.

Methods and Results: The study consisted of 30 consecutive adult patients, in which BIV implantation was accomplished in advanced renal disease (stage III and IV GFR 15 to 59) by electroanatomical 3D mapping (EAM).

Acute procedural success was 96% and only one patient LV lead implantation was unsuccessful due to unsuitable anatomy.

47 % of patients had BIV ICD implantation with zero contrast. Average contrast exposure for the group was 4.3 ml only. Average ratio of contrast use to GFR (glomerular filtration rate) was only 0.1. Improved mean GFR was observed from 42 to 50 post procedure (P value<0.01), and continued to improve to 48 at 3 and 6 month (P value<0.01) and improvement decreased to 45 and 44 beyond 6 month and 1 year (P value NS). There was no single case of contrast induced acute renal insufficiency (CI-ARI) due to minimal use of contrast.

69 % of the patients experienced an improvement in their functional class. A decrease in QRS duration was seen from 159 to 136 milliseconds (86% of patients had improved QRS duration); P value = <0.001. The average pre procedure ejection fraction (EF) for the group was 23%. The average EF post procedure for the group was 35%; P values = <0.001 (72% of patient had EF improvement).

93% of patient had either EF and/or GFR improvement suggesting substantial clinical benefit from the procedure.

There was no minor or major complications.

Conclusions: Implantation of BiV ICD using EAM with near zero contrast is feasible, safe and effective in patients with moderate to severe renal insufficiency. There is an added renal protection and benefit from procedure in this group of patients.

Introduction

The use of fluoroscopy has long proven itself as an invaluable tool in many cardiovascular procedures such as pacemaker and defibrillator implantation. More specifically, fluoroscopy aids in defining anatomical structures, navigation through those anatomical structures of the heart and allows for accurate fixation of the leads within the chambers of the heart.[1,2,3]

One prime example for the use of fluoroscopy arises with implantation of biventricular devices for resynchronization therapy. During the procedure, fluoroscopy helps to locate the ostium of the coronary sinus thereby allowing access for the LV lead. [4]

However, there is a variable degree of variance from person to person in regards to the anatomical location of the ostium. Likewise, it can be difficult to accurately define the anatomy within the heart. It is this variance that often lends itself to prolonged fluoroscopy times related to anatomical complexity. Furthermore, the fluoroscopy only provides a 2D view of catheter movement and position within the heart at times making it difficult to adequately position catheters. These limitations only increase the complexity of the case and leads to greater radiation and contrast exposure to the patient.

We have shown in our prior study the feasibility of 3 D mapping to reduce fluoroscopy and contrast use in patient with normal renal function. [1] However, there is no study to our knowledge that evaluated the feasibility of EAM in BIV ICD implantation in patients with advanced renal disease largely because of increased threat for of CI-AKI in those patients. This makes the utility of implantation of CRT device in patients with advanced renal disease limited and restricted and in most cases not even offered for fear of needing dialysis post procedure.

Aim of study

To evaluate the feasibility of EAM in reducing contrast exposure during implantation of BIV ICD or CRT device in patients with advanced renal disease.

Key Words

BiV ICD, Near Zero Contrast, Advanced renal disease, Three dimensional Electro-anatomical Mapping.

