TITLE: Impact of Technique on Quality of Agitated Saline Studies and Comparison with Orbis Microbubble Generator

AUTHOR / AFFILIATION: Madeline Jankowski, Northwestern Medicine

INTRODUCTION

Accurate shunt diagnosis based on an agitated saline echocardiogram or "bubble study" is dependent on production of uniform, long-lasting microbubbles resulting in extended opacification and improved bubble study quality. The process of manually agitating saline, which is standard of care (SoC), is inherently variable, producing unpredictable opacification levels and duration.

A novel device, the Orbis[™] Microbubble Generator, was developed to standardize production of agitated saline and provide long-lasting microbubbles, facilitating identification of right-to-left shunts.

The impact of inconsistent agitation on bubble quality has not been well documented. This evaluation assessed the variability on opacification levels with manually agitated saline compared to Orbis.

METHODS

The impact of the number of agitations (presses) and delay time to injection was assessed in benchtop and animal studies. SoC methods were compared against Orbis for opacification and duration levels. A recirculating water loop test chamber with ultrasound imaging capabilities measured opacification levels via mean gray value (MGV). Software analyzed maximum opacification and duration for each injection. An in-vivo porcine model was used to support opacification and duration findings.

RESULTS

Four, 10 and 20 manual agitation sequences were evaluated for opacification. Increased agitation led to higher peak opacification. The time lapse between agitation and injection correlated with opacification levels. A 5-6 second delay displayed lower MGV compared to a 1-2 second delay.

Since Orbis generates microbubbles in real-time, issues associated with manual agitation and delays do not apply. Orbis produced much higher peak opacification and longer duration versus SoC (Figure 1).



Figure 1: Opacification Comparison between SoC and Orbis

To validate benchtop findings in-vivo, Orbis and SoC injections were administered in a live porcine model. Orbis consistently scored higher than SoC for peak opacification and duration.

CONCLUSIONS

SoC demonstrated variable levels of opacification based on the number of agitations and time delay to injection. Orbis provided significantly better and more consistent opacification and duration. In vivo tests scored higher for image quality with Orbis than SoC. Orbis consistently provided outcomes that negated the issues associated with manually agitated saline providing improved bubble study quality and increased likelihood of visually detecting shunts.