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| Question |
| **Should wound clamps compared with other hemostatic techniques be used for adults and children with severe, life-threatening external bleeding?** |
| **Population:** | Adults and children with severe, life-threatening external bleeding |
| **Intervention:** | Wound clamp |
| **Comparison:** | Direct pressure or other hemostatic measures |
| **Main outcomes:** | Death owing to bleeding, cessation of bleeding (restoration of hemostasis), and time to hemostasis, death from any cause, decrease in bleeding, and adverse effects (e.g. wound infection, limb loss, re-bleeding, pain related to an intervention). Where possible, the Evidence to Decision tables also include information regarding outcomes related to provider ability to use / ease of use / feasibility / satisfaction (for method of bleeding control) and predictors of use/response (for method of bleeding control). |
| **Setting:** | All studies performed in the out-of-hospital setting (direct evidence), as well as studies providing indirect evidence about the effects of interventions collected in combat (military) settings, simulations (i.e. human volunteers, human cadaver or other models excluding animal models), and studies performed in the hospital setting, that clinical content experts judged as performed in sufficiently similar conditions to still be informative. |
| **Perspective:** | Of the first aid provider and/or patient |
| **Background:** | Traumatic injury is a leading cause of morbidity and mortality and a major cause of death from traumatic injury is uncontrolled bleeding. Tourniquets and hemostatic dressings have the potentially to prevent morbidity and mortality from traumatic bleeding. Therefore it is easy to see that first aid care is essential to help prevent injury related morbidity and mortality, as injured persons can exsanguinate from severe injuries in only a few minutes.Current first aid recommendations for an individual with severe, life-threatening external bleeding includes applying direct pressure as standard therapy. Tourniquets and hemostatic dressings have been found to control bleeding effectively, therefore may be considered for use when standard measures are unable to control hemorrhage or in the situation where a first aid provider is unable to use standard first aid practices (for tourniquets) or for body areas where a tourniquet cannot be applied or is unable to control bleeding (for hemostatic dressings). There is no or limited data supporting the use of pressure points, elevation, or localized cold therapy.  |
| **Conflict of interests:** | None identified |

# Assessment

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| ProblemIs the problem a priority? |
| Judgement | Research evidence | Additional considerations |
| ○ No○ Probably no○ Probably yes● Yes○ Varies○ Don't know | Traumatic injury is the leading cause of injury related morbidity and mortality throughout the world, resulting in millions of hospitalizations each year. The leading cause of preventable mortality in injured patients is uncontrolled hemorrhage (Jacobs 2014 67). Hemorrhage is cited as the primary cause of death in 35% of traumatic mortalities and often contributes to death ultimately attributed to other causes (Kauvar 2006 S3). In addition, trauma related deaths disproportionality affects those in low and middle income countries where well established pre-hospital trauma systems may not exist (World Health Organization 2018). |  |
| Desirable EffectsHow substantial are the desirable anticipated effects? |
| Judgement | Research evidence | Additional considerations |
| ○ Trivial○ Small● Moderate○ Large○ Varies○ Don't know |

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| **Certainty assessment** | **№ of patients** | **Effect** | **Certainty** | **Importance** |
| --- | --- | --- | --- | --- |
| **Study design** | **Risk of bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other considerations** | **wound clamp** | **other hemostatic techniques** | **Relative(95% CI)** | **Absolute(95% CI)** |  |  |
| Mortality due to bleeding - Civilian |
| observational studies (Tan 2016 1012)  | serious a | not serious  | not serious b | serious c | none  | 0/10 (0.0%)(Tan 2016 1012)  | -  | -  | -  | ⨁◯◯◯VERY LOW  | CRITICAL  |
| Cessation of bleeding - Civilian |
| observational studies  | serious  | not serious  | not serious b | serious c | none  | McKee et al. {McKee 2018 39} reported that the iTClamp stopped bleeding in 198/245 (81%) of applications. Tan et al. [Tan 2016 1012] reported cessation of bleeding with the iTClamp in 6/10 (60%) applications. | ⨁◯◯◯VERY LOW  | CRITICAL  |
| Time to hemostasis - Civilian |
| observational studies (Tan 2016 1012)  | serious  | not serious  | not serious b | serious c | none  | Average time to achieve hemostasis was 11 minutes (95% CI: 5 to 16).  | ⨁◯◯◯VERY LOW  | CRITICAL  |
| Mortality due to all causes - Civilian |
| observational studies (Tan 2016 1012) | serious  | not serious  | not serious b | serious c | none  | 0/10 (0.0%)  | -  | -  | -  | ⨁◯◯◯VERY LOW  | IMPORTANT  |
| Decrease in bleeding - Civilian (assessed with: Cessation or decrease in bleeding) |
| observational studies (Tan 2016 1012) | serious  | not serious  | not serious b | serious c | none  | 9/10 (90.0%)  | -  | -  | -  | ⨁◯◯◯VERY LOW  | IMPORTANT  |