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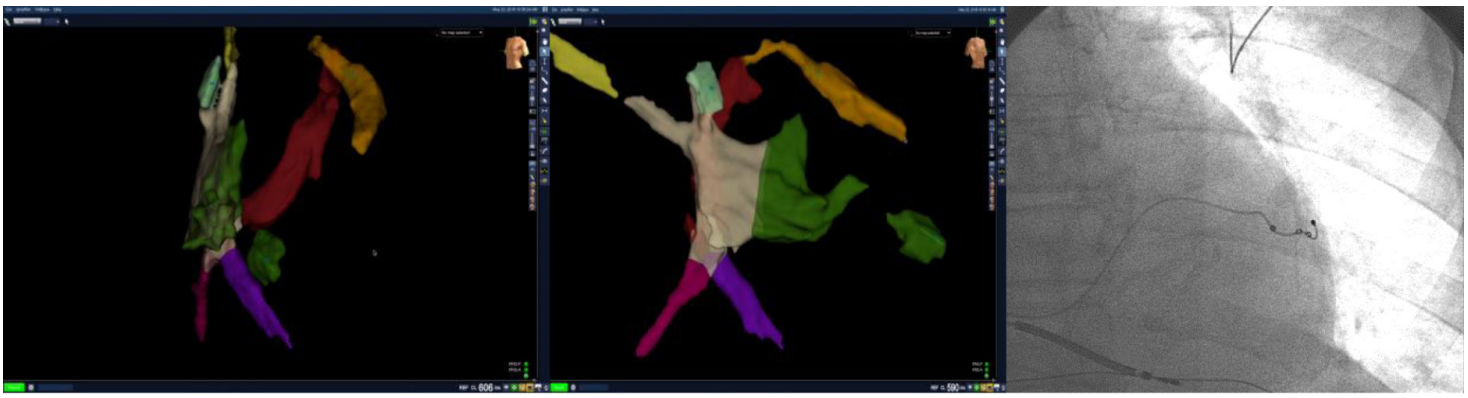

Figure 1: EAM of the coronary sinus veins with segmentation of the heart chambers and coronary venous branches using different colors (LAO and RAO projections)

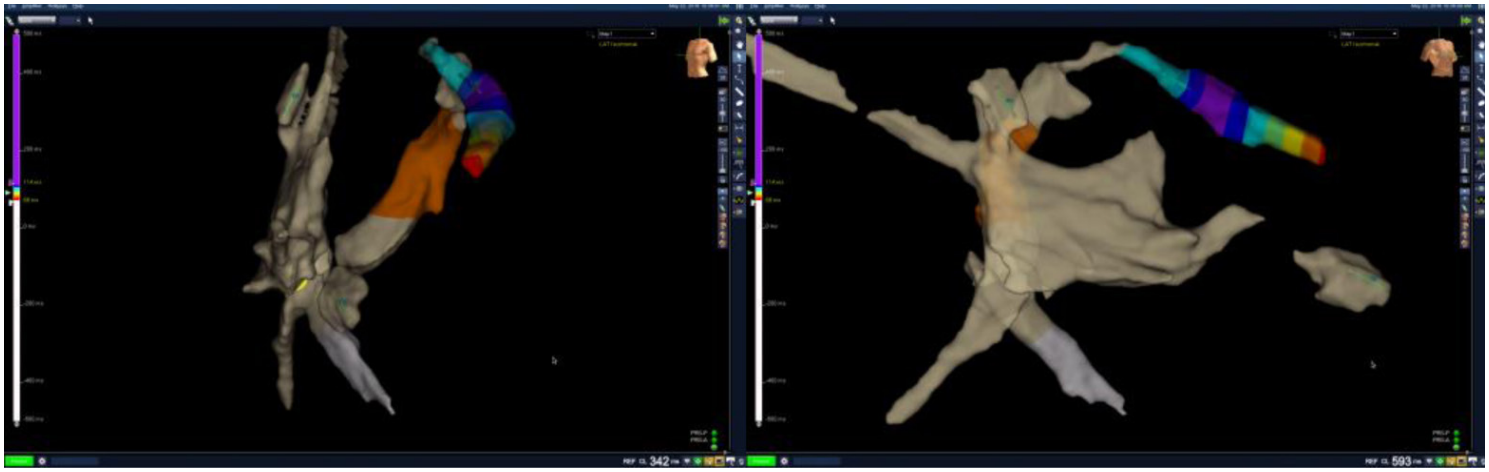

Figure 2: EAM of the coronary sinus veins with activation mapping showing the latest delay marked by the purple color at the mid left lateral branch. With fluoroscopy showing lead position in LAO 15 degree projection .

Table 1: Baseline characteristics for patients.

