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Article

EARLY DANGLING PROTOCOL POST LOWER EXTREMITY FREE FLAP SURGERY: AN EVIDENCE-BASED CASE REPORT

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ABSTRACT

Background: Free flap is tissue transplantation by including its feeding artery from one body part to another. Intravascular thrombosis is the main obstacle commonly faced in the anastomosed part. Yet, postoperative extremity mobilization has widely become the main question related to flap failure. Only a few studies explained the best time to perform lower extremity mobilization post free flap surgery to maintain adequate flap viability. This study aimed to find the effectiveness of the dangling protocol in reducing lower extremity free flap surgery complications.
Methods: A literature search was conducted through PubMed, Cochrane, and Embase in March 2022 using "Free tissue flap" or "free flap" AND "dangling protocol" or "early ambulation" AND "postoperative complication" keywords. Title and abstract screening, full-text reading, and eligibility assessment were performed to find related evidence regarding our clinical question.
Results: The two relevant articles are a systematic review and a clinical trial study. Both studies showed 94-100% flap viability after applying early dangling protocol as early as three days post lower leg free flap surgery with level evidence of IIB up to IV without any incidence of flap necrosis.
Conclusion: Early dangling protocol can be implemented safely after free flap surgery of the lower extremity without postoperative complications such as total or partial necrosis.

Keywords: *Free Tissue Flaps, Lower extremity, Postoperative period, Early Ambulation*

Latar belakang: Flap bebas adalah transplantasi jaringan dengan memasukkan pembuluh darahnya dari satu bagian tubuh ke bagian tubuh lainnya. Trombosis intravaskular merupakan kendala utama yang sering dihadapi pada bagian anastomosis. Namun, mobilisasi ekstremitas pasca operasi telah banyak menjadi pertanyaan utama terkait kegagalan flap. Hanya sedikit penelitian yang menjelaskan waktu terbaik untuk melakukan mobilisasi ekstremitas bawah pasca operasi flap bebas untuk mempertahankan viabilitas flap yang adekuat. Penelitian ini bertujuan untuk mengetahui efektivitas protokol dangling dalam mengurangi komplikasi operasi flap ekstremitas bawah.
Metode: Pencarian literatur dilakukan melalui PubMed, Cochrane, dan Embase pada bulan Maret 2022 menggunakan kata kunci "Free tissue flap" OR "free flap" DAN "dangling protocol" OR "early ambulation" AND "postoperative Complication". Skrining judul dan abstrak, pembacaan teks lengkap, dan penilaian kelayakan dilakukan untuk menemukan bukti terkait mengenai pertanyaan klinis kami.
Hasil: Dua artikel yang relevan adalah tinjauan sistematis dan studi uji klinis. Kedua studi menunjukkan viabilitas flap 94-100% setelah menerapkan protokol awal dangling paling cepat tiga hari setelah operasi flap bebas tungkai bawah dengan bukti tingkat IIB hingga IV tanpa kejadian nekrosis flap.
Kesimpulan: Protokol dangling dini dapat diimplementasikan dengan aman setelah operasi free flap ekstremitas bawah tanpa komplikasi pasca operasi seperti nekrosis total atau parsial.

Kata Kunci: *Flap Jaringan Bebas, Ekstremitas bawah, Periode pasca operasi, Ambulasi Dini*

Conflicts of Interest Statement:
The author(s) listed in this manuscript declare the absence of any conflict of interest on the subject matter or materials discussed.

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INTRODUCTION

Free flap is the transplantation of a body part to another by carrying the source of its vascularization and connecting it to the blood vessels in the recipient area. Free flap requires a microscope to anastomose blood vessels that are only 1-2 mm in size, both arteries and veins.[1] Free flap procedures provide the complexity of surgery with major challenges, including postoperative success rates. The success indicator is the flap viability by clinically assessing necrotic signs of the tissue.[2]

The surgical intervention of lower extremity free flap has the potential to significantly alter the lives of patients who are confronted with severe traumatic injuries or medical conditions. Postoperative complications may arise, including early flap failure or loss. A major challenge in free-flap reconstruction is thrombosis in the postoperative anastomotic portion of the vessel.[3] This blockage is like a snowball that can aggregate platelets, clogs blood vessels, and inhibit blood flow. Intravascular pressure has an important role in maintaining blood flow. The free flap procedure in the lower limbs presents more challenges because of the tendency of lower intravascular pressures than the upper body area, thus more prone to partial necrosis.[4,5]

