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A Modified Pressure Dressing to Avoid Severe Bleeding After Circumcision With a Disposable Circumcision Suture Device and a Discussion on the Mechanism of Bleeding With the Disposable Circumcision Suture Device

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ABSTRACT

Introduction: A novel type of a disposable circumcision suture device (DCSD) has been proved to be effective and safe; however, a few cases of severe bleeding took place after circumcisions.

Aim: To evaluate the effectiveness of a modified double-layer pressure dressing to avoid severe bleeding after circumcision with the DCSD, in our department in a prospective randomized controlled study, and discuss the mechanism of bleeding with DCSD.

Methods: Patients with redundant foreskin or phimosis were included between September 2018 and November 2019 and divided into 2 groups: In group A, the conventional pressure dressing was performed; in group B, an modified double-layer pressure dressing was performed.

Main Outcome Measure: The main outcomes and complications (surgical time, incidence of glans ischemia, severe bleeding rate, infection rate, pain level, total cost, and overall satisfaction) were collected and analyzed.

Results: A total of 624 patients were recruited for this study. There was no difference in the average age and body mass index between 2 groups. No patient suffered obvious glans ischemia. In group B, lower pain level, lower incidences of severe bleeding, and better satisfaction were recorded.

Conclusion: The mechanism of bleeding with the DCSD was discussed in this study, and the modified pressure dressing was proved effective, safe, and easy to perform. **W Jiang, J-li Fu, W-l Guo, et al. A Modified Pressure Dressing to Avoid Severe Bleeding After Circumcision With a Disposable Circumcision Suture Device and a Discussion on the Mechanism of Bleeding With the Disposable Circumcision Suture Device. Sex Med 2021;9:100288.**

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Key Words: Circumcision; Disposable Circumcision Suture Device; Superficial Dorsal Vein; DCSD; Pressure Dressing; Bleeding

INTRODUCTION

Redundant foreskin or phimosis is one of the most common male external genital diseases, and many methods of circumcision have been used worldwide.^{1,2} With the people's health consciousness

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increasing, circumcision is regarded as an effective treatment to to prevent genital human papillomavirus infection,³ HIV, and other sexually transmitted infections,^{4–7} particularly in countries of low and middle income, which has specific benefits but carries some minor risks as well. However, bleeding with circumcision has always been a crucial problem and drawn much attention,⁸ especially in patients with bleeding disorders^{9–11} or with lichen sclerosus.¹²

As a new method of circumcision, a novel type of a disposable circumcision suture device (DCSD) has been proved to be effective and safe, greatly simplifies the procedure, and significantly reduces surgical time compared with conventional circumcision.¹³ However, a few cases of severe bleeding were reported after the circumcisions with the DCSD, which need to visit the hospital at once for a secondary pressure dressing or even

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Declarations: The experimental protocol was established as per the ethical guidelines of the Helsinki Declaration and was approved by the IRB of our institution. All authors read and approved the final manuscript.

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Figure 1. (A) View of the dorsal part of the penis with severe bleeding. (B) Decomposition structure of the disposable circumcision suture device. (C) The measuring scale.

require a surgical intervention for suture hemostasis and recircumcision,¹⁴ consistent with the experience of our department (Figure 1A). The bleeding complications will surely add the patient's pain and mental stress and sometimes result in infections. However, there is no plenty reports published to deal with the bleeding complications yet. This study was designed to evaluate the effectiveness and safety of the modified pressure dressing to avoid severe bleeding after circumcision.

PATIENTS AND METHODS

Patient Recruitment

This study is a prospective randomized controlled trial and approved by our Institutional Review Board. All patients requiring circumcision for redundant foreskin or phimosis in our department between September 2018 and November 2019 were randomly allocated with random number table method into 2 groups (A, B). Patients with deformity, such as hypospadias or systemic hematological diseases, were excluded. If patients were suffering from genital tract infections or infections of the glans penis, the circumcision will be performed after the infections were clear.