Age	Average 70	(55-86)		
Gender	24 Male 6 Female			
Indication	LBBB (23)	RBBB (2)	RV pacing (1)	IVCD (4)
GFR	Average 41 (19-56)			
EF	23 (9-35)			
QRSD	158 (120-207)			
Functional class	25(class III), 4(class II)1(class IV)			
CKD stage	3(stage 4), 26 (stage 3)			

Methods

A retrospective analysis was performed on the last 30 consecutive cases where 3D-EAM was employed for BIV ICD implantation in patients with chronic renal disease. Chronic renal disease being defined as a patient whose GFR was 15 to 59 ml/min at baseline (n = 30). The technique employed for the implantations has been outlined below in step-like fashion.

Qualitative baseline data was obtained which included procedure indication, age, gender, functional class of heart failure, GFR pre, QRS duration pre, and ejection fraction pre for group.

Procedure outcome data was also collected and included total procedure time, total fluoroscopy time, total contrast used, GFR pre/post , QRS duration pre/post , and ejection fraction pre/post [Table 2]. Furthermore, GFR was monitored at time of implant, 0-1 month, 1-3 months, 3-6 months, 6-12 months and >12months [Figure 2]

Averages for these categories were then calculated for the group [Table 1,2].

Procedure for Near Zero contrast implantation of BIV ICD

1- Procedures were performed under monitored anesthesia care. Ultrasound (Sonosite) left axillary venous micropunture access was done eliminating need for fluoroscopy or contrast during these steps.

2- A Deflectable Quad 6 Fr EP catheter was advanced via the left axillary vein into the right atrium, right ventricle and into the CS while obtaining anatomy of the cardiac chambers using Ensite or precision St Jude/Abbott 3D mapping system [Figure 1]

Table 2: Procedural outcome .

Cases	GFR Pre	Post GFR 0-1mo	Post GFR 1-3 mo	Post GFR 3-6 mo	Post GFR 6-12 mo	Post GFR >12 mo	EF pre	EF post	Contrast (ml)	Ratio of contrast to GFR	Fluoroscopy time(min)	QRS pre (ms)	QRS post (ms)	Functional Class Pre	Functional Class Post	CKD Stage	Total Procedure Time (mins)
Case 1	33	33	39	27	27	41	25	25	0	0.00	0.3	151	122	2	1	3	61
Case 2	19	29	24	29	30	29	15	35	0	0.00	2.4	160	120	3	3	4	86
Case 3	46	48	47	47	39	45	22	22	0	0.00	6.2	152	144	3	3	3	146
Case 4	27	37	31	31	31	21	34	35	6	0.22	5.5	187	148	3	3	4	129
Case 5	50	56	56	56	56	56	30	40	0	0.00	3.11	159	129	3	1	3	103
Case 6	47	56	56	45	45	59	25	25	10	0.21	16.6	158	138	3	2	3	81
Case 7	40	40	31	44	25	28	30	47	0	0.00	1.22	153	118	2	1	3	81
Case 8	34	30	30	30	29	27	22	50	0	0.00	2.3	180	144	3	2	3	98
Case 9	45	46	54	54	57	77	23	45	4	0.09	19.5	174	159	4	2	3	198
Case 10	34	50	37	54	60	44	29	60	5	0.15	9.1	140	124	3	2	3	113
Case 11	28	32	32	32	35	32	35	45	0	0.00	12.3	197	125	3	3	4	132
Case 12	45	51	51	51	36	36	25	35	5	0.11	4.8	139	123	3	2	3	111
Case 13	46	52	58	43	31	37	13	21	10	0.22	5.1	132	144	3	3	3	86
Case 14	38	45	45	45	44	41	25	40	0	0.00	4.7	151	121	3	2	3	99
Case 15	47	68	68	68	64	65	15	15	0	0.00	1.9	183	153	3	1	3	123
Case 16	47	66	52	50	52	46	30	45	2	0.04	12.3	135	118	3	1	3	106
Case 17	47	61	57	49	49	46	30	25	8	0.17	12.3	165	142	3	1	3	120
Case 18	49	57	66	58	58	48	30	35	15	0.31	11.7	180	134	3	2	3	135
Case 19	44	56	50	58	53	44	15	26	3	0.07	5.1	118	110	3	3	3	70
Case 20	46	56	56	56	46	49	9	10	0	0.00	13.4	126	135	3	2	3	213
Case 21	39	33	33	33	34	29	30	45	3	0.08	13	150	112	3	2	3	195
Case 22	45	44	44	55	61	61	35	65	0	0.00	3.5	148	111	3	1	3	95
Case 23	45	45	44	44	50	41	20	30	24	0.53	7	188	126	2	1	3	95
Case 24	48	45	45	45	45	45	20	40	0	0.00	5.1	207	197	3	1	3	96
Case 25	41	57	45	47	43	37	10	LV lead not placed	3	0.07	18.4	170	170	3	3	3	153
Case 26	43	53	71	71	45	45	20	15	12	0.28	6.9	156	151	3	3	3	105
Case 27	39	60	48	42	39	39	30	45	4	0.10	14.22	159	162	2	1	3	97
Case 28	43	67	67	67	57	47	25	45	0	0.00	2.1	123	124	3	3	3	87
Case 29	47	60	41	44	46	41	10	32	0	0.00	2.3	180	137	3	1	3	77
Case 30	49	68	58	58	58	58	19	25	15	0.31	14.2	134	121	3	2	3	115
AVERAGE	41.70	50.03	47.87	47.77	44.83	43.80	23.37	35.28	4.30	0.10	7.89	158.50	135.40	2.90	1.93	3.10	113.53

