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**OREGON HEALTH AND SCIENCE UNIVERSITY**  
**OFFICE OF CLINICAL INTEGRATION AND EVIDENCE-BASED PRACTICE**  
Evidence-Based Practice Summary  
Venipuncture Pain Management Delegated Protocol

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**ASK THE QUESTION**

**Question 1:** In pediatric patients (greater than 6 month) and adult patients receiving venipuncture, does injecting lidocaine intradermally via J-TIP device, which uses gas pressure to disperse the lidocaine in a spray like fashion, reduce pain associated with pediatric venipuncture?

**SEARCH FOR EVIDENCE**

**Databases** included PubMed and Scopus, also looked at references and citing articles.

**PubMed search strategy included:**

("lidocaine"[MeSH Terms] OR "lidocaine"[All Fields]) AND ("phlebotomy"[MeSH Terms] OR "phlebotomy"[All Fields] OR "venipuncture"[All Fields]).

**Scopus search strategy included:**

Scopus was searched using articles that Afton Potter had previously identified or that were found in PubMed, and used Scopus' similar article feature. No specific keyword searching was completed in Scopus.

**Filters/limits** included research articles published in English



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## **CRITICALLY ANALYZE THE EVIDENCE**

**Question 1: In pediatric patients (greater than 6 month) and adult patients receiving venipuncture, does injecting lidocaine intradermally via J-TIP device, which uses gas pressure to disperse the lidocaine in a spray like fashion, reduce pain associated with pediatric venipuncture?**

Overall the level of evidence for this body of literature was moderate as the literature was somewhat indirect in addressing the question about the impact of the J-TIP device on pain reduction in pediatric patients undergoing venipuncture. One RCT and one quasi-experimental study with some serious design limitations directly addressed the question. A second RCT evaluated a similar device to J-TIP that used a lidocaine hydrochloride monohydrate powder intra-dermal system to reduce pain with venipuncture.

### *Pain Reduction Via J-TIP device*

A RCT of 205 children aged 1 to 6 years found a significant difference in venipuncture pain reduction with use of the J-TIP compared to a vapocoolant spray or sham treatment (intervention group: 0.26; 95% CI -0.31 to 0.82, control: 2.82; 95% CI 1.91 to 3.74, sham:1.68; 95% CI 0.83 to 2.52) (Lunoe et al., 2015).

A quasi-experimental quality improvement study examining data for 328 children aged 1 month to 21 years found that patients experienced less pain with J-Tip alone than with no intervention for pain relief (no intervention: 71% pain scale score >3 vs. J-tip® alone: 21% pain scale score >3) (Kearl, Yanger, Montero, Morelos-Howard, & Claudius, 2015).

### *Pain Reduction via lidocaine hydrochloride monohydrate powder intra- dermal system*

One RCT of 535 children aged 3 to 18 years was found using a device similar to J-TIP that used a lidocaine hydrochloride monohydrate powder intra-dermal system to reduce pain with venipuncture. The active system had significantly less pain compared to the sham placebo group (1.28 vs. 1.67;  $P=0.0022$ )(Schmitz, Zempsky, & Meyer, 2015).

A RCT of 693 adults aged 18 to 93 years was found using a 0.5mg lidocaine powder delivery system similar to J-TIP to reduce pain with venipuncture or intravenous cannulation. Treatment with the active system resulted in a statistically significant reduction in pain VAS scores ( $P=0.003$ ) (difference between age group adjusted LSMs=  $-4.63 \pm 1.55$  mm) during venipuncture or venous cannulation, which represents a 28% relative reduction compared with sham placebo (Zempsky, Schmitz, & Meyer, 2016).