Gravity theoretically increases capillary pressure, which causes interstitial edema and physiological venous congestion in a healthy limb. A healthy body instantly senses this increase in capillary pressure and stimulates the venoarteriolar reflex of the venous stretch receptors, which changes arteriolar tone and reduces proximal leg blood flow.[6,7] After the free flap technique, these reflexes and signals are automatically severed, and the anastomotic blood vessels take time to mechanically join physiologically. Thus, an extremity that has just received a free flap is at risk for vascular changes in anticipation of venous congestion leading to tissue desaturation and therefore a dangling protocol is suggested for post-operative procedure.[7]

The execution of dangling protocol is typically carried out during the postoperative period. In this particular protocol, patients suspend the reconstructed lower leg from the bedside to incrementally expose the free flap to heightened venous pressure caused by gravitational forces. Several studies have indicated that the implementation of dangling protocols was intended to mitigate the likelihood of postoperative complications, such as partial or complete flap necrosis. Despite this, this approach may result in a longer hospital stay and higher costs.[4,5]

In order to mitigate these potential hazards, it is imperative to conduct an empirical investigation into the efficacy of the early dangling protocol subsequent to lower extremity free flap surgery. This article is aimed to know whether early postoperative mobilization of lower limb free flap surgery with dangling protocol can impact flap viability.

CASE ILLUSTRATION

A 15-year-old boy presented with recurrent contractures. The patient had a history of chronic burns of about 60% body surface area due to fires four years before admission to the hospital. He was treated at the local hospital after the initial incident. Serial operations were performed to treat the impact of burns, such as excision, contractures release, and repeated split-thickness skin grafts (STSGs), but contractures recurred, especially on the left leg. When he came to Dr. Cipto Mangunkusumo Hospital (RSCM), he was in overall good condition. The left pedis showed linear dorsiflexion contractures of fingers II-V. The patient was planned for contracture release and closure of the dorsal pedis defect with an ALT (Anterolateral Thigh) free flap.

CLINICAL QUESTION

The proposed question in this study was whether in patients underwent free flap surgery in lower extremities, can early postoperative legs mobilization with dangling protocol impact flap viability?

METHOD

A literature search was conducted on March 22, 2022, through Pubmed, Cochrane, and EMBASE databases by three independent reviewers (TAF, FAD, OTY). The search was carried out by entering keywords that matched the clinical question along with relevant synonyms, including population, intervention, comparator, and outcome. The keywords used

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Table 1. Article search strategy

Database	Search Strategy
PubMed	((("Free Tissue Flaps"[mesh] OR "free flap*"[tw] OR "free tissue flaps*"[tw]) AND (("Leg"[mes "Leg"[tw]))) AND (("Early ambulation"[mesh] OR "dangling*"[tw] OR "dangling protocol*"[t "dangle protocol*"[tw]))
Cochrane	(((MeSH descriptor: [Free Tissue Flaps] explode all trees) OR ((free flap):ti,ab,kw) AND MeS descriptor: [Lower Extremity] explode all trees) AND ((MeSH descriptor: [Early Ambulation all trees) OR ((dangling):ti,ab,kw) OR ((dangle):ti,ab,kw))
Embase	('post free flap':ti,ab OR 'free tissue graft'/exp OR 'free flap':ti,ab,kw OR 'free flap transfer':ti, 'free flaps':ti,ab,kw OR 'free microvascular flap':ti,ab,kw OR 'free tissue flap':ti,ab,kw OR 'free flaps':ti,ab,kw OR 'free tissue graft':ti,ab,kw OR 'free tissue transfer':ti,ab,kw OR 'graft, free':t AND ('lower leg'/exp OR 'crural region' OR 'lower leg' OR 'regio cruris') AND ('dangling pr OR 'mobilization'/exp OR mobilization OR 'ambulation' OR 'early ambulation' OR 'early mo OR 'early mobilization' OR 'mobilisation' OR 'mobilization') AND ('graft necrosis'/exp OR 'fl necrosis' OR 'graft necrosis' OR 'skin flap necrosis' OR 'graft failure'/exp OR 'engraftment fai 'flap failure' OR 'flap loss' OR 'graft failure' OR 'graft loss')

were free flap surgery, dangling protocol, postoperative complications, and partial or total flap necrosis, with its equivalent in the title and abstract. We also reviewed references from relevant articles. Table 1 shows the search strategy.

We defined dangling protocol as early mobilization to widen the search. Postoperative complications were characterized by flap or graft necrosis. We found 12, 4, and 6 articles matching the keywords on Pubmed, Cochrane, and Embase, respectively. The titles and abstracts were briefly reviewed to include only those written in English and conducted on human subjects. Excluded articles were other than meta-analyses, systematic reviews, randomized clinical trials, and duplicate articles. The article search process is shown in Figure 1.