3- The RV lead was then advanced under EAM into the RV, the bipolar electrodes of the lead were attached to alligator clips in one terminal, and to the EP box in the other terminal and was displayed on the EP monitor. Care was taken not to apply more than usual mild pressure during advancement of any catheters or leads. R wave amplitude was monitored during advancement and a threshold of 5 mV or more was used as adequate marker for good endocardial lead contact.

Appropriate apical lead position was confirmed by EKG RV Pacing configuration or by limited fluoroscopy.

A snap shot fluoroscopy which was usually done after helix deployment to confirm adequate slack and helix deployment.

4. Likewise, RA lead advanced under EAM in the right atrium, parked in place to be later placed in the appendage at the end of LV lead implantation after peeling of left ventricular lead sheath.

5- An EP deflectable Quad 4 fr. catheter (St Jude INQUIRY) was advanced as a unit with the guiding coronary sinus (CS) sheath into the 9 fr. sheath and into the right atrium under EAM, alternatively the 6 Fr deflectable EP catheters were used.

Care was given to allow 3-5 cms of the EP catheter out of the sheath during advancement to avoid sheath trauma to the veins or the heart. The coronary sinus was subsequently cannulated under EAM as well as EGM guidance. This step was facilitated by the prior EAM of the coronary sinus. The 4 fr. EP catheter was advanced further towards the lateral border of the heart which acted as a support to advance the outer guiding sheath.

If during advancement of the EP catheter one of the branches of the lateral veins were cannulated we used this opportunity to advance the outer sheath at the os of that vein for later insertion of the coronary sinus lead through the guiding sheath.

6- The outer sheath was then advanced over the 4 fr EP catheter to the outer third of the coronary sinus and the 4 fr. EP catheter was then removed.

7- The LV lead was subsequently advanced through the outer guiding sheath with the BMW wire as one unit, BMW wire was protruding 2-3 cm outside the lead and a slight bend was previously shaped into the wire to allow for sub-selection of the target vein.