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 | One case series demonstrated the wound clamp ceased bleeding in the majority of the patients.  |
| Undesirable EffectsHow substantial are the undesirable anticipated effects? |
| Judgement | Research evidence | Additional considerations |
| ○ Large○ Moderate○ Small○ Trivial○ Varies● Don't know | There is no research to provide data on undesirable anticipated effects. | While the ability to prevent mortality and morbidity would be a potential beneficial effect, there is little literature to suggest first aid providers would be able to do so with this technology. It is felt by the task force that this technology would be too difficult for first aid providers to learn and there is potential harm.  |
| Certainty of evidenceWhat is the overall certainty of the evidence of effects? |
| Judgement | Research evidence | Additional considerations |
| ● Very low○ Low○ Moderate○ High○ No included studies | The certainty of the evidence across all outcomes was determined to be very low. Certainty downgrades were due to risk of bias, indirectness and imprecision.  | Very low certainly evidence with only one observational study (case series) in EMS providers |
| ValuesIs there important uncertainty about or variability in how much people value the main outcomes? |
| Judgement | Research evidence | Additional considerations |
| ○ Important uncertainty or variability○ Possibly important uncertainty or variability● Probably no important uncertainty or variability○ No important uncertainty or variability | No research evidence identified. | Like other forms of hemostasis for control of severe, life-threatening bleeding, the outcomes of reduced mortality and control of bleeding are valued. The main goal is to have rapid, effective bleeding cessation.While the outcome of cessation of bleeding is important there are no comparative studies with other methods of hemorrhage control. There is also minimal studies on wound clamps in the out of hospital setting.  |
| Balance of effectsDoes the balance between desirable and undesirable effects favor the intervention or the comparison? |
| Judgement | Research evidence | Additional considerations |
| ● Favors the comparison○ Probably favors the comparison○ Does not favor either the intervention or the comparison○ Probably favors the intervention○ Favors the intervention○ Varies○ Don't know | No research evidence identified. | With the paucity of evidence for lay providers and the availability of other techniques to control hemorrhage, the comparator of other hemostatic methods should be favored over wound clamps.  |
| Resources requiredHow large are the resource requirements (costs)? |
| Judgement | Research evidence | Additional considerations |
| ○ Large costs● Moderate costs○ Negligible costs and savings○ Moderate savings○ Large savings○ Varies○ Don't know | No research evidence identified.  | A search of cost for commercial devices suggests that these devices would be more expensive than direct manual pressure, but could be comparable to other methods of hemostasis such as hemostatic dressings our commercial tourniquets.  |
| Certainty of evidence of required resourcesWhat is the certainty of the evidence of resource requirements (costs)? |
| Judgement | Research evidence | Additional considerations |
| ○ Very low○ Low○ Moderate○ High● No included studies | No research evidence identified.  |  |
| Cost effectivenessDoes the cost-effectiveness of the intervention favor the intervention or the comparison? |
| Judgement | Research evidence | Additional considerations |
| ● Favors the comparison○ Probably favors the comparison○ Does not favor either the intervention or the comparison○ Probably favors the intervention○ Favors the intervention○ Varies○ No included studies | No research evidence identified. | While there are no direct studies, the cost of wound clamps appears to approximate the cost of hemostatic dressings or tourniquets. As those interventions (along with direct manual pressure) have more robust data for lay providers it is felt by the task force that the comparators are favored over the intervention (wound clamp).  |
| EquityWhat would be the impact on health equity? |
| Judgement | Research evidence | Additional considerations |
| ○ Reduced● Probably reduced○ Probably no impact○ Probably increased○ Increased○ Varies○ Don't know | No research evidence identified.  | If this type of device were recommended over the lower costs of some other hemostasis methods (e.g. direct manual pressure) it would decrease health equity. It does have a similar cost to hemostatic dressings and tourniquets, however those have more studies supporting their use.  |
| AcceptabilityIs the intervention acceptable to key stakeholders? |
| Judgement | Research evidence | Additional considerations |
| ○ No● Probably no○ Probably yes○ Yes○ Varies○ Don't know | An average user satisfaction measured on a scale from 1 to 10 was 7.7 (95% CI: 6.6 to 8.8) (Tan 2016 S3). | No data is available for lay first aid providers, the only study was completed using emergency services providers. Due to the cost of devices (including training/implementation) as well as the limited data on effectiveness, when compared to other hemostatic techniques, this may lead to a lower likelihood of acceptability. |
| FeasibilityIs the intervention feasible to implement? |
| Judgement | Research evidence | Additional considerations |
| ● No○ Probably no○ Probably yes○ Yes○ Varies○ Don't know | Tan et al (Tan 2016 S3) reported that the average usage satisfaction score was 7.7 | This intervention would not be easy to implement as there are no training resources for lay providers and a lack of evidence on use of these devices in the out of hospital setting.  |

