

Post-Market Clinical Evaluation Report for the effectiveness of
Intermittent Pneumatic Compression (IPC) Devices

BACKGROUND

Intermittent pneumatic compression (IPC) devices are used to aid in preventing blood clots in the deep veins of the limbs through improving venous circulation of patients who suffer deep vein thrombosis (DVT), pulmonary embolism (PE), and edema [3]. However, a recently published study reported that among critically ill patients who received pharmacologic thromboprophylaxis, adjunctive intermittent pneumatic compression did not result in a significantly lower incidence of proximal lower-limb deep-vein thrombosis than pharmacologic thromboprophylaxis alone [1]. Therefore, the purpose of this study was to provide an evaluation for the efficacy of the IPC devices that are available in the Saudi market, when these devices are used as intended by the manufacturers.

CLINICAL BURDEN

Indications for using IPC (DVT, PE, and Edema):

Deep vein thrombosis (DVT) is a blood clot (thrombus) that forms in one or more of the deep veins in the body (usually in legs). This can also happen if patients are immobile for a long period of time. In some cases, a deep clot in a leg vein can run through the blood circulation and penetrate in the lung vessel, which can cause a blockage in the vessel called a pulmonary embolism. Pulmonary embolism can cause severe shortness of breath and even sudden death. Edema, on the other hand, refers to the leakage of blood from vessels into the surrounding tissues [4]. Figure 1 below shows the formation of DVT and PE:

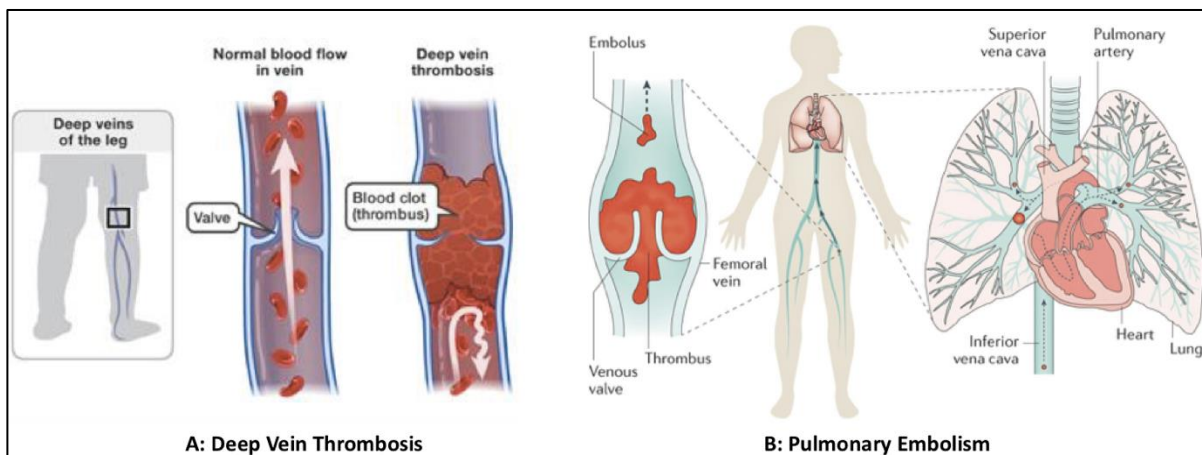


FIGURE 1: ILLUSTRATIONS OF: A: DEEP VEIN THROMBOSIS, AND B: PULMONARY EMBOLISM. [5], [6]

Using of IPC for treatment:

Intermittent pneumatic compression (IPC) devices uses cuffs around the legs that fill with air and squeeze the legs. The cuffs are attached to a pneumatic pump that supplies compressed air to inflate and deflate the cuff. The system offers sequential inflation and propels the vein blood from limb to heart, therefore enhance the blood circulation and helps prevent blood clots. IPC is used most often for people who have just had surgery. It may also be used after a stroke or to help treat lymphedema [3].

RISKS AND COMPLICATION

A recently published study reported that among critically ill patients who received pharmacologic thromboprophylaxis, adjunctive intermittent pneumatic compression did not result in a significantly lower incidence of proximal lower-limb deep-vein thrombosis than pharmacologic thromboprophylaxis alone [1].

