INFORMATION BRIEF (RAPID REVIEW)

SINGLE USE LATEX-FREE TOURNIQUETS

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
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Rapid Review
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TITLE: SINGLE USE LATEX-FREE TOURNIQUETS

PURPOSE

To review the effectiveness, safety and cost-effectiveness of single use latex-free tourniquets based on request from the Medical Resource Unit, Medical Development Division, Ministry Of Health Malaysia following a proposal to introduce the product to Ministry of Health.

BACKGROUND

Health care-associated infection (HAI), also referred to as "nosocomial" or "hospital" infection, is an infection occurring in a patient during the process of care in a hospital or other health care facility which was not present or incubating at the time of admission. HAI can affect patients in any type of setting where they receive care and can also appear after discharge. Furthermore, they include occupational infections among staff. Based on data from a number of countries, it can be estimated that each year, hundreds of millions of patients around the world are affected by HAI.[24] HAI are known to significantly complicate the length of hospitalization and raise the risk of mortality, and they can impact up to 10% of hospital inpatients. [7] Therefore, there will be a huge reduction in the expenditures placed on hospitals, the healthcare system, and society as a whole by avoiding and eliminating nosocomial infections.[1-6]

The main emphasis for tackling HAIs is focused on hand hygiene, which has been shown to reduce the incidence of HAI. Numerous hospital items have been the subject of studies such as stethoscopes, keyboards and tourniquets, which have all been shown to act as vector for hospital pathogens. Reusable tourniquets are considered a risk factor for the development of puncture site infections or catheter related blood stream infection. There were several studies that have cultured reusable tourniquets demonstrated that they can be contaminated by *methicillin resistant staphylococcus aureus* (MRSA) and other pathogens in clinical environments which can contribute to HAI. [8,9,10,11,12,13,14,15,24,25] Numerous studies have identified MRSA-positive colonies of *S. aureus* on reusable tourniquets,[9,13,14,16] while others reported no MRSA growth on tourniquets.[17,18]

According to World Health Organization (WHO) guidelines, the infection control procedures that help to prevent health-care associated infections are include hand hygiene, use of glove, cleaning and disinfection of tourniquets. For all items include tourniquet to be used on more than one patient, health organizations should ensure that the material's designed can be cleaned and disinfected.[25]

From the documents provided by the [redacted] , single use tourniquet from [redacted] is a constricting or compressing device that is manufactured from high quality thermoplastic elastomer material which is eco-friendly. It is used to apply pressure to a limb or extremity to limit the flow of blood. This technology is produced with special characteristics such as latex-free to avoid allergy, smooth and textured anti-slip surface and also available in form of ready cut or perforated roll packaging. It is also claimed that the tourniquet offers good

performance, minimizes abrasions to the skin and this product are medically safe and certified by ISO, FDA and the Medical Device Authority of Malaysia.[19]

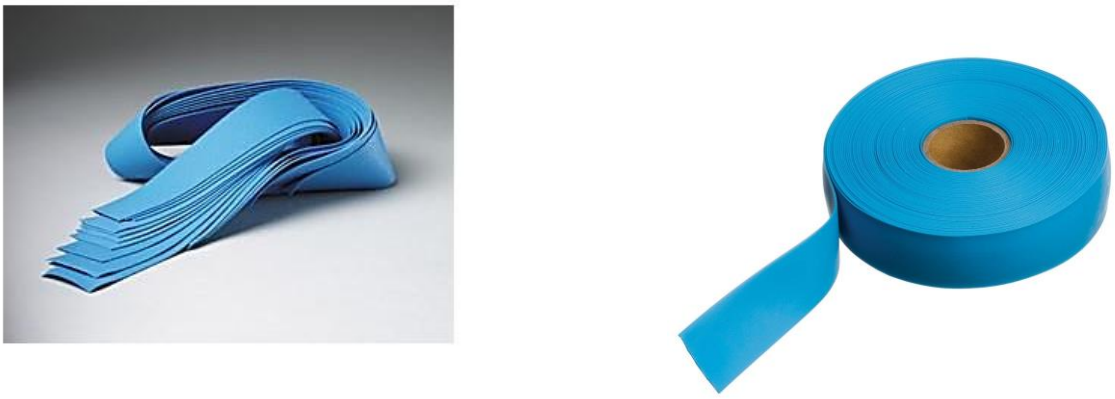

Figure 1: Single-use latex free tourniquet [19]

EVIDENCE SUMMARY

There was no evidence retrieved on the [redacted] single use latex-free tourniquet from the scientific databases such as Medline, Pubmed and from the general search engines [Google Scholar] except for U.S. Food and Drug Administration (USFDA). In the USFDA database, [redacted] single use latex-free tourniquet was registered as non pneumatic tourniquet with registered establish number 3020767858. The search was limited to english language and human with no limit years of publication. A total of two controlled trials studies and one guideline were found to be relevant and included in this review.

