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| Question | |
| **Should hemostatic dressings with or without direct pressure compared with direct pressure alone be used for adults and children with severe, life-threatening external bleeding?** | |
| **Population:** | Adults and children with severe, life-threatening external bleeding |
| **Intervention:** | Hemostatic dressings with or without direct pressure (manual or pressure to the round with a compression dressing, compression bandage, or compression device) |
| **Comparison:** | Direct manual pressure or direct pressure to the wound with a compression dressing, compression bandage, or compression device |
| **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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| Problem Is 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). | While direct manual pressure is the gold standard for hemorrhage control in life-threatening bleeding, the addition of a hemostatic dressing could enhance the effect of direct manual pressure. |
| Desirable Effects How substantial are the desirable anticipated effects? | | |
| Judgement | Research evidence | Additional considerations |
| ○ Trivial ○ Small ●  Moderate ○ Large ○ Varies ○ Don't know | | **Certainty assessment** | | | | | | | **№ of patients** | | **Effect** | | **Certainty** | **Importance** | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **№ of studies** | **Study design** | **Risk of bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other considerations** | **hemostatic dressing without direct pressure** | **direct manual pressure or pressure dressing** | **Relative (95% CI)** | **Absolute (95% CI)** | | Mortality due to bleeding - not reported | | | | | | | | | | | | | | - | - | - | - | - | - | - | - | - | - | - | - | CRITICAL | | Cessation of bleeding - Civilian | | | | | | | | | | | | | | 1 {Hatamabadi 2015 e23862} | randomised trials | serious | not serious | serious | serious | none | 80/80 (100.0%) | 80/80 (100.0%) | not estimable | **0 fewer per 1,000** (from -- to --) | ⨁◯◯◯ VERY LOW | CRITICAL | | Cessation of bleeding - Civilian | | | | | | | | | | | | | | 7 | observational studies | serious e | not serious | not serious | not serious | none | Among a total of 218 patients receiving hemostatic dressing from seven case series in the civilian setting: median proportion of patients with complete cessation of bleeding was 79% (range 70% to 100%) {Brown 2009 1; Leonard 2016 441; Rhee 2008 1093; Te Grotenhuis 20161007; Travers 2016 2016 391; Warrier 2018 epub} | | | | ⨁◯◯◯ VERY LOW | CRITICAL | | Cessation of bleeding - Military | | | | | | | | | | | | | | 1 | observational studies | serious e | not serious | not serious | serious f | none | Among 35 patients receiving hemostatic dressing from one case series in the military setting: 31/35 (88.6%) achieved cessation of bleeding. {Weppner 213 220} | | | | ⨁◯◯◯ VERY LOW | CRITICAL | | Cessation of bleeding - In-hospital | | | | | | | | | | | | | | 2 | randomised trials | serious g | not serious | very serious h | serious f | none | In one RCT {Waragai 2011 262}hemostasis was achieved in all pediatric patients who had undergone cardiac catheterization with arterial access (8/8 vs. 13/13). In the second RCT {Balzer 2007 693} in patients who underwent vascular interventional procedures with femoral artery access, 95% (57/60) achieved bleeding cessation with hemostatic dressing compared with 100% (60/60) with manual compression (RR=0.95, 95% CI: 0.90-1.01; p=0.24). i | | | | ⨁◯◯◯ VERY LOW | CRITICAL | | Cessation of bleeding - In-hospital | | | | | | | | | | | | | | 1 | observational studies | serious j | not serious | very serious h | serious f | none | Among patients undergoing coronary angiography, all achieved hemostasis with hemostatic dressing (50/50) and with manual compression (38/38) {Tjiong 2012 88}. | | | | ⨁◯◯◯ VERY LOW | CRITICAL | | Cessation of bleeding - Simulation | | | | | | | | | | | | | | 1 | observational studies | serious l | not serious | serious l | serious m | none | Simulation study in a laboratory wound model of bleeding with 10 applications in each group. Cessation of bleeding, as measured by cessation of flow of liquid, was achieved in 50% (5/10) of hemostatic dressing (mini cellulose sponge injector) applications compared with 10% (1/10) with regular dressing {Kragh 2015 974}. | | | | ⨁◯◯◯ VERY LOW | CRITICAL | | Hemostasis within 5 minutes - Civilian | | | | | | | | | | | | | | 1 {Hatamabadi 2015 e23862} | randomised trials | serious b | not serious | serious b | not serious n | none | 41/80 (51.2%) o | 26/80 (32.5%) | **RR 1.58** (1.08 