Surgical Process

The patients were placed in the supine position and received local dorsal penile nerve block injection with 2% lidocaine (10 ml) as described elsewhere.¹⁵ In this study, a DCSD (Jiangxi Lang He Medical Instrument Co, Ltd Ji'an, China) was used for patients. It mainly consists of bell-shaped glans pedestal, suture staples, ring-shaped blade, handle, and shell (Figure 1B). Different sizes were available, and a suitable-sized device was selected before surgery by using the measuring scale (Figure 1C). In group A, when the surgery began, the glans was covered by a bell-shaped glans rest. The foreskin was constrained around the rod, and the rod was inserted into the hole of the circumcision device. The topmost knob was tightened, the safe unit was removed, then the handles were clenched to trigger the DCSD. The handles were kept clenched for 5–10 seconds, then the control knob was rotated counterclockwise to remove the inner rod and the outer pole, by that time, the redundant foreskin was already cut and the incision was simultaneously anastomosed with suture staples. Then, the whole shaft of the penis was pressed immediately for 1 minute. The procedures have also been well described by other articles.^{12,13,16} Then, the circular wound was dressed with a self-adhesive flexible bandage (Figure 2A and 2B).

In group B, the difference with group A existed in the way of pressure dressing. After the circumcision with the DCSD, a modified double-layer dressing was performed: the inner layer consisted of a self-adhesive flexible bandage, covering the whole shaft of the penis from the coronary sulcus to the root of the penis; the outer layer consisted of a self-adhesive flexible bandage covering the circular wound, adjacent to the balanus (Figure 2C and 2D).

Postoperative Treatment

All the patients in 2 groups were prescribed oral antibiotics (cefuroxime 250 mg, bid) for 3 days, and estradiol valerate was used orally (1 mg, qn) for 1 week to relieve nocturnal penile erection, while no analgesic drugs were administered. All the patients were asked to keep the pressure dressing clean and dry, avoid excess physical activities for 1 week, and sexual stimulation and activities were forbidden for 1 month.



Figure 2. (A) View of the dorsal part of pressure dressing in group A. (B) View of the ventral part of pressure dressing in group A. (C) View of the dorsal part of pressure dressing in group B. (D) View of the ventral part of pressure dressing in group B.

In group A, the pressure dressing would be changed and the incision would be checked 3-5 days after surgery, and the bandage would be removed 7 days after surgery. In group B, the outer layer would be removed 12-24 hours after surgery (the next morning), which was usually performed by patients themselves, and the inner layer, as same as group A, would be changed and the incision would be checked 3-5 days after the surgery, and the bandage would be removed 7 days after the surgery.

Evaluations

- (i) Preoperative characteristics of the patients such as age and body mass index (BMI) were recorded.
- (ii) Surgical time including the time from anesthesia to the end of surgery.
- (iii) The incidence of ischemia of balanus: It was observed and recorded by experienced surgeons.
- (iv) The incidence of severe bleeding: Severe bleeding was defined as which need to visit hospital again for urgent pressure dressing or require a surgical intervention for suture hemostasis and recircumcision by the time circumcision was just finished or few hours later.

- (v) The incidence of incision infection: It was determined based on the check of the wound by experienced surgeons.
- (vi) Pain level: A visual analog score was used for pain scoring, with 0 indicating lowest pain level and 10 indicating extremely painful, to record the pain level within 24 hours or 1 week after surgery.
 - (vii)The total cost: The total cost of each patient were recorded, including the cost of operation and the cost happened during the wound healing.
- (viii) The overall satisfaction: A satisfaction score was used for satisfaction scoring, with 0 indicating not satisfied at all and 5 indicating extremely satisfied, to record the satisfactory level within 1 week after surgery.

Statistical Analysis

Statistical analyses were carried out on SPSS statistical software (version 25.0). Mean and percentages were used for a description of data. Continuous variables were presented as mean \pm SD, and *t* test was adopted for numerical data comparison, with the significance level set at 0.05 or less.