<b>PICO Question 1: In pediatric patients (greater than 1 month) receiving venipuncture, does injecting lidocaine intradermally via J-TIP device, which uses gas pressure to disperse the lidocaine in a spray like fashion, reduce pain associated with pediatric venipuncture?</b>						<b>Lower Quality Rating if:</b> <input type="checkbox"/> Studies inconsistent <i>(When there are differences in the direction of the effect, populations, interventions or outcomes between studies)</i>  <input checked="" type="checkbox"/> Studies are indirect <i>(Your PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)</i>  <input type="checkbox"/> Studies are imprecise <i>(When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)</i>  <input type="checkbox"/> Publication Bias <i>(e.g. pharmaceutical company sponsors study on effectiveness of drug)</i>
Author/Date/Journal	Purpose of Study	Study Design	Sample & Setting	Outcomes	Design Limitations	
(Lunoe et al., 2015)  Annals of Emergency Medicine	Determine whether the J-Tip decreased venipuncture pain in young children compared with vapocoolant spray.	RCT  Children aged 1 to 6 years were randomized into 3 groups: intervention (J-Tip), control (vapocoolant spray), and sham (vapocoolant spray and pop of an empty J-Tip).	This study was conducted from July 1, 2013, to August 8, 2013, in the outpatient laboratory at a tertiary care children's hospital. Two hundred five children enrolled: intervention 96, control 53, and sham 56.	There were no between-group differences in baseline characteristics. <b>There was no mean change in pain scores from device to venipuncture in the intervention group (0.26; 95% confidence interval [CI] -0.31 to 0.82), but there was an increase in pain in the control (2.82; 95% CI 1.91 to 3.74) and sham (1.68; 95% CI 0.83 to 2.52) groups.</b>  This change was greater for the control and sham compared to the intervention group. There was no difference in venipuncture success between groups. No severe adverse events occurred. Minor adverse events were the same between groups.	Study Limitations = <input checked="" type="checkbox"/> None <b>RCT &amp; Quasi-Experimental Studies</b> <input type="checkbox"/> Insufficient sample size <input type="checkbox"/> Lack of randomization <input type="checkbox"/> Lack of blinding <input type="checkbox"/> Stopped early for benefit <input type="checkbox"/> Lack of allocation concealment <input type="checkbox"/> Selective reporting of measures <input type="checkbox"/> Large losses to F/U <input type="checkbox"/> Baseline Demographics	
(Schmitz et al., 2015)  Clinical Therapeutics	Determine if a lidocaine hydrochloride monohydrate powder intra-dermal system designed to provide cutaneous analgesia is efficacious, safe, and tolerable for pediatric subjects compared with a sham placebo system.	RCT  Subjects were randomized to receive the needle-free powder lidocaine delivery system (active system, 0.5mg of lidocaine /21±1 bar of pressure [n = 269]) or sham placebo (n = 266).	The efficacy-evaluable population included 508 patients (256 in the active system group and 252 in the sham placebo group). Subjects included a broad spectrum of pediatric patients, including outpatients undergoing phlebotomy or outpatient procedures as well	The active system group had significantly less pain compared with the sham placebo in all age groups combined according to the modified Wong-Baker FACES scale (1.28 vs. 1.67; P = 0.0022). Secondary efficacy analyses found that the active system resulted in less pain as assessed by subjects' VAS pain assessments aged 8–18 years (15.23 [1.49] mm vs 18.04 [1.51] mm; P = 0.1856),	Study Limitations = <input checked="" type="checkbox"/> None <b>RCT &amp; Quasi-Experimental Studies</b> <input type="checkbox"/> Insufficient sample size <input type="checkbox"/> Lack of randomization <input type="checkbox"/> Lack of blinding <input type="checkbox"/> Stopped early for benefit <input type="checkbox"/> Lack of allocation concealment <input type="checkbox"/> Selective reporting of measures <input type="checkbox"/> Large losses to F/U	<input type="checkbox"/> Increase Quality Rating if: <input type="checkbox"/> Large Effect  Level of evidence for studies as a whole:  <input type="checkbox"/> High



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			as inpatients undergoing major or minor procedures. Included were subjects (3–18 years) in 3 age groups: 3–7, 8–12, and 13–18 years.		<input type="checkbox"/> Baseline Demographics	<input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Low <input type="checkbox"/> Very Low
(Kearl et al., 2015)  The Clinical Journal of Pain	To develop an optimal protocol for pre-venipuncture/IV start pain management by investigating the impact of adding the use of Buzzy® prior to the use of the J-tip®.	Quasi-Experimental Study-Quality Improvement  Data were collected prospectively as part of a nurse-driven quality improvement project to incorporate “ouchless” interventions. Pediatric emergency department patients aged 1 month to 21 years were prospectively enrolled in Phase 1 (J-tip® only) then Phase 2 (Buzzy® + J-tip®) for analgesia prior to venipuncture or IV start.	Conducted in a 14 bed academic, urban PED with an annual census of 22,000 pediatric patients per year. This was a non-randomized convenience sample. Because not every patient had a full data set, 137 patients were included in assessment of pain with application of the J-tip® from the J-tip®/Buzzy® group and 197 from the J-tip® alone group, but only 133 and 195 respectively were assessed for venipuncture. Full data sets were analyzed for 28 patients with no analgesia.	With the combined intervention (phase 2), 14.2% of patients had a pain scale score >3 with venipuncture and 16.1% had a pain scale score >3 with application of the J-tip® itself. <b>With no intervention for pain relief, 71% of patients experienced a pain scale score &gt;3 for venipuncture. With the J-tip® alone (phase 1), 21% had a pain scale score &gt;3 with venipuncture and 22.3% had a pain scale score &gt;3 with application of the J-tip® itself.</b>	Study Limitations = <input type="checkbox"/> None <b>RCT &amp; Quasi-Experimental Studies</b> <input checked="" type="checkbox"/> Insufficient sample size <input checked="" type="checkbox"/> Lack of randomization <input checked="" type="checkbox"/> Lack of blinding <input type="checkbox"/> Stopped early for benefit <input checked="" type="checkbox"/> Lack of allocation concealment <input type="checkbox"/> Selective reporting of measures <input type="checkbox"/> Large losses to F/U <input checked="" type="checkbox"/> Baseline Demographics	
(Zempsky et al., 2016)  The Clinical Journal of Pain	To evaluate the efficacy, safety, and tolerability of a needle-free powder lidocaine delivery system compared with sham placebo	RCT  Patients were randomized to receive either the needle-free powder lidocaine	This multicenter study was conducted between March 26, 2007 and August 23, 2007. A total of 693 adults (18 to 93 y of age)	Treatment with the active system resulted in a <b>statistically significant reduction in pain VAS scores (P=0.003) (difference between age group adjusted LSMs= -4.63±1.55 mm) during</b>	Study Limitations = <input type="checkbox"/> None <b>RCT &amp; Quasi-Experimental Studies</b> <input type="checkbox"/> Insufficient sample size <input type="checkbox"/> Lack of randomization <input type="checkbox"/> Lack of blinding	