to 2.31) p | **19 more per 100** (from 3 more to 43 more) | ⨁⨁◯◯ LOW | CRITICAL | | Time to hemostasis - Civilian | | | | | | | | | | | | | | 2 | observational studies | serious e | not serious | not serious | serious f | none | One series of cases with massive traumatic hemorrhage reported that the median time to hemostasis when using chitosan-coated gauze (ChitoGauze) was 1 minute (interquartile range: 0 to 3 minutes) {te Grotenhuis 2016 1007}, and the other series of traumatic cases reported cessation of bleeding with chitosan-based dressing (HemCon) within 1 minute in 35% of patients, within 3 minutes in 74%, within 10 minutes in 79%, and within 10 minutes or longer in 100% {Brown 2009 1}. | | | | ⨁◯◯◯ VERY LOW | CRITICAL | | Time to hemostasis - In-hospital | | | | | | | | | | | | | | 14 | randomised trials | not serious | not serious | very serious h | not serious | none | Fourteen RCTs with a total of 2,419 patients undergoing endovascular procedures showed that time to hemostasis was consistently shorter with hemostatic dressing compared to direct pressure in all RCTs {Waragai 2011 262; Balzer 2007 693; Zhu 2010 582; Schwartz 2009 53; Sairaku 2011 157; Nguyen 2007 801; Narins 2008 579; Miekusch 2006 23; McConnell 2012 e1; Kordestani 2012 501; Kang 2017 e0181099; Behler 2009 159; Arbel 2011 1104; Trabattoni 2012 53}. The range of means among 13 RCTs that reported the mean time to hemostasis: 4.6-17.8 minutes with hemostatic dressings compared to 12.4-43.5 minutes with direct manual pressure, and the range of mean differences among these studies ranged from 2.00 minutes (95% CI: 0.46-3.54) to 32.00 minutes (95% CI: 28.03-35.97). | | | | ⨁⨁◯◯ LOW | CRITICAL | | Mortality due to all causes - Civilian | | | | | | | | | | | | | | 3 | observational studies | serious e | not serious | not serious | serious f | none | One civilian study reported no deaths among 14 patients that received zeolite-based hemostatic pad (QuikClot Combat Gauze) in the pre-hospital setting {Rhee 2008 1093}, a second study reported no deaths among 10 patients receiving expandable hemostatic mini-sponges {Warriner 2018 424}, and another study reported 6 deaths among 30 patients treated by Fire Department responders which were likely not due to bleeding according to the authors {Travers 2016 391}. | | | | ⨁◯◯◯ VERY LOW | IMPORTANT | | Mortality due to all causes - Military | | | | | | | | | | | | | | 1 | observational studies | serious r | not serious | not serious | serious f | none | Among 190 patients all-cause mortality was 11% (3/28) mortality in those receiving hemostatic gauze and 6% (9/162) in those who did not (unadjusted RR=1.93, 95% CI: 0.56-6.69; p=0.39) {Schauer 2009 53}. | | | | ⨁◯◯◯ VERY LOW | IMPORTANT | | Mortality due to all causes - Military | | | | | | | | | | | | | | 5 | observational studies | serious e | not serious | not serious | serious f | none | Among 197 patients receiving hemostatic dressing in five case series, median all-cause mortality was 7%, and ranged from 0% to 23% {Weppner 2013 220; Shina 2015 S204; Pozza 2011 31; Ran 2010 584; Cox 20090 248S}. | | | | ⨁◯◯◯ VERY LOW | CRITICAL | | Mortality due to all causes - In-Hospital | | | | | | | | | | | | | | 2 | randomised trials | not serious | not serious | very serious h,t | serious u | none | Two RCTs in the hospital setting with a total of 1,028 patients undergoing endovascular procedures: one RCT showed no benefit in hemostatic dressings compared with direct pressure alone as no deaths occurred in either group (0/50 vs 0/50 [RR=1.00, 95% CI: 0.02-49.44; p=1.0){Politi 2011 65}. A second RCT showed no benefit in all-cause mortality for hemostatic dressings compared to pneumatic compression as no deaths occurred in either group (Neptune: 0/303; D-Stat Dry: 0/303; Femostop: 0/302) {Schwarz 2009 53}. | | | | ⨁◯◯◯ VERY LOW | IMPORTANT | | Blood loss (assessed with: number of blood-soaked gauzes 10x10 cm) | | | | | | | | | | | | | | 1 {Hatamabadi 2015 e23862} | randomised trials | serious a | not serious | serious b,w | not serious | none | 80 | 80 | - | MD **0.43 gauzes fewer** (0.85 fewer to 0.01 fewer) x | ⨁⨁◯◯ LOW | IMPORTANT | | Decrease in bleeding - Civilian (assessed with: Cessation or decrease in bleeding) | | | | | | | | | | | | | | 3 | observational studies | serious e | not serious | not serious | not serious | none | In three case series with a total of 120 patients receiving hemostatic dressing the median proportion of patients achieving either bleeding cessation or decrease in bleeding was 93% (ranging from 89% to 100%). {Travers 2016 391; Peters 2014 28; Te Grotenhuis 2016 1007} | | | | ⨁◯◯◯ VERY LOW | IMPORTANT | | Decrease in bleeding - Military (assessed with: Cessation or decrease in bleeding) | | | | | | | | | | | | | | 7 | observational studies | serious e | not serious | not serious | not serious | none | In seven case series with a total of 259 patients receiving hemostatic dressing the median proportion of patients achieving either bleeding cessation or decrease in bleeding was 91% (ranging from 79% to 100%). {Weppner 2013 220; Schauer 2017 101; Shina 2015 S204; Pozza 2011 31; Ran 2010 584; Cox 2009 248S; Wedmore 2006 655} | | | | ⨁◯◯◯ VERY LOW | IMPORTANT | | Decrease in bleeding - Simulation | | | | | | | | | | | | | | 2 | observational studies | serious l | not serious | serious l | serious y | none | In one study with 20 applications in a laboratory wound model, 10 in each group, blood loss, as measured by volume of liquid from the mannequin, showed a benefit for hemostatic dressings compared to direct pressure with a standard gauze as liquid loss was 93ml with hemostatic dressings (cellulose mini sponge injector) compared to 113ml with the bandage roll{Kragh 2015 974}. The second study with 16 applications in a mannequin model, 4 applications in four different groups, showed reduced bleeding, as measured by liquid loss from the manikin, with full application of the QuikClot Combat Gauze compared to no use of the gauze {Kragh 2014 1130}. | | | | ⨁◯◯◯ VERY LOW | IMPORTANT |  |  | | --- | |  | | Overall, hemostatic dressings demonstrated cessation of bleeding when used and a faster time to hemostasis. |
| Undesirable Effects How substantial are the undesirable anticipated effects? | | |
| Judgement | Research evidence | Additional considerations |
| ○ Large ○ Moderate ● Small ○ Trivial ○ Varies ○ Don't know | |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Rebleeding - Civilian | | | | | | | | | | | 2 | observational studies | serious e | not serious | not serious | serious f | none | In two case series with a total of 84 patients treated with hemostatic dressing, one study showed a 0/18 (0%) rebleeding rate {Peters 2014 28}, and the other study 2/66 (3%) {te Grotenhuis 2016 1007}. | ⨁◯◯◯ VERY LOW | IMPORTANT | | Rebleeding - In-hospital | | | | | | | | | | | 9 | randomised trials | not serious | not serious | very serious h | serious u | none | In nine RCTs with a total of 2,453 patients receiving endovascular procedures, there was little to no difference in rebleeding rates between the hemostatic dressing and direct pressure groups. {Waragai 2011 262; Balzer 2007 693; Schwarz 2009 53; Sairaku 2011 157; Nguyen 2007 801; Mlekusch 2006 23; Kang 2017 e01811099; Tabattoni 2012 53; Dai 2015 192} | ⨁◯◯◯ VERY LOW | IMPORTANT | | Any complications/adverse events - Civilian | | | | | | | | | | | 6 | observational studies | serious e | serious aa | not serious | serious u | none | There were five case series with a total of 257 patients receiving hemostatic dressing. Three case series (124 patients) that used chitosan-based dressing {Brown 2009 1; te Grotenhuis 2016 1007; Peters 2014 28} and 1 case series (30 patients) using kaolin-based hemostatic pad (QuikClot Combat Gauze) {Travers 2016 391} reported no adverse effects. However, one series of 10 cases receiving expandable hemostatic mini-sponges reported one case of retained sponges requiring surgical wound extension and retrieval {Warriner 2018 424}, and one case series of 83 patients with QuikClot zeolite-based granules reported that 25% of patients experienced mild to severe pain and discomfort associated with the exothermic reaction from QuikClot, with 3 burn cases {Rhee 2008 1093}. | ⨁◯◯◯ VERY LOW | IMPORTANT | | Any complications/adverse events - Military | | | | | | | | | | | 3 | observational studies | serious e | serious ab | not serious | serious u | none | There were three case series with a total of 82 patients receiving hemostatic dressing. One case series (64 patients) that used chitosan-based dressing {Wedmore 2006 655} and one case series (14 patients) using kaolin-based hemostatic pad (QuikClot Combat Gauze) {Ran 2010 584} reported no adverse effects. However, one case series that used QuikClot zeolite-based granules reported that 2/4 (50%) patients experienced superﬁcial burns in the soft tissues and at the wound edges as an apparent result of the exothermic reaction {Cox 2009 1537}. | ⨁◯◯◯ VERY LOW | IMPORTANT | | Any complications/adverse events - In-hospital | | | | | | | | | | | 4 | randomised trials | not serious | not serious | very serious h | serious u | none | Four RCTs with a total of 1,040 patients undergoing endovascular procedures. Three RCTs reported no major complications including major bleeding in either group Balzer et al.