 Table 1. Preoperative characteristics of the patients in 2 groups

Study group	n	Age (y)	BMI*
A [†]	297	24.8 ± 6.1	24.9 ± 1.7
B [†]	327	25.1 <u>+</u> 6.3	25.1 ± 1.6

*BMI = body mass index.

[†]Group A: the conventional pressure dressing was performed; group B: the modified double-layer pressure dressing was performed.

RESULTS

A total of 624 patients were recruited for this study, with 297 patients in group A, 327 patients in group B. No significant statistical difference of age or BMI was found between the groups (P > .05) (Table 1). All the patients were followed up until the bandages were removed off (on the 7th day after surgery).

The statistical results were compared between 2 groups (Table 2). There was no serious bleeding happened in group B (0 of 327), significantly lower than group A. In group A, the active bleeding originated from the frenulum in 3 of 13 patients (23.1%) within 24 hours after surgery and the dorsal aspect of the penis in 10 of 13 patients (76.9%) within 12 hours after surgery. All 3 bleeding cases originated from the frenulum being treated well with pressure dressing, while all the 10 bleeding cases originated from the dorsal aspect of the penis by undergoing a suture hemostasis and recircumcision. At the follow-up, the average total cost of group B is lower than that of group A, and a significantly better satisfaction level was recorded in group B. In addition, there was another statistically significant difference found: in group A, the average BMI of patients with hemorrhage is much higher than the patients without hemorrhage (P < .01).

DISCUSSION

In our department, more than 500 adult circumcisions are performed annually with the DCSD since 2014. Compared with the conventional circumcisions, circumcisions with the DCSD have obvious advantages of shorter operation time, less blood lose, better satisfaction, lower pain level, and better cosmetic appearance and also a clear disadvantage of higher price owing to the cost of the DCSD.^{12–15} As a result, the DCSD is widely used in more and more medical institutions. However, there are still different conclusions on the blood loss; as reported, there is more intraoperative blood loss and a few cases of severe post-operative bleeding,^{12,17} while another conclusion indicates that circumcisions with the DCSD experienced significantly less intraoperative blood loss compared with conventional circumcisions.¹⁸

In previous clinical work, we have treated many patients with severe bleeding after circumcisions with the DCSD, which caused a lot of pain and mental stress to patients and increased the incidence of infection and edema of cause, which is also reported by Wang.¹³ As per our observation, which is consistent with the opinion of Ozdemir,¹⁹ the bleeding usually originates

from the frenulum (rich in blood vessels) and and superficial dorsal vein (SDV).²⁰

Because the bleeding spot in the frenulum is close to the incisal edge, the blood will outflow through the gaps between suture staples and could not form a huge hematoma subcutaneously, so the active bleeding in the frenulum could always be well controlled by pressure dressing. But, the bleeding spot in the dorsal aspect of the penis is far away from the incisal edge, thus the blood will sedimentate and form a huge hematoma immediately or hours later after circumcision, which make a secondary pressure dressing difficult and always lead to a surgical intervention.

In the process of surgical intervention, removing all the suture staples will be the first step, then we would find the huge hematoma and severe tissue edema in the dorsal aspect of the penis, which made it difficult to find the active bleeding spot, especially in those cases hours later after circumcision. After the hematoma and edematous tissue were removed, sometimes we could find the bleeding spot and suture it, while there were also some times that we could not find the bleeding spot, anyhow, a proper pressure dressing over the whole penile shaft could surely prevent a recurrent bleeding.

During the circumcision, the DCSD was triggered to cut the redundant foreskin and simultaneously sutured the incision with suture staples. Compared with conventional circumcisions, there are many reasons that may lead to the blood loss with the DCSD: first, there is no electric coagulation hemostasis during the surgery; second, suture staples sometimes break the walls of blood vessels partly, which making blood leak out; third, the wide gaps between the suture staples make it difficult to clip all the vessels; and fourth, because the broken ends of the vessels retracted toward the root of the penis, the conventional pressure dressing could not press the retracted vessels well, which maybe the main cause of the severe bleeding in the dorsal aspect of penis. Based on the aforementioned theory, we designed this study to evaluate a method for avoiding severe bleeding with DCSD.

