

Chlorhexidine or Povidone-Iodine

Do We Follow the Guidelines or the Package Insert?

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We face a conundrum. Several publications (American Society of Regional Anesthesia and Pain Medicine [ASRA] guidelines,^{1,2} NEJM,³ and probably the upcoming ASA practice advisory on infectious complications) contain recommendations for the use of chlorhexidine (CHG) for skin antisepsis prior to neuraxial blocks (spinal and epidurals). This is despite the warning on the package inserts for Chloraprep⁺ and Chlorascrub (both products contain chlorhexidine plus alcohol) that says “**Do not use for lumbar puncture or in contact with the meninges.**” Because of this warning, commercial spinal and epidural kits do not include products that contain CHG. Povidone-iodine (PI) does not have this warning on the package insert.

There are eight ASRA recommendations for aseptic techniques and regional anesthesia.² The following relates to skin preparation:

Alcohol-based chlorhexidine antiseptic solutions significantly reduce the likelihood of catheter and site colonization and maximize the rapidity and potency of bactericidal activity when compared to other solutions. Therefore, **alcohol-based chlorhexidine solutions should be considered the antiseptic of choice before regional anesthetic techniques** (Grade A*).

A bit of background: Chlorhexidine gluconate (CHG) was patented in 1954. It is bactericidal on both gram-positive and gram-negative bacteria as well as fungicidal. A number of studies⁵ have documented the superiority of CHG to povidone-iodine. The ASRA guidelines² provide an excellent summary.

There is **minimal percutaneous penetration**⁶ of CHG although it adheres to the stratum corneum, which increases its length of action. CHG is **toxic to nerves, eyes and ears** when it is injected directly into the CSF, eye⁷ and ear.

*Grade A: Requires at least one prospective, randomized, controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation.

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In a study with many different chemicals injected into the CSF of monkeys, neurotoxicity was seen with all compounds studied, including CHG.⁸

It also is not surprising that letters to the Anesthesia Patient Safety Foundation (APSF) from Medi-Flex, Inc. (now Cardinal Health, Inc.), the manufacturer of Chloraprep, skirt the issue of CHG for skin preps for neuraxial procedures.^{9,10} In my opinion, it is highly unlikely that the package insert for Chloraprep, Chlorasrub, and other CHG preparations will be changed given the costs to the respective manufacturers of submitting safety data to the FDA for label changes. In addition, with so many physicians already using CHG for neuraxial procedures, there is little economic motivation to formalize its use with FDA approvals. Indeed, upon contacting the FDA, the ASRA Advisory Panel on Infectious Complications found that the lack of approval for dural puncture was not due to toxicity concerns, but lack of scientific data.¹¹ However, notwithstanding this regulatory problem, the ASRA Advisory Panel felt strongly that although the FDA had not approved CHG before lumbar puncture, CHG's significant advantage over povidone-iodine for onset, efficacy, and potency, warranted a Panel recommendation for its use before regional anesthetic techniques.

The ASA Practice Advisory for the Prevention, Diagnosis, and Management of Infectious Complications Associated with Neuraxial Techniques will be presented for approval by the ASA House of Delegates in October 2009. It too is likely to recommend chlorhexidine for skin preparation before neuraxial techniques.

So back to the conundrum. If we use povidone-iodine for skin preparation and the patient develops a bacterial meningitis after a spinal puncture, we could be criticized for not using CHG as recommended by the guidelines. Alternatively, if we use CHG and the patient develops a neural deficit for whatever reason, we could be criticized for using CHG. It then becomes a battle of the experts.

References

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