{Balzer 2007 693}: 0/60 vs 0/60 [RR=1.00, 95% CI: 0.02-49.60; p=1.0]). Dai et al.{Dai 2015 192}: 0/300 vs 0/300 (RR=1.00, 95% CI: 0.02-50.24; p=1.0). Politi et al{Politi 2011 65}: 0/50 vs 0/50 (RR=1.00, 95% CI: 0.02-49.44; p=1.0)]. One RCT reported 2/100 (2.0%) major bleeding complications in the hemostatic dressing group compared with 4/100 (4.0%) in the manual pressure group (RR=0.50, 95% CI: 0.09-2.67; p=0.68) {Trabattoni 2012 53}. | ⨁◯◯◯ VERY LOW | IMPORTANT | | Patient discomfort - In-hospital | | | | | | | | | | | 1 | randomised trials | not serious | not serious | very serious h | serious u | none | In an RCT with 95 patients {Behler 2009 159}, the mean patient self-reported discomfort with the interventional procedure was greater in the hemostatic dressing group compared with the pressure dressing group. | ⨁◯◯◯ VERY LOW | IMPORTANT | | Patient discomfort - In-hospital | | | | | | | | | | | 2 | observational studies | serious r | not serious | very serious h | serious u | none | Two cohort studies with a total of 224 patients undergoing endovascular procedures. One study showed no significant difference in pain scores (on a 0-10 scale) between the hemostatic dressing and direct pressure groups.{Tjiong 2012 88} The other study showed no difference in patient satisfaction using a 1-10 scale between hemostatic dressing and manual compression (9.7% [SD 0.5] vs. 9.4% [SD 1.0]; p=0.4) {Arbel 2011 1104} | ⨁◯◯◯ VERY LOW |  | | There are reported adverse events with use of hemostatic dressings, namely pain and bleeding.  Rebleeding rates are similar with hemostatic dressings compared with direct pressure along  Additional considerations not evaluated in the included studies: First generation hemostatic dressings with zeolite were associated with exothermic reactions and associated tissue damage. Newer mucoadhesive agents (Chitosan-derived) lack exothermic reaction, broken down by enzymatic reaction. Because they are shellfish based, there is theoretical risk of allergic reaction although no reports to date. Procoagulant supplementor- type of hemostatic dressings may not work with hypothermia and potential risk of distal thrombus formation. |
| Certainty of evidence What 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 with a few exceptions. Certainty downgrades were typically due to risk of bias, indirectness and/or imprecision. | There is a mix of certainty of evidence. If considering the most critical outcomes and evidence found within, namely those reporting cessation of bleeding, the evidence certainty is overall very low.  In considering these results, the level of certainly is very low due to study design as well as indirectness, with results extrapolated from the hospital setting following endovascular procedures, or from simulation studies.  In addition, many included studies are single-arm (i.e., without a control group or comparison) and were included due to lack of RCTs or cohort studies. Simulation studies were included where data was lacking or included to explore feasibility of use by lay providers, despite the very low level of certainty of this study design. |
| Values Is 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.  There is no specific research evidence regarding the value of hemostatic dressings or direct pressure specifically. |
| Balance of effects Does 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 | Research demonstrates that hemostatic dressings stop hemorrhage and do it more quickly than direct pressure or pressure dressings alone.  Cessation of bleeding at any time following injury was 100% with both a hemostatic dressing and direct pressure alone in one RCT {Hatamabadi 2015 e23862} in the in-hospital civilian trauma setting. Cessation of bleeding at any time following an in-hospital endovascular procedure was comparable in two RCTs {Balzer 2007 693, Waragai 2011 262} with 141 participants and one observational study {Tjiong 2012 88} with 88 participants (very low certainty evidence).  In one RCT {Hatamabadi 2015 e23862} with civilian trauma casualties in the in-hospital setting, cessation of bleeding was achieved within 5 minutes of initiating treatment in 41/80 (51.2%) patients receiving chitosan-coated hemostatic gauze compared with 26/80 (32.5%) receiving pressure dressings (RR, 1.58; 95% CI, 1.08-2.31). The range of mean differences in bleeding cessation from treatment initiation following endovascular procedures from 14 in-hospital RCTs {Waragai 2011 262; Balzer 2007 693; Zhu 2010 582; Trabattoni 2012 53; Schwarz 2009 53; Sairaku 2011 157; Nguyen 2007 801; Narins 2008 579; Mlekusch 2006 23; McConnell 2012 E1; Kordestani 2012 501; Kang 2017 e0181099; Behler 2009 159; Arbel 2011 1104} with low certainty evidence varied from 2 minutes (95% CI, 0.46-3.54) to 32 minutes (95% CI, 28.03-35.97), favoring hemostatic gauze (low certainty evidence).  