This was done also under EAM with the lead likewise connected

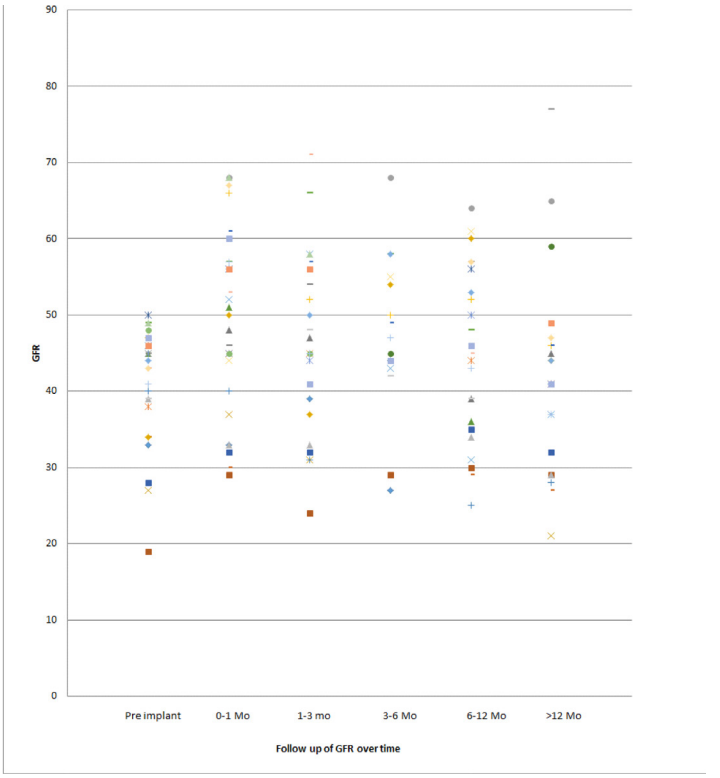

Figure 3: **Pre and post procedure GFR presented for the 30 patients in the NZC group notice the remarkable improvement post procedure first 6 months.**

to the connecting box via standard alligator clips. The lead with the BMW wire was used as one unit to try to cannulate the target vein if any resistance was felt the unit was withdrawn back to sheath to straighten the lead and another attempt is made till target vein was cannulated.

The targeted vein was previously identified from prior coronary venous road map. If map is not available careful various manipulations of lead, wire, subselective sheaths inserted with the 4 fr EP catheter were usually sufficient to subselect a branch.

Selection is preferred in the lateral and posterior aspect of the LV . Also, basal or mid segments of the LV were achieved in all cases. If multiple branches were cannulated we usually chose the more lateral branch with more LV to RV separation, alternatively the branch with the latest LV activation is chosen to maximize CRT benefit to patients [Figure 1]. We also used the multipolar Quatro (St Jude) LV lead in most cases to help with multiple configurations in case of diaphragmatic pacing or high thresholds. We also used the multi-pacing device option if there are more than 2 good thresholds available.

8- Limited Fluoroscopic exposure was done usually snap shot in RAO and LAO to assess if the three leads have adequate slack and if the helix of the atrial and right ventricular leads were properly deployed. It also confirms that all lead positions are adequate. Adding or removing of slack if needed was done at this stage.

9- Pacing optimization was done in multiple vectors and VV timing optimization done to choose the narrowest QRSd or the most delayed portion of the LV.

10- Patients with more difficult anatomy limited fluoroscopy and contrast was needed to overcome difficulty in the usual traditional way.

Results

The study consisted of 30 consecutive adult patients, in which BIV implantation was accomplished in advanced renal disease (stage III and IV GFR 15 to 59) by EAM. Acute procedural success was 96% and only one patient LV lead implantation was unsuccessful due to unsuitable anatomy.

There were no major or minor complications amongst the group. There were no changes in lead performance in all devices during follow up.

47% of patient had there BIV ICD implantation with zero contrast. Average contrast exposure for the group was 4.3 ml. Average ratio of contrast use to GFR (glomerular filtration rate) was only 0.1. Improved mean GFR was observed from 42 to 50 post procedure (P value <0.01), continued to improve to 48 at 3 and 6 months (65% of patients had GFR improvement at 3 months) (p value <0.01) and improvement decreased to 45 and 44 beyond 6 month and 1 year (P value NS). There was no single case of contrast induced acute renal insufficiency (CI-ARI) due to minimal use of contrast.

