

Chlorhexidine Gluconate as a Conducting Medium Is Noninferior to Ultrasound Gel in Ultrasound Image Quality: A Blinded, Randomized Comparative Study

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ABSTRACT

Background: Ultrasound imaging is increasingly used by physicians for both diagnostic and image-guided procedures. A coupling medium is used to facilitate transmission of ultrasound waves from the transducer to tissues by eliminating air interference. The ideal coupling medium would be inexpensive, provide effective transmission, and neither introduce infection nor damage the skin or transducer. Ultrasound gel, a commonly used coupling medium, has the potential to transmit infection. This blinded, randomized study assessed the noninferiority of ultrasound image quality using chlorhexidine gluconate with isopropyl alcohol as coupling medium compared with ultrasound gel.

Methods: Sixty different locations were imaged on 2 healthy volunteers. The order of use of the 2 coupling media was randomized at each location without changing the imaging site or ultrasound settings. The images were then coded to facilitate blinding. Two blinded reviewers evaluated the coded images using a comparative rating scale.

Results: Chlorhexidine gluconate demonstrated a slightly improved image quality (mean 2.53; 95% CI, 2.46-2.60) compared with ultrasound gel (mean, 2.42; 95% CI, 2.35-2.50) ($P = .04$).

Conclusions: The commonly used skin antiseptic chlorhexidine gluconate with isopropyl alcohol demonstrated noninferior image quality compared with ultrasound gel and may represent a more economical alternative for ultrasound-guided interventions, with the potential to reduce infectious complications.

INTRODUCTION

Ultrasound imaging has become a commonly used imaging modality because of its portability and dynamic visualization. While generally considered one of the safer imaging modalities, it is not without risks. Ultrasound transducers perform the dual function of generating and receiving ultrasound waves. As the waves travel through tissues, they undergo a decrease in intensity and amplitude called attenuation, with different tissues having different attenuation coefficients, allowing appreciation of the subtleties in the reflected image. Acoustic impedance is the resistance offered by tissues to ultrasound waves. The difference between the acoustic impedances of adjacent media determines the amount of ultrasound wave energy reflected.¹ When the difference is greater, more waves are reflected back to the transducer. Because air has an acoustic impedance significantly

lower than that of tissues, ultrasound waves are reflected, resulting in loss of penetration through the skin. Ultrasound conducting or coupling media minimize this effect by narrowing the acoustic impedance difference between air and skin, thus allowing for effective transmission of ultrasound waves from the transducer through the skin.¹

The ideal conducting medium would be cost-effective, provide good transmission, and neither introduce infection nor damage the skin or transducer. Multiple conducting media have been studied, including sterile water, olive oil, hand sanitizer, and cornstarch, in addition to ultrasound gel (USG),² which has been widely used for many decades. It is available in both single-use sterile sachets and multiuse bottles. However, concerns persist regarding the potential

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for nosocomial infections associated with multiuse bottles despite its being labeled as bacteriostatic.^{3,4} Studies have shown that even with the use of sterile USG, skin contamination can occur with certain bacteria, possibly because of the development of resistance or degradation of the parabens.⁵ Various parts of ultrasound equipment have been shown to be susceptible to contamination and bacterial growth, and environmental bacteria have been identified in heated USG.⁶ There is also concern of contact dermatitis associated with additives in USG, particularly parabens.⁷

Chlorhexidine gluconate (CHG), or the commercially available Chloraprep solution, is a commonly used broad-spectrum antimicrobial biguanide used for skin antisepsis. It contains 2% weight/volume chlorhexidine gluconate and 70% volume/volume isopropyl alcohol. Clinical practice guidelines recommend the use of alcohol combined with another agent, such as CHG, for surgical-site antisepsis.⁸ As CHG is routinely used before ultrasound-guided procedures, we hypothesized that it could also serve as a coupling medium and provide ultrasound image quality similar to that of USG.

METHODS

The study was approved by the Human Studies Institutional Review Board. Two healthy volunteers underwent ultrasound examinations at different anatomical locations commonly used for ultrasound-guided interventions. Ultrasound settings were kept constant throughout the study to allow accurate comparison. At each location, CHG and USG were used as the conducting medium in random order. Randomization was performed using sealed envelopes. The investigator performing the ultrasound examinations was not blinded to the conducting medium. This resulted in 60 images obtained using CHG and 60 images with USG, for a total of 120 images. Once obtained, the images were numbered and coded to deidentify the medium used before evaluation.

Two reviewers, blinded to the medium used for each image, evaluated image quality. The images were rated on a 3-point scale, with a score of 3 representing superior image quality.