Evidence from two RCTs {Schwarz 2009 53; Politi 2001 65} in the in-hospital setting following arterial puncture wounds for endovascular procedures and one cohort study (Schauer 2017 101) from a military setting showed no difference in all-cause mortality between patients treated with hemostatic dressings compared with direct pressure alone (very low certainty evidence for both).  Regarding complications, both re-bleeding rates (nine in-hospital RCTs {Balzer 2007 693; Dai 2015 192; Kang 2017 e0181099; Nguyen 2007 801; Mlekusch 2006 23; Schwarz 2009 53; Sairaku 2011 157; Trabattoni 2012 53; Waragai 2011 262} and major complications (four in-hospital RCTs {Balzer 2007 693; Dai 2015 192; Politi 2011 65; Trabattoni 2012 53}were comparable between hemostatic dressing and direct pressure (very low certainty evidence for both) . Subject discomfort was higher with hemostatic dressing in one in-hospital RCT {Tjiong 2012 88} and comparable with direct pressure in two in-hospital cohort studies {Kang 2017 e0181099; Arbel 2011 1104} following endovascular procedures (very low certainty evidence for both).  Regarding complications, both re-bleeding rates (nine in-hospital RCTs) and major complications (four in-hospital RCTs) were comparable between hemostatic dressing and direct pressure (very low certainty evidence for both) {Waragai 2011 262; Balzer 2007 693; Trabattoni 2012 53, Schwarz 2009 53; Sairaku 2011 157; Politi 2011 65; Nguyen 2007 801; Mlekusch 2006 23; Kang 2017; Dai 2015}. Subject discomfort was higher with hemostatic dressing in one in-hospital RCT and comparable with direct pressure in two in-hospital cohort studies following endovascular procedures (very low certainty evidence for both) {Tjiong 2012 88; Kang 2017 e0181099; Arbel 2011 1104}. | The desirable effects (cessation of bleeding, hemostasis) compared with the undesirable effects (pain) probably favor use of the intervention (hemostatic dressing) compared with use of direct manual pressure or pressure dressing/bandage/device. |
| Resources required How 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.  We were able to review medical supply catalogs and sales websites. | There would be a cost to purchase and stock devices as well as training to implement them. Training costs would include development of material, training aids, instructor training and first aid provider training.  Hemostatic dressings will require initial expense and replacement costs due to use and expiration.  Based on review of these sites, in Belgium hemostatic dressings costs: QuickClot: 60€ Selox applicator 40€ or bandage: 60€. In comparison passive dressings (without hemostatic agents): 15€ Simple hemostatic dressings in first aid (used by Belgian Red Cross): +/-1€ New Israeli bandages: 10€.  Dressings range in price in different countries  From $10 to $50 USD.  Inclusion of a hemostatic dressing in a first aid kit is estimated to add US$20 – US$40 to the price of a kit.  There is an element of human resource use included. Holding direct manual pressure takes away an individual from performing other interventions. This could be of detriment in an incident where there are multiple people injured or if a person has multiple life-threatening concerns (e.g. airway compromise and bleeding). |
| Certainty of evidence of required resources What 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. | Very little data is available to assess the individual and population cost of hemostatic dressing implementation. The cost of these dressings can be found online. |
| Cost effectiveness Does 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. | The costs of being prepared for the unlikely event of an uncontrollable bleed likely to be high from a system point of view and moderately high from an individual point of view. However, if a hemostatic dressing results in control of life-threatening bleeding, and a life saved, the benefit outweighs the cost of the dressing.  As more hemostatic dressings become commercially available, the cost is these dressings is anticipated to further decrease. |
| Equity What 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. | As these agents offer an expense above direct manual pressure alone, this may reduce health equity to rural areas that may be less likely to afford hemostatic dressings but may benefit most due to prolonged transport times. In addition, on a systems level, some organizations may not be able to purchase these due to the cost |