EVALUATION OUTCOMES

The effectiveness of Intermittent pneumatic compression (IPC) devices for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and edema were evaluated considering three directions: a review of the recently published papers in the topic, opinions of specialized societies and the feedbacks of Saudi related experts.

Part 1: Clinical paper review**1.1 An overview of the search criteria**

The data for the last five years were retrieved for all clinical studies that discuss the research question. As a result, 63 articles were acquired, and screened first for duplication, and then through scanning the abstract as guided by the clarified inclusion criteria. Lastly, 31 recent and specific articles were obtained and read in full, as shown in figure 3.

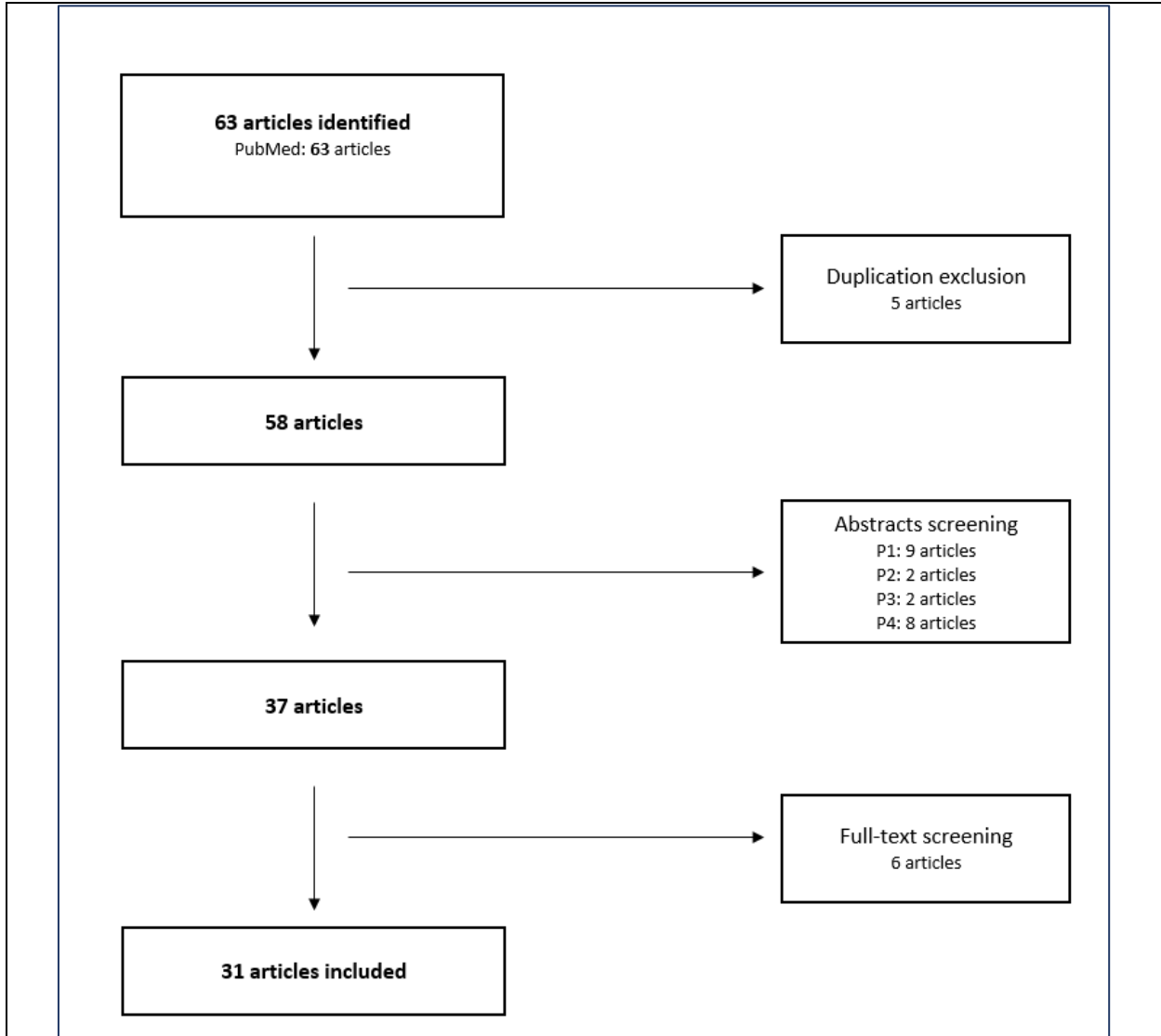


FIGURE 2: A SCHEMATIC REPRESENTATION OF THE PAPER SCREENING PROCESS.