# Summary of judgements

|  | **Judgement** |
| --- | --- |
| **Problem** | No | Probably no | Probably yes | **Yes** |  | Varies | Don't know |
| **Desirable Effects** | Trivial | Small | **Moderate** | Large |  | Varies | Don't know |
| **Undesirable Effects** | Large | Moderate | Small | Trivial |  | Varies | **Don't know** |
| **Certainty of evidence** | **Very low** | Low | Moderate | High |  |  | No included studies |
| **Values** | Important uncertainty or variability | Possibly important uncertainty or variability | **Probably no important uncertainty or variability** | No important uncertainty or variability |  |  |  |
| **Balance of effects** | **Favors the comparison** | Probably favors the comparison | Does not favor either the intervention or the comparison | Probably favors the intervention | Favors the intervention | Varies | Don't know |
| **Resources required** | Large costs | **Moderate costs** | Negligible costs and savings | Moderate savings | Large savings | Varies | Don't know |
| **Certainty of evidence of required resources** | Very low | Low | Moderate | High |  |  | **No included studies** |
| **Cost effectiveness** | **Favors the comparison** | Probably favors the comparison | Does not favor either the intervention or the comparison | Probably favors the intervention | Favors the intervention | Varies | No included studies |
| **Equity** | Reduced | **Probably reduced** | Probably no impact | Probably increased | Increased | Varies | Don't know |
| **Acceptability** | No | **Probably no** | Probably yes | Yes |  | Varies | Don't know |
| **Feasibility** | **No** | Probably no | Probably yes | Yes |  | Varies | Don't know |

# Type of recommendation: No recommendation MADE

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| --- | --- | --- | --- | --- |
| Strong recommendation against the intervention | Conditional recommendation against the intervention | Conditional recommendation for either the intervention or the comparison | Conditional recommendation for the intervention | Strong recommendation for the intervention |
| ○  | ○  | ○  | ○  | ○  |

# Conclusions

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| Recommendation |
| Due to the lack of comparative evidence, we are unable to recommend for or against the use of wound clamps by first aid providers in the out-of-hospital setting in comparison with other hemostatic techniques for severe, life-threatening external bleeding.  |
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| Justification |
| * In considering the data, only one study (Tan 2016 1012) demonstrates the use of wound clamps in the pre-hospital setting. This study was a small observation study of 12 patients managed by healthcare professionals and that it did not include lay providers. While outcomes in this study were good, the Task Force believes that wound clamps could pose a potential risk for harm when used inappropriately.
* The Task Force recognizes that wound clamps represent a significant cost, and therefore, may increase health care disparity, and in many instances would not be feasible to implement.
* The Task Force also places significant value on the perceived risks of placing a wound clamp by lay providers over the limited data on benefit. As the Task Force believes there are other appropriate alternatives with more robust evidence and believes in the concept of doing no harm we chose not to recommend wound clamps for first aid providers.
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| Subgroup considerations |
| N/A |

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| Implementation considerations |
| N/A |

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| Monitoring and evaluation |
| N/A |

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| Research priorities |
| Studies looking at the use of these devices in an out of hospital setting, and most specifically by first aid providers are needed. |

**References**

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