Sixty nine percent of the patients experienced an improvement in their functional class. Furthermore, a decrease in QRS duration was seen from 159 to 136 milliseconds P value= <0.001 (86% of patients had improved QRS duration). The average pre procedure EF for the group was 23%. The average EF post procedure for the NZC group was 35% P values = <0.001 (72% of patient had EF improvement).

One hundred percent of the patients who had BiV implanted experienced GFR improvement, QRS improvement and/or EF improvement [Figure 4] of which 93% had either EF and/or GFR improvement suggesting substantial clinical benefit from the procedure.

62% of patients with improved EF had a concomitant improvement of GFR. We also noted that all 7 patients with EF < 20 had a significant improvement of GFR suggesting even more benefit in those patients with severely reduced EF due to improvement of cardio renal syndrome.

Total fluoroscopy exposure was minimal with an average fluoroscopy time of 7.9 minutes.

Discussion

Cardiac resynchronization therapy (CRT) with an implantable cardioverter-defibrillator (ICD) plays an important role in reducing heart failure morbidity and improving survival in patients with severe left ventricular (LV) dysfunction, intraventricular conduction

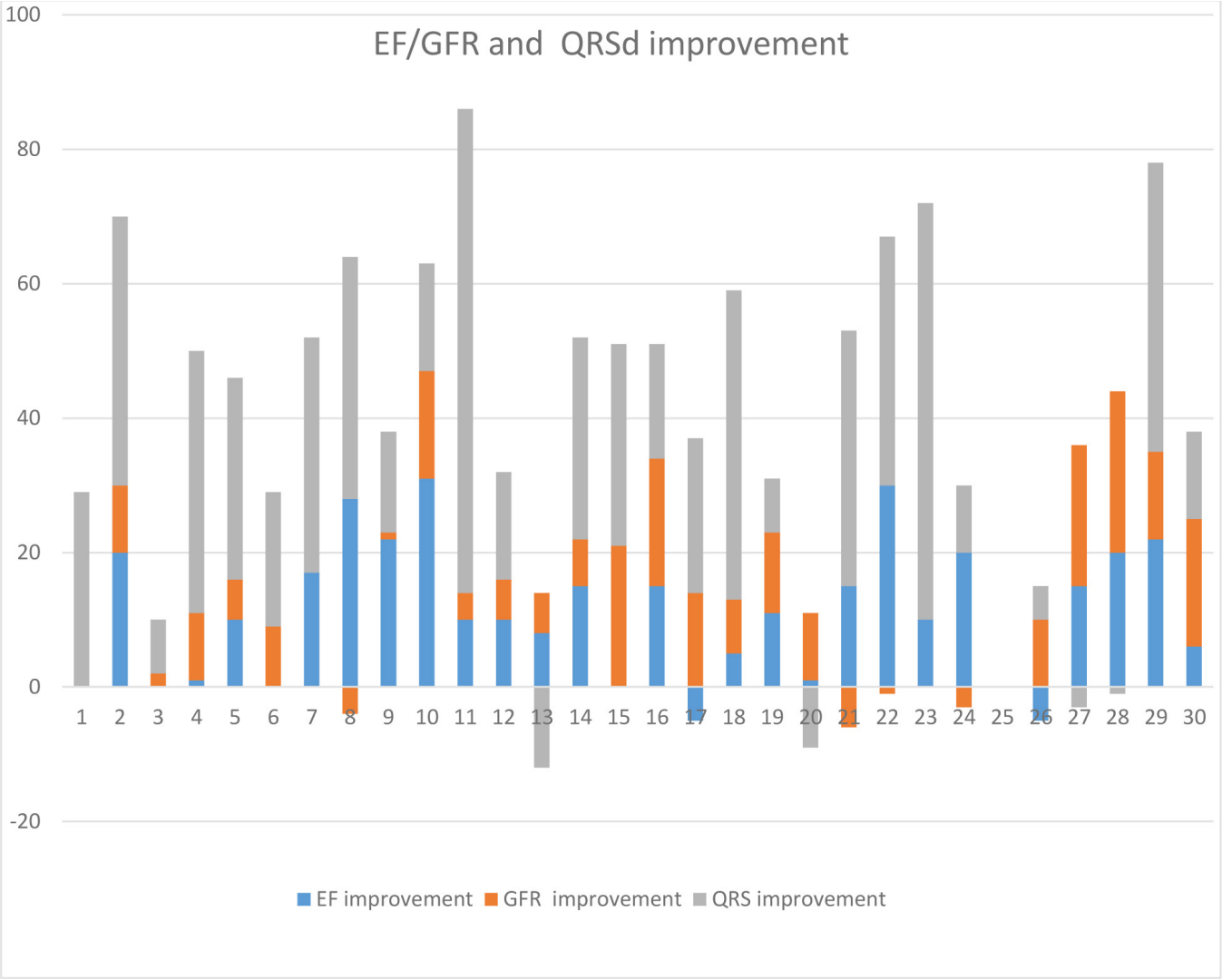

Figure 4: **Diagram showing EF improvement, GFR Improvement and QRS improvement post procedure.**

delay, and heart failure symptoms despite optimal medical therapy. However, there are still significant limitations to this therapy. For one, biventricular device implantation may be associated with significant radiation and contrast exposure. In addition, approximately 30% of patients do not experience improvements in heart failure symptoms or LV function with CRT [5].

However, the number of BIV ICD implantations is increasing due to inclusion of class II and class I ischemic patients with LBBB as indications. Patients undergoing these procedures can be exposed to a significant amount of radiation and contrast. Some patients also undergo multiple procedures further adding to their cumulative radiation and contrast exposure.