RESULTS

Two studies were retrieved in response to our clinical inquiry, comprising a systematic review publication and a randomized clinical trial that was not incorporated in the former study. In the study conducted by Lee ZH, et al.[4], titled "Dangle protocols in lower extremity reconstruction," a cohort of patients who underwent microvascular reconstruction of the lower limbs were examined. The study compared the implementation of dangling protocols immediately after surgery versus seven days post-surgery, and evaluated the success rate of flap outcomes along with the factors that influenced them.

The study involved a systematic review of eleven articles, which were assessed based on

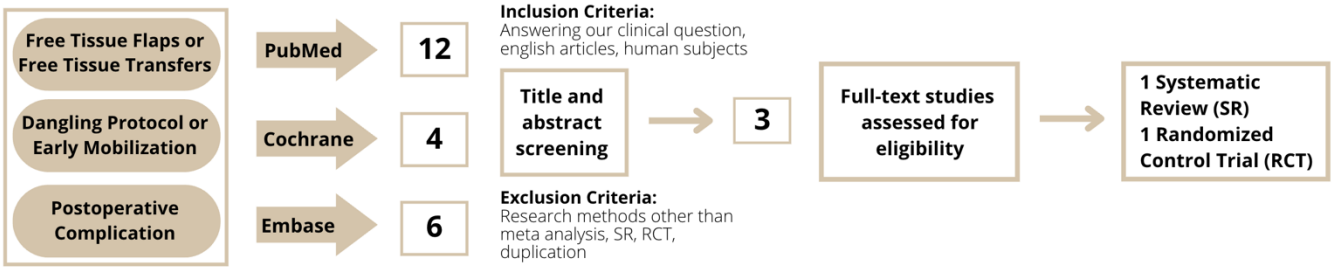

Figure 1. Article workflow stages

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evidence levels ranging from IIb to IV. The sample sizes of the studies ranged from 8 to 150, while the age range of participants spanned from 6 to 89 years. There was variability observed in the temporal aspects of the articles, including the timing, duration, and frequency. The cohort studies and randomized clinical trial study have reported a success rate of 94-100% for the flap in both the intervention and control groups. The calculation of the magnitude effect, including measures such as odds ratio or relative risk, as well as the heterogeneity test, were not performed due to the absence of a meta-analysis. The protocol may be subject to modification by active smoking, diabetes, and hypertension. The early initiation of the dangling protocol is deemed to be a secure approach for diverse flap locations, sizes, and indications. The patient's length of stay was reduced when protocol initiation was dangled on day 3, as opposed to limb mobilization that commenced on day 7 post-surgery.[4]

This systematic review indicates that the fasciocutaneous axial flap exhibits a greater capacity to withstand postoperative protocols of a more aggressive nature when compared to muscle flaps. The utilization of a protocol involving flaps possessing multiple venous anastomoses resulted in superior flap viability, despite the presence of comorbidities such as diabetes mellitus in the patient.[4]

This study has explicitly delineated the extant literature search methods, inclusion and exclusion criteria for article selection in accordance with the PRISMA 2020's systematic review checklist. The research question was also clearly laid out, namely to look for protocols in patients' mobilization post microvascular reconstruction surgery. Nevertheless, the authors only mentioned the terminology for existing studies without stating whether it is a text word or MeSH category. It conducted a comprehensive search across three prominent databases: PubMed, Embase-OVID, and Cochrane CENTRAL. The search filter was consistent with the research aims. In addition, the authors incorporated citations from pertinent scholarly publications to support their evaluations. The majority of the studies conducted were cohort in nature, with only a single randomized clinical trial being carried out. This article highlights the pertinence of the aforementioned study to the domain of postoperative management in the context of microvascular reconstruction.[4]

Jokuszies et al. conducted a study with a similar clinical inquiry to ours: Can the early start of dangling procedure in lower extremity free flap reconstruction affect the clinical outcome in patient underwent free flap surgery in the lower extremities? It compared dangling implementation three versus seven days postoperative. We employed CONSORT 2010 to evaluate the data encompassed within the trial. The study effectively presented its contextual framework and research aim. Nevertheless, variations were observed in the ratio of surgical indications and the age of patients. The study lacked clear specification of patient characteristics, including radiation history subsequent to tumor resection and the presence of comorbidities that could potentially hinder vascularization to the post-anastomotic flap. The study did not specify the methodology for generating the random allocation sequence and the specific type of randomization utilized.[5]

