

## Antiseptic Agents FactFinder

*Committed to providing helpful information to our members about key patient safety issues, the International Spine Intervention Society's Patient Safety Committee has developed a FactFinder series. FactFinders will explore and debunk myths surrounding patient safety issues. The intent of this FactFinder is to address the efficacy of two different antiseptic agents: povidone-iodine and chlorhexidine-alcohol solutions.*

**Myth #1: Povidone iodine and chlorhexidine in alcohol are equally effective antiseptic agents for use in percutaneous spine procedures.**

**Fact: Chlorhexidine in alcohol is the preferred preparation for all spine procedures.**

For the first edition of the International Spine Intervention Society's Guidelines,<sup>1</sup> this question was answered on the basis of expert opinion. Various, the guidelines allowed for "Solutions for skin preparation may be an iodine-based solution (e.g. povidone-iodine), chlorhexidine, or an alcohol-based antiseptic (e.g. chlorhexidine 0.5% in 70% alcohol)".<sup>1</sup> For lumbar disc stimulation, expert opinion at the time favored a Betadine preparation.<sup>1</sup>

Since the publication of the first edition Guidelines, evidence has appeared. This evidence was brought to my attention by the infection control staff of my hospital, when we were preparing an ethics application. They were disappointed that we were still in the old days of iodine preparations.

The evidence came from a prospective, randomized controlled study<sup>2</sup>. This showed that the infection rate, following typical surgical procedures, was significantly less if a chlorhexidine-alcohol solution was used than if iodine was used. The risk of infection was reduced by 40% if chlorhexidine was used. The preparations used were 2% chlorhexidine gluconate in 70% isopropyl alcohol, and an aqueous solution of 10% povidone-iodine. The study was large, with sample sizes of 431 and 466; and sufficiently powered to show a statistically significant difference between infection rates of 9.5% ( $\pm 2.8$ ) and 16.1% ( $\pm 3.3$ ). It was published in a premier journal. So, we can trust in the peer-review and statistical analysis.

Society members might retort that the procedures that they perform are not like abdominal surgery, and they do not encounter infection rates as large as 16.1% or 9.5%; therefore, this evidence is not directly applicable to their circumstances. However, the issue is not comparative rates of infection; the issue is the efficacy of an antiseptic agent.

The study cited compared two agents in a hostile environment, in which infection was reasonably likely. Under those hostile conditions, a chlorhexidine-alcohol solution was demonstrably more effective than iodine. That evidence promises that chlorhexidine in alcohol will also be more efficacious than iodine under less hostile conditions, such as for percutaneous procedures on the spine.

For this reason, the forthcoming second edition of the guidelines exclusively recommends 2% chlorhexidine in 70% alcohol as the preferred preparation for all spine procedures.

Although chlorhexidine in alcohol has been shown to be superior to aqueous iodine, it has not been determined if chlorhexidine in alcohol is superior to alcohol alone.

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**Myth #2: Chlorhexidine increases the risk for neurologic complications.**

**Fact: Although animal studies conducted on rats in 1984 demonstrated an association between chlorhexidine and neurotoxicity,<sup>3</sup> no clinical studies have identified neurotoxicity as a complication with antiseptic skin preparation.**

An abstract presented at an American Society of Regional Anesthesia and Pain Medicine conference discussed findings of a retrospective cohort study assessing the incidence of neurologic complications following spinal anesthesia and chlorhexidine skin antiseptics compared with the overall established incidence of neurologic complications following spinal anesthesia (without consideration of skin antiseptics protocol) as previously reported in the literature (0.005% to 0.13%).<sup>4</sup> A total of 11,095 patients received 12,495 spinal anesthesia procedures during the study period. All patients received 2% chlorhexidine gluconate plus 70% isopropyl alcohol for skin antiseptics prior to spinal anesthesia. The incidence of neurologic complications associated with spinal anesthesia was identified at 0.04%. This incidence is no different from previously reported rates of neurologic complications after spinal anesthesia without attention to skin antiseptics. These results support the conclusion that chlorhexidine can be safely used for skin antiseptics in patients undergoing spinal anesthesia without increasing the risk for neurologic complications.

***SPECIAL NOTE: Read the Label***

Before using chlorhexidine-alcohol formulations, it is critical that physicians carefully review the product labeling regarding indications, warnings and

directions. The solution and fumes are flammable, and there are specific suggestions included to reduce the risk of fire.

Step-by-step instructions for use are provided on the product label. Noteworthy are the instructions to apply to the site using repeated back-and-forth strokes of the applicator for approximately **30 seconds**, completely wetting the treatment area with antiseptic. It is also critical to allow the area to air dry for approximately **30 seconds**. Excess solution should not be blotted or wiped away.

Additionally, the warnings indicate that the solution should not be used for lumbar puncture or come in contact with meninges. Based upon our review of the existing literature, this warning appears to have no basis in evidence; rather, it appears to be a means to offer legal protection to manufacturers (similar to those warnings placed on steroid formulations indicating “not for epidural use”). If the instructions are followed and the chlorhexidine is given ample time to air dry, the chances that even a trace amount of the solution would come into contact with the dura are minimal.

### References

1. Bogduk N (ed). Practice Guidelines for Spinal Diagnostic and Treatment Procedures. International Spine Intervention Society, San Francisco, 2004.
2. Darouiche RO, Wall MJ, Itani KM, Otterson MF, Webb AL, Carrick MM, Miller HJ, Awad SS, Crosby CT, Mosier MC, AlSharif A, Berger DH. Chlorhexidine-alcohol versus Povidone-iodine for surgical-site antisepsis. *New Engl J Med* 2010; 362:18-26.
3. Henschen A, Olson L. Chlorhexidine-induced degeneration of adrenergic nerves. *Acta Neuropathol (Berl)* 1984; 63:18-23.
4. Sviggum HP, Arendt KW, Jacob AK, Mauermann ML, Horlocker TT. The risk of neurologic complications following chlorhexidine antisepsis for spinal anesthesia. *Regional Anesthesia and Pain Medicine. Conference: 36th Annual Regional Anesthesia Meeting and Workshops, ASRA 2011 Las Vegas, NV United States. Conference Publication: (var.pagings). 36 (5), 2011.*