| Acceptability Is the intervention acceptable to key stakeholders? | | |
| Judgement | Research evidence | Additional considerations |
| ○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know | * HemCon ChitoGauze – 83% (55/66) providers were "satisfied or very satisfied" with using chitosan-coated gauze dressing {Te Grotenhuis 2016 1007} * HemCon ChitoGauze – Satisfaction rated with a mean of 7.6 (out of 10) {Brown 2009 1} | Studies demonstrate that both military and emergency medical services providers are willing to apply hemostatic dressings. No data is yet available for first aid providers.  Some devices have obtained FDA (US) approval, others have not.  Many providers have no (or limited) experience with these dressings.  There is likely regional variability in acceptability.  There is a current study underway looking at first aid provider acceptance of hemostatic dressings. This may help determine the level of acceptability. |
| Feasibility Is the intervention feasible to implement? | | |
| Judgement | Research evidence | Additional considerations |
| ○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know | HemCon ChitoGauze – 83% (55/66) providers were "satisfied or very satisfied" with using chitosan-coated gauze dressing {Te Grotenhuis 2016 1007}  * HemCon ChitoGauze – Satisfaction rated with a mean of 7.6 (out of 10) {Brown 2009 1} * Skills testing within 6 months of training and implementation of QuikClot Combat Gauze showed proficiency of 98.5% (326 of 331 providers) {Zietlow 2015 48} | Feasibility data primarily comes from military and emergency medical services implementation  Hemostatic dressings have been used in the military and emergency medical services, however, the data regarding implementation in the lay first aid setting is limited. There are legal and prescribing barriers in some countries as hemostatic dressings are considered medications in countries such as Belgium and Australia. However, there is the consideration that if first aid guidelines recommend either hemostatic dressing or tourniquets this may help overcome those barriers. Training issues must be considered for either agent.  In some countries, such as Australia, they are only available through a prescription, making access potentially difficult. |

# 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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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 |
| ○ | ○ | ○ | X | ○ |

# Conclusions

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| Recommendation |
| We suggest that first aid providers use a hemostatic dressing with direct pressure in comparison with direct pressure alone for severe, life-threatening external bleeding (weak recommendation, very low certainty of evidence). |
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| Justification |
| * In making this recommendation the Task Force was strongly influenced by one RCT {Hatamabadi 2011 e23862} in which a larger percentage of participants (51.2% compared with 32.5%) achieved cessation of bleeding within 5 minutes when a hemostatic dressing was used with direct pressure compared with direct pressure alone. * In Task Force discussion we recognized that it is pressure that stops bleeding and, when used appropriately, hemostatic dressings can be used as an adjunctive therapy to direct pressure to help stop life-threatening external bleeding. * The task force recognizes that the use of hemostatic dressings provides an additional material and training expense that may increase healthcare disparity in some cases. In addition, implementation of the use hemostatic dressings in some areas may not be feasible due to restrictions in availability for lay providers. Therefore, we feel that local conditions may dictate the availability and type of hemostatic dressing. |

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| Subgroup considerations |
| N/A |

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| Implementation considerations |
| Training materials would need to be developed and be flexible from country to country (or region to region). |

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| Monitoring and evaluation |
| Groups who implement the device should track use and success of use (and adverse events) |

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| Research priorities |
| There is limited research on the use of hemostatic dressings by first aid providers and if one type of device or agent is superior to another. |

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