No participant withdrew from the clinical trial. The research findings indicate that there was no discernible distinction between the two groups, as the overall rate of successful flap outcomes was 100%. The study's RR, absolute risk reduction (ARR), relative risk reduction (RRR), and number needed to treat (NNT) are not computable. The age of the patient in our case was 15 years, whereas the minimum age of the patients in the referenced study was 17 years. The dangling protocol is a tool-agnostic protocol that can be implemented universally. According to the study, implementing a combined dangling/wrapping procedure at an early and aggressive stage did not negatively impact flap circulation. This enables patients to be mobilized after free flap transfer to the lower extremity. This study's findings support the implementation of the early dangling protocol in our patient population.[5]

DISCUSSION

The dangling protocol is a procedure to flex and hang the knee at the edge of the bed at 90 degrees. This physiologically challenge the newly anastomosed vessels of the flap to gravity-related intravascular pressure by decreasing the desaturation severity, and potentially reduce the hospital stay.[4,5] Two relevant articles resulted from literature search through the PubMed, Cochrane, and Embase databases based on the PICO and clinical questions. Before translating

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the article evidence into everyday practice, there are some potential advantages and limitations of the two articles we reviewed that need to be discussed further.

The advantage of the first article is that all articles in this study presented a 94-100% flap success. The included studies were from 1997 - 2018. Despite two people that carried out the search, this systematic review might have a selection bias, where only studies with positive results were included. A limitation of this systematic review is that the number of subjects from each study was too low to reach clinically significant conclusions. The high variability from one study to another in implementing the dangling protocol is also something to note, ranging from the first postoperative day to the seventh day. This study made the average recommendation starting on day three.[4] Some studies used a bandage or a wrap as an adjunct to therapy, and some did not. There were also differences in measuring outcomes or assessing observations, such as using Doppler, tissue oximetry, or clinical assessment.[4]

In the second article, a randomized controlled clinical trial, 31 patients underwent free flaps in the lower limbs.[5] Patients were randomly assigned to 2 groups, with the first group underwent the seventh day of the dangling protocol and the second group underwent the more aggressive (wrapping and dangling) protocol on the third day. The protocol was initiated with a duration of 5 minutes, three times a day, and doubled each day for four days, eventually reaching 50 minutes on day 5. Before and after the protocol, flaps were assessed clinically by direct observation (color, capillary refill, venous congestion, turgor, and flap temperature). There were no flap complications. In the second group, the average duration of hospitalization was longer. This is suspected because the most common etiology was fracture cases requiring medical rehabilitation before discharge.

The second article is considered relatively valid based on several criteria. First, the group was allocated randomly. Second, both groups equally received preoperative therapy, such as the same dose of low molecular weight heparin, intraoperative heparin, and mean arterial pressure of >70 mmHg maintenance. In this study, no blinding was performed. However, as the outcome was objective, the absence of blinding did not affect the study results.

Based on the two articles that were critically reviewed and discussed,[3,4] patients who underwent free flap surgery on the lower limbs can undergo the dangling protocol on the third day without affecting flap viability. The dangling protocol in question begins with five minutes twice a day, then 3 times a day on the next day, continued for ten minutes three times a day, and so on at a constant rate. The protocol can be discontinued after the leg has been suspended for 30 minutes of three times a day and is well tolerated. Flaps are considered intolerant if there are signs of venous insufficiencies, such as distal swelling and a bluish color. However, with high flap viability of nearly 100% in all groups observed in all reviewed articles, this protocol is good enough to be implemented.

The systematic review article established specific criteria that may trigger the initiation of the dangling protocol within a week following the surgical procedure. For patients who do not have any comorbidities and have not experienced significant tissue injury, it is advisable to utilize a fasciocutaneous flap type or a muscle flap with two venous anastomoses, where the free flap size is less than 250 cm^2. In such cases, it is recommended to initiate the dangling protocol on the third day, with flow through anastomoses and two venous anastomoses. This is in line with a study that prospectively analyzed early ambulation following lower extremity microsurgical reconstruction, demonstrating successful dangling without any signs of mottling within three days after the surgery.[8] Whereas, the dangling protocol was initiated on the seventh day following the surgical procedure in individuals who presented with extensive flaps, comorbidities, significant trauma, and a single venous anastomosis on the muscle flap.

CONCLUSION

All obtained studies showed the implementation of the dangling protocol in patients post free flap surgery of the lower limbs. However, the right time to start the dangling protocol was divided into two groups to attain successful flap viability, namely patients with multiple comorbidities, using muscle-related flap, and involving only one vein anastomosis; and groups with no or minimal comorbidities with more than one venous anastomosis. These conditions should be well considered in planning the free flap surgeries of the lower extremity. The dangling protocol can be implemented safely as

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early as postoperative day 3 without postoperative complications, such as total or partial necrosis.

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