For the most part, the use of 3D EAM for identifying anatomical structures of the heart had been relegated to EP studies and ablations. [6, 14] As the technology continues to advance, its applications are growing. The technology has advanced enough allowing Naurizio Del Greco and colleagues to demonstrate feasibility of electroanatomical mapping in the implantation of a CRT-ICD device. [2] These findings were replicated by our prior cohort study demonstrating the safety and feasibility of EAM in BIV ICD implantation. [1]

Another area driving the push for implementation of electroanatomical 3D mapping involves the subset of patients in which fluoroscopy or contrast exposure poses too high of a risk or is even contraindicated. These subsets include the pediatric patient, those patients who are pregnant and patients with advanced renal disease.

Jason Payne MD and colleagues demonstrated the use of electroanatomical mapping in the implantation of pacemaker in a pregnant patient.[7]

Individuals with chronic kidney disease or near end stage kidney disease represent another high risk population. In this population exposure to contrast may induce further renal damage and possibly lead to dialysis. Celik and his colleagues identified independent

predictors for CI-AKI as low ventricular ejection fraction, e-GFR < 60ml/min and contrast volume (CV)-e-GFR ratio of greater than 2 in patients undergoing primary PCI.[8] Furthermore, contrast volume to GFR ratio of 3.9 has been specified to predict CIN development with 71% sensitivity and 80% specificity in patients undergoing TAVI.[9]

CI-AKI is a serious and frequent procedural complication of CRT-D implantation with a significant negative influence on long-term survival [10]. The risk of CI-AKI with CRT implantations is substantial. Data on CI-AKI in patients undergoing cardiac resynchronization therapy is limited.