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	in adults.	delivery system (0.5mg lidocaine/21±1 bar pressure; active system) or a sham placebo 1 to 3 minutes before a required venipuncture or intravenous (IV) cannulation.	who required venipuncture or venous cannulation participated in this study. The active system group included 345 patients who received the needle-free lidocaine powder delivery system, whereas 348 patients received sham placebo. No patients discontinued from the study.	<p><b>venipuncture or venous cannulation, which represents a 28% relative reduction compared with sham placebo.</b></p> <p>A statistically significant difference was observed between treatment groups in the analysis of pain VAS scores from historical venipuncture or venous cannulation compared with the current study procedure (P=0.0002) (difference between age-group adjusted LSMs= <math>-7.2 \pm 1.9</math> mm), in which treatment with the active system resulted in a lower relative pain score than did treatment with sham placebo.</p> <p>the pain-free responder rate was significantly higher in the active system group than in the sham placebo group (89/345 [25.8%] vs. 25/348 [7.2%], respectively; P&lt;0.0001).</p>	<input type="checkbox"/> Stopped early for benefit <input checked="" type="checkbox"/> Lack of allocation concealment <input type="checkbox"/> Selective reporting of measures <input type="checkbox"/> Large losses to F/U <input type="checkbox"/> Baseline Demographics	
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The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix A.

## REFERENCES



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- Kearl, Y. L., Yanger, S., Montero, S., Morelos-Howard, E., & Claudius, I. (2015). Does Combined Use of the J-tip(R) and Buzzy(R) Device Decrease the Pain of Venipuncture in a Pediatric Population? *Journal of Pediatric Nursing*, 30(6), 829-833. doi:10.1016/j.pedn.2015.06.007
- Lunoe, M. M., Drendel, A. L., Levas, M. N., Weisman, S. J., Dasgupta, M., Hoffmann, R. G., & Brousseau, D. C. (2015). A Randomized Clinical Trial of Jet-Injected Lidocaine to Reduce Venipuncture Pain for Young Children. *Ann Emerg Med*, 66(5), 466-474. doi:10.1016/j.annemergmed.2015.04.003
- Schmitz, M. L., Zempsky, W. T., & Meyer, J. M. (2015). Safety and Efficacy of a Needle-free Powder Lidocaine Delivery System in Pediatric Patients Undergoing Venipuncture or Peripheral Venous Cannulation: Randomized Double-blind COMFORT-004 Trial. *Clin Ther*, 37(8), 1761-1772. doi:10.1016/j.clinthera.2015.05.515
- Zempsky, W. T., Schmitz, M. L., & Meyer, J. M. (2016). Safety and Efficacy of Needle-free Powder Lidocaine Delivery System in Adult Patients Undergoing Venipuncture or Peripheral Venous Cannulation: A Randomized, Double-Blind, Placebo-controlled Trial. *Clin J Pain*, 32(3), 211-217. doi:10.1097/ajp.0000000000000257

## **Appendix A. GRADE criteria for rating a body of evidence on an intervention**

Developed by the GRADE Working Group



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### ***Grades and interpretations:***

High: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low: Any estimate of effect is very uncertain.

### ***Type of evidence and starting level***

Randomized trial—high

Observational study—low

Any other evidence—very low

### ***Criteria for increasing or decreasing level***

#### **Reductions**

Study quality has serious (–1) or very serious (–2) problems

Important inconsistency in evidence (–1)

Directness is somewhat (–1) or seriously (–2) uncertain

Sparse or imprecise data (–1)

Reporting bias highly probable (–1)

#### **Increases**

Evidence of association† strong (+1) or very strong (+2)

†Strong association defined as significant relative risk (factor of 2) based on consistent evidence from two or more studies with no plausible confounders Very strong association defined as significant relative risk (factor of 5) based on direct evidence with no threats to validity.