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A Contemporary Update of the Safety of Enhanced External Counter Pulsation in Controlled Clinical Trials

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In the United States, approximately 10 million people suffer from refractory angina and based on evidence from a recent real-world analysis of a multi-payer database, 28% of patients have recurring angina 1-year post-PCI [1]. With trials like the International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) highlighting no additional benefit in outcomes with an invasive approach post mechanical revascularization for residual angina, novel methods to manage angina in conjunction with pharmacotherapeutic and mechanical revascularization options are getting a renewed focus. A leading non-pharmacologic therapy with established safety and efficacy is enhanced external counter pulsation (EECP) [2].

EECP was approved by the US Food and Drug Administration (FDA) in 1995 and is utilized for the management of refractory angina in patients who fail to respond to pharmacotherapy or revascularization. It has a class IIb recommendation from the American College of Cardiology and American Heart Association since 2002 and is recommended in the 2019 European Society of Cardiology Guidelines. The EECP system consists of a compressor, a console, a treatment table, and three sets of lower extremity manometry cuffs, very similar in appearance to blood-pressure cuffs. These pneumatic cuffs are wrapped around the patient's calves, thighs, and buttocks with the inflation and deflation timed to the patient's electrocardiogram to ensure proper gating to the cardiac cycle. This mechanism stimulates blood flow to the heart, with evidence showing improvement in markers associated with morbidity and mortality, including improved physical capacity, symptom burden, and overall quality of life.

Despite over 400 peer-reviewed publications on EECP, its adoption has been limited in-part due to the lack of specialized centers across the country [3]. Further, on-site physician supervision may provide barriers to establishing such specialized EECP treatment centers. As such, most facilities are typically found at larger medical centers, which creates challenges for access to broader, and particularly rural, communities.

Knowledge of the frequency of on-site physician engagement during EECP therapy in the published literature and the odds of treatment related serious adverse events (TRSAE) in the coronary artery disease (CAD) patient population would help drive protocol supervision refinements. An assessment of controlled clinical trials was performed with the intention of a meta-analysis determining the odds of a TRSAE and the frequency of physician engagement relative to a control group. A PubMed/Google Scholar search along with hand searching of references was conducted from inception to June 12, 2023. Controlled clinical trials published in the English language evaluating EECP regardless of stable angina/CAD were included. Review of the available data lacked description for the need for on-site supervising physician engagement in these studies thus preventing a meta-analysis. However, treatment related serious adverse events were reported and assessed, allowing us to produce a qualitative review.

Ultimately, 8 controlled trials were available for inclusion [4-11]. A total of 371 patients were included for the EECP group with 284 patients included for the control group. Based on the studies treatment protocols, this would translate to 12,985 total treatment hours .

No instances of on-site physician engagement or TRSAE were reported in any of the clinical trials for the EECP group. To explore this further, an investigation into the FDA Manufacturer and User Facility Device Experience (MAUDE) database along with inquiring with the largest specialized EECP center in the country, revealed no instances of on-site physician engagement or TRSAE across 343,150 treatment hours spanning 9 years and encompassing a recent time period in which remote direct supervision has been allowed. Of note, the MAUDE database did report 1 instance of hematoma, but it was not related to the EECP treatment [12]. EECP has a low rate of minor adverse events based on an evaluation of 2,289 patients across 84 treatment facilities from the EECP Clinical Consortium [13]. In the current analysis, only the study by Arora et al, provided granular data on all adverse experiences that occurred. Treatment related minor effects such as skin abrasion, bruise or blister, and leg/back pain were the only statistically significant findings (Table 1).

This brief report is important because with better understanding and diagnosis of obstructive and non-obstructive CAD, novel approaches like EECP offer a safe management option. A broader strategy for specialized EECP centers would unlock critical access to care especially in remote health areas (care deserts). The public health emergency during COVID-19 further demonstrated the safety profile of EECP as zero reports requiring the supervising physician to intervene were noted during a time-period when remote direct-supervision was utilized. Compounded by reports that patient satisfaction is directly associated with compliance and improved health outcomes, these findings are compelling. This article provides an important update on the safety profile of EECP encompassing data from the last two decades.

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Table 1: Treatment related serious adverse effects in EECP controlled clinical trials.

Article #	Author, year	Study Design	Patient Population	EECP, N	EECP Regimen	Serious AE	Control Group, N	Control	Serious AE
1	Wang, 2021	R, CT Parallel	CAD + Stable Angina	80	35 hours	0	88	Pharmacotherapy	0
2	Beck, 2015	R, B, Sham-CT Parallel	Stable Angina with mild to moderate LVD	10	35 hours	0	7	35 hours of sham EECP	0
3	Kozdağ, 2012	CT, Parallel	CAD + HF	47	35 hours	0	21	Matched control group	0
4	Bondesson, 2010	CT, Parallel	CAD + Stable Angina	100	35 hours	0	53	Pharmacotherapy	NR
5	Braith, 2010	R,Sham-CT Parallel	CAD + Stable Angina	28	35 hours	0	14	35 hours of sham EECP	0
6	Levenson, 2007	R, Sham-CT Parallel	CAD	15	35 hours	0	15	35 hours of sham EECP	0
7	Shechter 2003	CT, Parallel	CAD + Stable Angina	20	35 hours	0	20	Matched control group	0
8	Arora 1999	R, B, Sham-CT Parallel	CAD + Stable Angina	71	35 hours (once or twice per day)	0	66	35 hours of sham EECP (once or twice per day)	0

NR=Not reported, CAD=Coronary artery disease, HF=heart failure, R=randomized, B=blinded, CT=controlled trial, AE=adverse event.

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