EFFICACY/ EFFECTIVENESS

There was no evidence retrieved on the effectiveness of [redacted] single use latex-free tourniquets. However, there was a study comparing single use tourniquets with reusable tourniquets in terms of pinching, comfortness and easy of use. Kerstein RL and Fellowes C (2009) conducted a study to compare patient and phlebotomist experiences of the author's single use tourniquet (Tournistrip TM) with current available reusable and disposable alternatives options within a phlebotomy outpatient setting in two major West London teaching hospitals. The study was performed over a four week period in November 2006. All eligible patients and phlebotomists whom undergo venepuncture procedure filled in a questionnaire. The patients answered the questionnaire aimed at gaining feedback on comfort and appearance compared to their personal experiences of alternatives and rubber gloves for venepuncture. The questions were answered using a Likert Scale, either numbered 0 to 6 (even integers only) or progressive statements of agreement. While the phlebotomists filled in a questionnaire giving their opinion on its ease of use compared to alternatives, its appearance and their overall rating was measured using Likert Scale. The study found that 72% of patients found the Tournistrip TM was comfortable during use with 95% reporting no considerable pinching and overall 85% of patients found this disposable

tourniquet was as good as reusable tourniquets. From phlebotomist's data, 95% of phlebotomist found them as easy to use. [20]

Thompson SM et al. (2011) conducted a prospective randomised clinical trial to compare the bacterial load of sterile and disposable elastic exsanguination tourniquets (EETs) versus reusable non-sterile pneumatic tourniquets used for the control of bleeding in lower limb surgical procedures. Patients from two district general hospitals in one NHS trust were randomized to either sterile or non-sterile tourniquet groups. The patients were screened for methicillin-resistant *Staphylococcus aureus* (MRSA) prior to surgery in accordance with trust guidelines. Samples were taken from the ties around the non-sterile tourniquet prior to surgery using an aseptic sterile technique. A biopsy of the main body of the sterile tourniquet was taken at the end of the procedure in a sterile fashion using a new surgical blade and new surgical gloves and gown. A total of 34 non-sterile and 36 sterile tourniquets were sampled. The specimens were sealed in universal containers and taken to the microbiological laboratories in the same trust. They were examined and tested by one biomedical scientist throughout who was blinded to the source of the tourniquet samples. The samples were placed onto whole Columbia blood agar plates and an aseptic technique was used to transfer both sides of the tourniquet to the agar. The plates were then incubated at 35°C for 48 hours in air. The results show unequivocally that the sterile EET is growth-free, whereas the non-sterile pneumatic tourniquet is contaminated in 23 of 34 of cases (68%) and the bacterial species identified are commonly found on human skin or excretions including coagulase-negative *staphylococcus spp*, the most common area of joint infection was found in total knee replacement and arthroscopy. From this study the author conclude that, this study clearly documented the bacterial load of pneumatic tourniquets and presented the fact that an alternative EET is not contaminated thus, using contaminated non-sterile tourniquets in surgical procedures that often involve insertion of foreign materials into the human body is not advisable [22]

SAFETY

From U.S. FDA website, [redacted] single use latex-free tourniquet was registered as non pneumatic tourniquet (registered establish number [redacted]). Besides, this technology as claimed was obtain ISO certificate and registered with Medical Device Authority of Malaysia . International guideline from WHO state that tourniquets are a potential source of *methicillin-resistant Staphylococcus aureus* (MRSA), with up to 25% of tourniquets contaminated through lack of hand hygiene on the part of the phlebotomist or reuse of contaminated tourniquets. To avoid contamination, any common-use items, should be visibly clean before use on a patient, and single-use items should not be reused.[25]

COST-EFFECTIVENESS

There was no evidence retrieved on cost effectiveness of [redacted] single use latex-free tourniquet. The price for [redacted] single use latex-free tourniquet was approximately between [redacted] and [redacted] per pieces depending on type of packaging requested.[19]

To cater for all inpatient and outpatient phlebotomy procedures according to Ministry of Health laboratory workload in year 2022, it may incur a budget of [redacted] to [redacted] for the procurement of the [redacted] single use latex-free tourniquets at the current range of price.[27] This calculation assumes that each sample taken and sent will require the use of one piece of tourniquet.

CONCLUSION

There was no evidence retrieved on [redacted] single use latex-free tourniquet. There was limited evidence on single use tourniquet for venepuncture purpose which showed single use tourniquet was preferable than reusable tourniquet in terms of pinching, comfortness and easy of use. There was insufficient evidence on usage of single use tourniquet on cross contamination reaction. Thus, more evidence is required. The introduction of [redacted] single use latex-free tourniquets in Ministry of Health facilities will incur a significantly high financial implication and should be taken into consideration.

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