1.2 Current-evidence in the efficacy of IPC for lymphedema.

IPC seems to be an effective treatment option for lymphedema, as revealed by multiple studies (Ref.[1], [4], [12], [37], [38], and [59]). However, one study [34] showed that IPC is a moderately effective and one study [40] have shown that IPC is not effective.

1.3 Current-evidence in the efficacy of IPC for Deep Vein Thrombosis (DVT).

Overall, IPC was shown to be an effective treatment option for Deep Vein Thrombosis (DVT), as reflected by multiple studies (Ref. [16], [36], [39], [43], [47], and [58]). Nevertheless, other studies (Ref. [21] and [62]) show that IPC is moderately effective.

1.4 Current-evidence in the efficacy of IPC for embolism.

The review includes two big meta-analyses that were designed to investigate the efficacy of IPC to treat embolism (Ref. [24] and [56]). Both studies indicate that IPC is an effective treatment option to the treatment of embolism.

1.5 Current-evidence in the efficacy of IPC for radiocephalic fistulas.

There were two studies addressing the effectiveness of IPC for radiocephalic fistulas (Ref. [2] and [3]), where IPC is revealed to be moderately effective.

Part 2: Specialized Societies

First, The Asian venous thromboembolism guidelines recommended to utilize IPC system as an option for patients undergoing general or gynecological surgery with moderate risk of (DVT) and (PE). It was recommended to use the device in combination with aspirin for patients undergoing major orthopedic surgeries like total hip replacement, total knee replacement and proximal hip fracture surgery. [7] According to the American College of Chest Physicians Evidence-Based Clinical Practice Guidelines, it was suggested to use mechanical prophylaxis, preferably with (IPC) for patients at low and moderate risk for VTE. Also, it was suggested to use IPC for patients at moderate to high risk for VTE who are at high risk for major bleeding complications. [8] [9] Similar results were provided in the clinical guideline for VTE by the National Institute for Health and Clinical Excellence (NICE). [10]

According to the Australian and New Zealand working party on the management and prevention of venous thromboembolism guideline, IPC reduces the incidence of DVT and more effective than other mechanical techniques in high risk patients in combination with anticoagulants, or when anticoagulants are contraindicated. [11] The German Society of Phlebology believes that IPC is a safe and effective treatment method for thromboembolism prophylaxis, decongestive therapy for edema, and to positively influence arterial and venous circulation to improve clinical symptoms and accelerate ulcer healing in both the outpatient and inpatient care setting. In conclusion, these clinical guidelines illustrate that the use of IPC is effective whenever the device is used as intended for the treatment of DVT, PE, and edema.

Part 3: Saudi user experience

A Saudi user experience was obtained by sending a survey to the hospitals, whose were chosen depending on their high number of IPC purchases among other hospitals in Saudi Arabia. The analysis of the obtained responses show that the device is significantly effective and they notice an improvement for reducing the blood clots when using IPC. In addition, they found that the device is easy to use and effective as indicated.

SFDA ACTIONS

From the literature review, it was concluded that the IPC is working as intended. Thus, no extra regulatory action should be applied.

SFDA RECOMMENDATIONS

Recommendations for healthcare professions:

- Intermittent pneumatic compression (IPC) is an effective and inexpensive method of reducing the risk of deep vein thrombosis (DVT).
- Intermittent pneumatic compression devices are appropriate for venous thromboembolism (VTE) when used in accordance to current clinical guidelines.
- Among patients with postoperative leg edema, local tissue blood perfusion can be improved by the use of IPC, which can result in decreased local leg swelling. In addition, the current evidence suggested that IPC effectively helps to reduce a phlebolympheidema.
- Adverse events are extremely rare if IPC is used correctly. The device is safe and effective treatment option if the indication and application are correct -also as an add-on therapy-, especially for the treatment of the described vascular diseases and edema as well as thrombosis prophylaxis.

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For further information or inquiries related to this study, you may contact us at: cia.md@sFDA.gov.sa

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