Of the data available the TRUST CRT trial showed that among the 98 subjects of the trial, 10 patients (10.2 %) developed CI-AKI after CRT-D implantation.[7] In patients with glomerular filtration rate (GFR) <60 mL/min/1.73 m2 on admission, the incidence of CI-AKI was almost two-fold (15.4 %) higher than in subjects with GFR ≥60 (8.3 %). CRT-D recipients with CI-AKI had significantly higher mortality rate (50.0 %) compared to those without CI-AKI (17.0 %) during 30 months of follow-up. [11]

Furthermore, Cowburn et al. demonstrated 14 % occurrence of contrast-induced nephropathy defined as at least 25 % increase in serum creatinine from the baseline within 48 h after contrast exposure during CRT implantation. [10]

According to CIN (contrast induced nephropathy)Consensus Working Panel from 2006, CIN is responsible for approximately 11 % of hospital-acquired renal failure cases [9] Thus, these findings coming mainly from registries, where coronary angiograms and PCI were the leading causes of CI-AKI, are similar to the incidence of CI-AKI demonstrated in CRT recipients.[12]

Gregory A. Tester et al were able to demonstrate this in their large subject population (Eight hundred and twenty-two subjects) in which patients were divided based on the amount of procedural contrast used into tertile 1 (<55 mL, 257 patients), tertile 2 (55–94 mL, 261 patients), and tertile 3 (≥95 mL, 304 patients). Contrast-induced nephropathy occurred in 5.4% of patients in tertile 1, 5.4% in tertile 2 and 11.8% in tertile 3 (P = 0.004). Among the tertiles, lead positioning was optimal in 95, 80 and 66%, respectively (P < 0.0001). In this study most patients had kidney function baseline GFR 57 ± 21 mL/min. [13]

It is therefore expected that CIN would be even more substantiated with patients with poor renal function.

We have shown in prior study the feasibility of 3 D mapping to reduce fluoroscopy use in patients with normal renal function. However, there is no study to our knowledge that evaluated the feasibility of EAM in BIV ICD implantation in patients with advanced renal disease largely because of increased threat for of CI-AKI in those patients. Making the utility of implantation of CRT device in patients with advanced renal disease restricted and in most cases not even offered for fear of needing dialysis post procedure. In our paper we were able to substantially reduce contrast exposure to minimal with an average contrast volume to GFR ratio of 0.10 and maximum ratio of 0.2 which is well below the ratio of 2 at which CI-AKI is observed in other studies.

This is the first study to demonstrate feasibility of EAM in near elimination of contrast use during BIV implantation in patients with advanced renal disease. A population in which the risk for contrast induced nephropathy is substantial as described above. Despite the added steps of EAM there was a favorable procedure time which may be attributed to the facilitation of 3 D mapping to navigate leads in target sites rather than 2 D fluoroscopy technology, also the use of Quadripolar leads in selected cases may have eliminated some time when diaphragmatic stimulation or high thresholds were encountered.

Study Limitation

We do recognize a number of limitations to our study which includes small, non-randomized study, performed by a single operator who has experience in use of EAM techniques during catheter ablation and have performed various ablations including atrial fibrillation, ventricular tachycardia without use of fluoroscopy. Given small sample size statistical power is not very high as well. With that being said, we do report a strategy for zero contrast implantation of BiV device that can be utilized in experienced centers with EAM to safely implant BiV ICD in patients with renal disease.

Uncontrollable variables such as patient anatomy and underlying patient comorbidities influence outcomes as well and are much more difficult to control for. Further ongoing studies evaluating feasibility, efficacy and safety will need to be performed.

Another set of limitations involve the EAM system itself. The technology is fairly expensive and would require capital cost for those centers where the EAM system is not available. The EAM system itself also requires technical expertise to drive the EAM system along with experience level of lab personnel. Both of which could lead to added costs, procedure times.

Although there is added cost to the procedure there may be a potential for cost saving overall if we factor the decreased hospital stay, improved renal function and the delay of early dialysis in this patient population with this technique. Cowburn PJ et al showed that the mean length of hospital stay post-procedure in patients developing contrast nephropathy was 19+/-18 (SD) days versus 4+/-5 days for those patients with stable renal function post CRT implantation [10].

Disclosures

No financial disclosures.

Conclusion

Further studies will be needed to evaluate safety and efficacy of this technique on a broader patient population.

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