In group B, a double-layer dressing was performed: the inner layer covered the whole shaft of the penis, which could give the bleeding spots from both the frenulum and SDV a proper pressure, even if there is a distinct contracture of SDV; the outer layer covered the circular wound, adjacent to the balanus, providing extra pressure to the frenulum, which would be removed 12–24 hours after circumcision. However, it should be noted that there was 1 patient in group B who suffered an active bleeding in the frenulum in the first night, and the bleeding stopped spontaneously after an hour of bed rest, which may due to the nocturnal penile erection.

Moreover, to prevent intraoperative hematoma formation, the whole shaft of the penis should be pressed immediately for 1 minute after the DCSD are removed, so that the bleeding from either the frenulum or SDV could be temporarily controlled, and operators could have sufficient time to perform the pressure dressing with no hurry.

Table 2. Comparison of operative and postoperative characteristics between the 2 groups

Study group	A^{\dagger} (n = 297)	B [†] (n = 327)	P values
Age (y)	24.83 ± 6.1	24.95 ± 6.3	.810
BMI*	24.9 ± 1.7	25.1 ± 1.8	.230
Surgical time (min)	12.0 ± 2.1	11.9 ± 1.6	.428
Ischemia of balanus	0/297	0/327	
Severe postoperative bleeding	13/297	0/327	.000
Incision infection	10/297	2/327	.012
Pain level within 24 h	5.98 ± 1.20	5.65 ± 1.07	.000
Pain level within 1 wk	3.49 ± 1.24	3.26 ± 1.30	.025
The total cost	2,513.3 ± 434.6	2,428.3 ± 46.6	.001
The overall satisfaction	3.10 ± 0.49	3.43 ± 0.66	.000
	Patients without hemorrhage (n = 13)	Patients with hemorrhage (n $=$ 284)	
BMI within group A	24.75 ± 1.625	27.92 ± 1.498	.000

Values are mean \pm SD.

*BMI = body mass index.

[†]Group A: the conventional pressure dressing was performed, group B: the modified double-layer pressure dressing was performed.

There are also other aspects important to avoid severe bleeding, such as leaving a proper length of the frenulum (0.5-1.0 cm) is beneficial for the pressure dressing; having a good rest in the first 2-3 days; preventing the bandage from falling off especially in the first 2-3 days; estrogenic drugs should be used to relieve the nocturnal penile erection; and patients should press the whole shaft of penis tightly when an active bleeding take place and visit the hospital at once.

As per our results, in group B, a lower pain level was recorded. The total cost in group A was higher than that of group B owing to the suture hemostasis and a longer time to cure.

Notably, there was a marked difference in BMI between the patients with hemorrhage and the patients without hemorrhage in group A. One possible explanation is that the penis of patients with high BMI was concealed in the thick underlying fatty layer, which made the pressure dressing more difficult and the bandage more easily to fall off. So, when coming to patients with high BMI, suturing the SDV before circumcision, a tighter pressure dressing and reminding the patients of being aware of the postoperative bleeding would be necessary.

CONCLUSIONS

The mechanism of bleeding with DCSD is discussed in this study, the modified pressure dressing was proved effective, safe, and easy to perform and could probably be extended to the circumcisions with other techniques or devices or even patients with bleeding disorders or lichen sclerosus, which requires further study.

Nevertheless, our study does have certain limitations, such as only patients older than 16 years of age were recruited, so the conclusions of patients younger than 16 years of age could not be obtained; lack of preoperative blood tests, patients with bleeding disorders were undiagnosed, so the effectiveness to patients with bleeding disorders could not be evaluated either.

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