The Table shows the estimated power achieved by the study at a 5% significance level with 58 pairs of ultrasound images obtained with the 2 media, each evaluated by 2 raters, if the images obtained with the 2 media have equivalent quality, ie, $P(\text{worse})389 = P(\text{better})$. The power calculation is based on formulas for a noninferiority test with 1 rater, modified to include a variance inflation factor of $[1+(m-1) \rho]$ for m raters with between-rater correlation ρ . The power of the study depends on

Figure. Ultrasound Transverse View of the Anterior Neck Using Chlorhexidine Gluconate (A) and Ultrasound Gel (B)

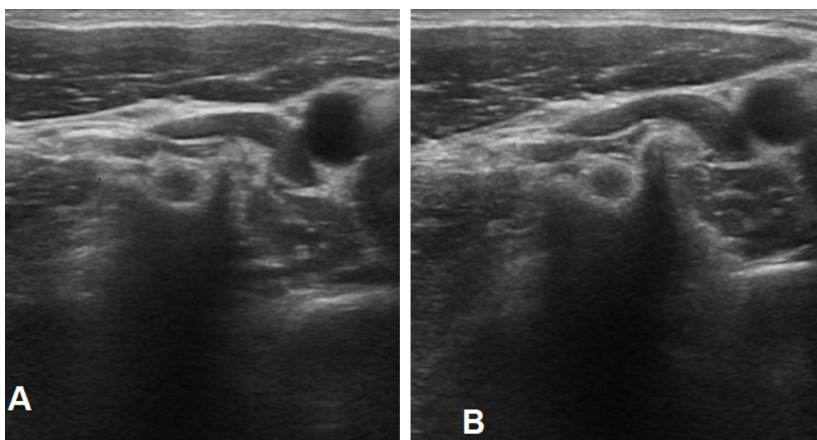


Table. Sample Size Calculation

Probability of Tie	Intraclass Correlation Between Raters			
	0.7	0.8	0.9	1
55%	77.8%	75.7%	73.7%	71.8%
60%	81.9%	80.0%	78.0%	76.2%
65%	86.2%	84.4%	82.6%	80.9%
70%	90.4%	88.9%	87.4%	85.9%

the extent of agreement between the 2 raters and the proportion of ties (“same” calls); therefore, a range of plausible scenarios is presented. The selected sample size was based on a 60% probability of ties and a correlation of 0.8 to achieve 80% power. Agreement between the 2 raters was quantified using weighted κ and reported with a 95% confidence interval.

RESULTS

The raters commented that it was not possible to differentiate which image were obtained using CHG versus USG as the conducting medium. They graded image quality as comparable between CHG and USG, with a mean score of 2.53 (95% CI, 2.46–2.60) for CHG and a mean score of 2.42 (95% CI, 2.35–2.50) for USG ($P = .04$). CHG had an interrater reliability of 0.59 compared with 0.54 for USG (Figure).

DISCUSSION

This study demonstrates that CHG provides image quality comparable to that of USG as a coupling medium. We have used CHG as a coupling medium for more than a decade at our institution without any CHG-related adverse events during more than 10000 ultrasound-guided procedures with good results.

In a blinded randomized study, Williams II et al compared image quality and time required to visualize carotid artery and internal jugular vein using saline and USG and found them to be

comparable.³ Saline is likely to flow away from the site under the influence of gravity, requiring continuous irrigation. In a blinded, randomized, crossover study involving 34 patients, corn starch and commercial USG showed no difference in image quality. Although inexpensive, corn starch raises concerns regarding infection risk during ultrasound-guided interventions.⁴

With the primary goal of reducing cost, investigators prepared different formulations using aloe vera as the main ingredient, with additives including parabens, a polymer, triethanolamine, and disodium ethylenediaminetetraacetic acid (EDTA). They found that these formulations had acoustic impedance and quality similar to those of USG.⁹ Another study compared 9 commonly available liquids, including water, shampoo, lotion, hand sanitizer, maple syrup, olive oil, soap, and sunscreen, with USG and found comparable image quality for all products except sunscreen; however, sterility remained a limitation.²

Because of its antimicrobial properties, hand sanitizer may offer advantages and cost savings compared with sterile USG sachets.¹⁰ To reduce infection risk, one study compared nonsterile USG and USG fortified with 0.5% chlorhexidine and 70% ethyl alcohol in 20 volunteers undergoing ultrasound imaging. Swabs obtained from various sites, including the skin, transducer, and gel, yielded no bacterial growth in the fortified-USG group.¹¹

The potential benefits of CHG as a coupling medium include slightly enhanced image quality and potentially reduced costs and infection risk. One disadvantage is the need for reapplication as it evaporates, necessitating maintenance of a fluid coupling medium. In addition, because of its alcohol content, CHG is not considered safe for use during radiofrequency ablation or electrocautery because of the associated fire hazard.

CONCLUSIONS

This study provides preliminary evidence demonstrating the non-inferiority of ultrasound image quality with CHG compared with USG as coupling medium for ultrasound-guided interventions. In addition, the use of CHG may decrease infectious complications because of its antimicrobial properties. Larger studies are needed to evaluate the cost-effectiveness of CHG and its potential to reduce infection risk.

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